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

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

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

RESERVATION OF LEADER TIME

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

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

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

The assistant legislative clerk read as follows:

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

Pending:

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

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

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

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

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

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

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

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

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

The assistant legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2107

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

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

The assistant legislative clerk read as follows:

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

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

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

The amendment is as follows:

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

At the end of title XI, add the following:

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

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

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

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

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

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

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

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

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

''(b) APPROVED CANADIAN PHARMACY.—

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

''(A) is located in Canada; and

''(B) that the Secretary certifies—

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

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

''(2) PUBLICATION OF APPROVED CANADIAN PHARMACIES.—The Secretary shall publish on the Internet Web site of the Food and Drug Administration a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs in accordance with subsection (a).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

That is Mr. Tauzin—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

route of administration, dosage form, and strength as a prescription drug approved by the Secretary.''

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

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

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

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

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

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

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

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

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

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

There appears to be a sufficient second.

The yeas and nays were ordered.

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

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

The assistant legislative clerk proceeded to call the roll.

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

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

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

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

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

RECOGNITION OF THE MINORITY LEADER

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

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

The ACTING PRESIDENT pro tempore. The leader is correct.

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

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

STUDENT LOAN INTEREST RATES

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

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

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

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

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

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

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

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

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

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

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

THANKING SENATOR ENZI

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

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

HONORING OUR ARMED FORCES

SPECIALIST DAVID W. TAYLOR

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

At this time we are thinking of SPC David W. Taylor's family and his friends as I recount his story for the Senate, including his mother Sarah Taylor, his grandmother Laura Klutey, and many other beloved family members and friends. David was preceded in death by his father Kevin Taylor.

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

Sergeant Addington remembers:

David seemed to live for the job, and while others would whine and complain in the field, David would just sling up his hammock and settle in. He was at home in the woods, a natural outdoorsman.

David, who grew up in the woods, fit in perfectly. He seemed born to do this job, and I felt sorry for any Taliban that he was bound to run into in Afghanistan. The Taliban got lucky this time.

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

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

I yield the floor.

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

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

This legislation, which has been the model of bipartisanship and effective legislating on the part of Chairman

HARKIN and Ranking Member ENZI, is critically important to the people of New Jersey and the Nation.

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

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

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

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

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

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

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

AMENDMENT NO. 2107

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

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

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

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

AMENDMENT NO. 2109

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

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

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

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

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

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

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

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

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

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

As I have said—and as my friends who are managing this bill have said—

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

With that, I yield the floor and suggest the absence of a quorum.

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

The legislative clerk proceeded to call the roll.

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

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

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

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

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

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

With that, I suggest the absence of a quorum.

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

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2107

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

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

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

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

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

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

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

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

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

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

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

The McCain amendment would improve drug safety, it would not threaten drug safety. It would open trade to lower-cost drugs, and it would make other consumers around the world start paying for some of the research and development the American consumer is paying such a high price to

provide. We should do all we can to get miracle drugs originated and developed, but the American consumer should not be paying the entire bill. We need to make sure Americans have even greater, more affordable access to lifesaving drugs by opening the doors to competition in the global pharmaceutical industry.

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

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Wyoming.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I ask my colleagues to oppose the amendment.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arizona.

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

AMENDMENT NO. 2111

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

Under current law, a generic drug company that is the first to file an abbreviated new drug application for an existing patented drug is entitled to 180 days of market exclusivity once the generic drug is approved. In other words, they have the exclusive market on it for half a year. This creates a powerful incentive for drug companies to bring generic drugs to market.

The present amendment would dilute this right of 180 days of exclusivity and potentially require the exclusivity period to be shared with another drug company's product. Under the amendment, the only way a generic drug company that files the first ANDA could be assured of getting 180 days of

market exclusivity is by litigating a challenge to the validity of the branded drug's patent all the way to a final judgment.

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

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

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

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

AMENDMENT NO. 2109

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

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

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

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

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

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

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

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

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

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

I urge my colleagues to oppose the Sanders amendment.

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

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

NUCLEAR SUBMARINE FIRE

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

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

AMENDMENT NO. 2107

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

I applaud Senator MCCAIN, who obviously has been a very valuable ally in this effort for many years. But he proposed a very limited approach to address those who have concerns with the idea of importing prescription drugs. I, for one, cannot understand why there

is such a fundamental concern about this issue because, first of all, Americans have been facing tremendous increases in prescription drug prices for far too long. I think it is at a point at which Congress should address this issue, and precisely on this particular piece of legislation that is before us today. It could not be more appropriate to have this amendment offered on this legislation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The American taxpayer is underwriting more than $30 billion of research—basic and applied research—at

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

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

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

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

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

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

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

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

I yield the floor.

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

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

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

The PRESIDING OFFICER. Is there objection?

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

The assistant legislative clerk read as follows:

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

The amendments, as modified, are as follows:

AMENDMENT NO. 2142, AS MODIFIED

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

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

(2) by adding at the end the following:

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

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

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

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

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

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

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

AMENDMENT NO. 2145, AS MODIFIED

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

At the end of title XI, add the following:

SEC. 11___. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

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

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

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

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

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

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

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

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

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on the Judiciary and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

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

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

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

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

AMENDMENT NO. 2146, AS MODIFIED

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

At the end of title XI, insert the following:

Subtitle D—Synthetic Drugs

SECTION 1141. SHORT TITLE.

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

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

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

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

''(2) In paragraph (1):

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

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

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

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

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

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

''(B) Such term includes—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 1144. PROHIBITION ON IMPOSING MANDATORY MINIMUM SENTENCES.

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

SYNTHETIC DRUGS

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

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

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

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

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

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

and approved by the Senate Judiciary Committee?

Mr. HARKIN. Absolutely.

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

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

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

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

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

AMENDMENT NO. 2142, AS MODIFIED

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

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

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

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

AMENDMENT NO. 2146, AS MODIFIED

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

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

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

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

The PRESIDING OFFICER. The senior Senator from New Mexico.

AMENDMENT NO. 2111

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

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

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

The assistant legislative clerk read as follows:

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

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

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

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

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

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

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

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

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

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

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

drugs at a significant cost to everyone who is involved in the health care system.

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

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

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

According to a letter sent to the FDA Director Hamburg last year from some of my colleagues in the Senate indicating that the Federal Government was spending $2.4 billion a year on Lipitor, they estimated that bringing a generic version to market would generate somewhere between $4 billion and $6.7 billion in savings annually to people who are purchasing this drug in this country.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. SCHUMER addressed the Chair.

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

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

The PRESIDING OFFICER. On the Bingaman amendment?

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

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

AMENDMENT NO. 2146

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

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

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

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

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

EDUARDO SAVERIN

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

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

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

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

Senator CASEY and I have proposed a response. Our bill would bar Saverin—

and others like him—from reentering the country. It would also re-impose taxes on investment income earned in the United States even if an expatriate is living abroad.

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

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

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

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

But I think that most Americans agree that paying a mere 15 percent in capital gains taxes on a sum of $3 billion or $4 billion is not too much to ask a person, especially a person who fled their own homeland because their native society could not provide a reasonable level of security to their family.

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

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

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

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

Yes, Eduardo Saverin did well by being in America.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

While on right wing radio they ask:

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

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

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

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

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

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

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

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

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

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

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

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

wing as cowards, as self-absorbed, as traitors.

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

It is off the deep end.

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

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

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

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

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

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

Last August, our Nation's creditworthiness became a second casualty of the far right's insistence on low taxes for the wealthy. The right wing was so dug in against any reasonable fiscal compromise that they forced a manufactured crisis over raising the Nation's debt limit. This caused the first-ever downgrade of our Nation's credit rating.

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

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

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

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

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

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

It is perverse.

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

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

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

Sadly, the answer of the extreme right is no.

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

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

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

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

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

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

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

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

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

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

Thank you. I yield the floor.

The PRESIDING OFFICER. The senior Senator from Wyoming.

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

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

I yield the floor to the Chair.

The PRESIDING OFFICER. The Senator from Iowa.

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

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

The PRESIDING OFFICER. Is there objection?

Mr. VITTER addressed the Chair.

The PRESIDING OFFICER. The Senator from Louisiana.

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

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

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

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

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

The PRESIDING OFFICER. Is there objection?

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

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

The assistant majority leader is recognized.

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

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

The assistant majority leader.

AMENDMENT NO. 2127

Mr. DURBIN. Mr. President, today we are considering a bill that will improve the FDA's ability to assure the safety of drugs in our medicine cabinets and medical devices in our hospitals. The FDA is an essential guardian of the public's health and safety. In the past few years, FDA has faced obstacles that call on the agency to adapt and respond to the evolving nature of reviewing, manufacturing, and distributing drugs and devices.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and, when necessary, identify alternative sources of the drug to ensure we maintain a supply for patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

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

MAY 21, 2012.

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

DEAR SENATOR DURBIN: Consumers Union applauds your efforts to strengthen dietary supplement safety by requiring manufacturers to register their products with the Food

and Drug Administration (FDA). Specifically, your proposed amendment to the Food and Drug Administration Safety and Innovation Act (S. 3187) would require manufacturers to provide the FDA with accurate and up-to-date information regarding each dietary supplement product they manufacture, a list of ingredients included in those products, and a copy of the product labels.

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

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

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

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

Sincerely,

CHUCK BELL,
Programs Director Consumers Union.
IOANA RUSU,
Regulatory Counsel Consumers Union.

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

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

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

I yield the floor.

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

AMENDMENT NO. 2111

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

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

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

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

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

Those were the FTC's words.

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

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

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

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

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

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

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

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

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

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

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

I yield the floor.

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays are ordered.

The Senator from New Mexico.

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

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

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

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

I urge my colleagues to support the amendment.

The PRESIDING OFFICER. The Senator from Wyoming.

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

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

The problem with this amendment, however, is that its scope is much broader and could lead to unintended consequences that could harm consumers and increase costs. That is why I must oppose it. The amendment uses a machete when a scalpel might solve the problem. Not all patent settlements are abusive. They do not all lead to higher costs. In fact, some settlements can actually expedite generic drugs coming to market. According to one recent study by RBC Capital Markets, patent settlements helped expedite 24 of the 37 most recent generic drug approvals.

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

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

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

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

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

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

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

I yield the floor.

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

The yeas and nays have been ordered.

This is a 60-vote threshold vote.

The clerk will call the roll.

The assistant bill clerk called the roll.

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

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

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

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

[Rollcall Vote No. 105 Leg.]

YEAS—28

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

NAYS—67

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

NOT VOTING—5

Blumenthal	Hutchison	Mikulski
Crapo	Kirk	

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

AMENDMENT NO. 2108

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

The PRESIDING OFFICER. The Murkowski amendment No. 2108.

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

The PRESIDING OFFICER. That is already the order.

There are now 2 minutes equally divided.

Ms. MURKOWSKI. Madam President, I ask for support of the amendment

that is before us. This is an amendment that will actually strengthen the role of NOAA as the Federal agency that has oversight over our fisheries.

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

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

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

The PRESIDING OFFICER. The majority leader.

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

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

The Senator from Kansas.

Mr. HARKIN. Regular order, please.

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

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Massachusetts.

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

I urge my colleagues to oppose this amendment.

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The clerk will call the roll.

The bill clerk called the roll.

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

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

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

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

[Rollcall Vote No. 106 Leg.]

YEAS—46

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

NAYS—50

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

NOT VOTING—4

Blumenthal	Hutchison
Crapo	Kirk

The amendment (No. 2108) was rejected.

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

The Senator from Tennessee.

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

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

Mr. CORKER. About 3 or 4 minutes.

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

Mr. CORKER. On the bill.

Mr. HARKIN. Madam President, parliamentary inquiry.

The PRESIDING OFFICER. The Senator from Iowa.

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

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

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

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

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

Mr. CORKER. Three minutes.

Mr. HARKIN. OK, that is fine.

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

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

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

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

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

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

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

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

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

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

I think I have stayed within my time limit.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Wyoming.

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

The PRESIDING OFFICER. The Senator from Ohio.

AMENDMENTS NOS. 2145 AND 2146

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

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

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

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

The good news is progress is being made in places such as Scioto County and around the country thanks to the good work of health professionals, law enforcement, local, State, and Federal officials, along with community groups, families, schools, churches, and others. But they need some help. More work needs to be done, and one critical tool they are looking for in the fight against prescription drug abuse is a better way to monitor prescription drug use. There are databases around the country called prescription drug monitoring programs. They allow States to monitor and track the dispensing of prescription drug medications by health care providers to be able to identify and stop the abuse of people getting prescriptions for these drugs in various different doctors' offices and in what have been called pill mills. Preliminary research has shown monitoring programs are highly effective in stemming the tide of abuse. That is why 48 States and 1 territory now have them, with 41 of them operational.

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

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

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

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

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

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

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

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

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

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

Mrs. HAGAN. I would request 6 minutes.

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

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

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

I am particularly proud to support this bill because of what it will mean for patients who are suffering with diseases, who do not have access to adequate treatments, or who do not have access to any treatment at all. This bill we are voting on includes key provisions of the TREAT Act—the Transforming the Regulatory Environment to Accelerate Access to Treatments Act—which I introduced in February.

These important provisions will expedite the review of treatments for serious or life-threatening diseases without compromising the FDA's already high standards for safety and effectiveness.

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

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

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

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

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

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

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

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

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

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

Companies with footprints in North Carolina are partnering with our world-class universities to improve the health of people all across the globe every day by researching, discovering, and developing lifesaving treatments for those suffering from these devastating diseases.

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

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

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

I yield the floor.

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

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

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

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

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

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

We have examples of awful things that have happened. Interpol and the United States have seized millions of counterfeit pills. These drugs were made in unsanitary conditions and were deadly and ineffective. Remember the contaminated Heparin from China that killed over 150 people. Then there was cough syrup made from antifreeze instead of glycerin. Seventy-eight people died. There are also the ineffective

drugs that may not kill you but certainly won't improve your health. I could list more, but I urge my colleagues to go talk to the FDA, FBI, and Customs and Border Protection and hear firsthand what they have experienced.

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

If you want safety, then defeat the McCain amendment.

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

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

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

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

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

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

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

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

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

AMENDMENT NO. 2131

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

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

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

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

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

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

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

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

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

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

Other examples of bipartisan legislation we worked on, in one case the

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

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

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

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

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

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

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

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

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

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

This bill also makes medicines safer for millions of children, improves the FDA's tools to police the global drug supply chain, and reduces the risk of drug shortages. There are a number of amendments that are being offered to the bill—we have voted on a couple of those—and one of the amendments that we will be voting on, I believe, a little later this afternoon is legislation that would, in my view, weaken or contaminate our country's supply of prescription drugs and put our patients and our health care system at risk.

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

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

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

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

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

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

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

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

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

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

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

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

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

So responding to folks in Delaware and Iowa and across the country, we are working together. We are not just working together on a couple of things

but on a whole host of things, a whole litany of provisions and laws and proposals that do what: help us to create a more nurturing environment for job creation and job preservation. That is a good thing. That is a very good thing.

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

The PRESIDING OFFICER. The Senator from Iowa.

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

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

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

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

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

AMENDMENT NO. 2107

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

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

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

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

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

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

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

Right now the drugs in our country are safe and effective, as we have seen by the results. Thanks to Senator HARKIN and Senator ENZI, this bill will even make our drugs more safe. Americans deserve real peace of mind. When they open the pill bottle and swallow their medicine, they have to know the product is safe and effective.

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

I yield the floor.

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

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

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

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

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

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

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

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

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

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

I also thank Governor Earl Ray Tomblin and Congressman NICK RAHALL for their tireless work on this

issue, along with Congressman VERN BUCHANAN of Florida, who is doing excellent work to end pill mills. As we all know, last night's vote gives this amendment a solid step forward, but there is much work remaining to give our communities the right tools to fight this epidemic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I will give just one more example:

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Iowa.

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

The PRESIDING OFFICER. There is 3 minutes.

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

The PRESIDING OFFICER. The Senator is recognized.

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

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

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

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

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

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

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

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

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The Senator from Iowa.

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

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

AMENDMENT NO. 2143

Mr. HARKIN. Madam President, we are rapidly approaching a vote on the

Paul amendment, and I know the Senator wants to have a couple of minutes to speak on that.

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

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

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

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

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

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

I yield the floor.

The PRESIDING OFFICER. Who yields time?

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

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

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

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

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

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

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

Thank you. I urge support for my amendment.

The PRESIDING OFFICER. The Senator from Iowa.

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The question is agreeing to the motion.

The clerk will call the roll.

The assistant legislative clerk called the roll.

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

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

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

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

[Rollcall Vote No. 107 Leg.]

YEAS—78

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

NAYS—15

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

NOT VOTING—7

Akaka	Heller	Stabenow
Blumenthal	Hutchison	
Boxer	Kirk	

The motion was agreed to.

AMENDMENT NO. 2107

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

Who wishes the floor?

The Senator from Arizona.

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

In a normal world, this would probably require a voice vote. But what we are about to see is the incredible influence of the special interests, particularly PhRMA, here in Washington,

where people who cannot afford it will have to make a choice between eating and medicine. They will not be allowed to purchase a medication at less than half the price, many times, than they will in American pharmacies in Canada.

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

The PRESIDING OFFICER. The Senator from New Jersey.

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

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

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

The PRESIDING OFFICER. The majority leader.

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

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

The yeas and nays have been ordered.

The clerk will call the roll.

The bill clerk called the roll.

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

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

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

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

[Rollcall Vote No. 108 Leg.]

YEAS—43

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

NAYS—54

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

NOT VOTING—3

Blumenthal	Hutchison	Kirk

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

AMENDMENT NO. 2109

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

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

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

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

I ask for a ''yes'' vote.

The PRESIDING OFFICER. The Senator from Wyoming

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

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

I ask that the Senate oppose the amendment.

I yield the floor.

The PRESIDING OFFICER. All time has expired.

Under the previous order, this amendment is subject to a 60-vote threshold for adoption.

The question is on agreeing to the amendment.

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The clerk will call the roll.

The assistant bill clerk called the roll.

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

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

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

The result was announced—yeas 9, nays 88, as follows:

[Rollcall Vote No. 109 Leg.]

YEAS—9

Bennet	Franken	Sanders
Brown (OH)	Levin	Schumer
Durbin	McCain	Whitehouse

NAYS—88

Akaka	Coburn	Hoeven
Alexander	Cochran	Inhofe
Ayotte	Collins	Inouye
Barrasso	Conrad	Isakson
Baucus	Coons	Johanns
Begich	Corker	Johnson (SD)
Bingaman	Cornyn	Johnson (WI)
Blunt	Crapo	Kerry
Boozman	DeMint	Klobuchar
Boxer	Enzi	Kohl
Brown (MA)	Feinstein	Kyl
Burr	Gillibrand	Landrieu
Cantwell	Graham	Lautenberg
Cardin	Grassley	Leahy
Carper	Hagan	Lee
Casey	Harkin	Lieberman
Chambliss	Hatch	Lugar
Coats	Heller	Manchin

McCaskill	Pryor	Tester
McConnell	Reed	Thune
Menendez	Reid	Toomey
Merkley	Risch	Udall (CO)
Mikulski	Roberts	Udall (NM)
Moran	Rockefeller	Vitter
Murkowski	Rubio	Warner
Murray	Sessions	Webb
Nelson (NE)	Shaheen	Wicker
Nelson (FL)	Shelby	Wyden
Paul	Snowe	
Portman	Stabenow	

NOT VOTING—3

Blumenthal	Hutchison	Kirk

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

The Senator from North Carolina.

AMENDMENT NO. 2130 WITHDRAWN

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

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

Mr. BURR. I thank the Chair.

AMENDMENT NO. 2127

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote in relation to amendment No. 2127, offered by the Senator from Illinois, Mr. DURBIN.

Mr. DURBIN. Mr. President, this is a very simple amendment. If you go into the drugstore and look at the prescription drugs, every one of them has been registered with the FDA. The over-the-counter drugs have all been registered. When you go to the dietary supplement section, there is no requirement under the law for the company selling those products to register the name of the product, the ingredients of it, or a copy of the label.

The GAO did a study in 2009, and the FDA said we need this information to protect American consumers. From what? One of them is an example on this chart. This is a Chinese product that was imported into the United States, put up for sale, and then we discovered that one of the ingredients was life-threatening. It was never registered with the FDA, and there was no disclosure of its ingredients.

If you want to sell from the counters in America, shouldn't you be required, whether you are from China, India, Mexico, or anywhere in the United States, to register your product, the ingredients in it, and a copy of the label? The FDA says they need this information to keep America safe.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, first of all, this is a drug and device bill, not a food bill. We addressed food issues in the food safety bill 2 years ago. That doesn't solve the problem Senator DURBIN talked about. This bill is a very delicate balance. We have worked on this for 18 months. Stakeholders all over the country, consumers, the pharmaceutical industry, and pharmacists all support this bill. This would upset that delicate balance.

I say to the Senator that every supplement has a label, the ingredients, and the potency, by law, on every single item sold as a supplement. This is a drug bill, not a food bill.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I strongly oppose this amendment. I will be voting to table it, and I encourage my colleagues to do the same. It would impose another layer of regulations on an industry that already has a workable regulatory framework. It is totally unnecessary, and it will only increase costs for those who use dietary supplements.

I wish to make a few points clear.

First, HHS already has authority to impose an immediate ban on any dietary supplement that poses imminent hazard to public health.

Second, four previous FDA Commissioners and a former Deputy Commissioner agree that DSHEA already provides sufficient oversight of this industry. This amendment would strap the FDA with a huge burden at a time when the agency is already struggling to perform its current core responsibilities.

Third, it unnecessarily expands registration requirements without adding any additional consumer protections.

All this amendment does is penalize good companies, while doing nothing to go after the bad.

In the end, as a result of this amendment, consumers will suffer by paying higher prices for their supplements.

This amendment is bad for the FDA and bad for consumers. The Senate should reject it.

We already have a regulatory framework under DSHEA that works. A new intrusive regulatory regime is totally unnecessary. I urge my colleagues to vote with me to table this amendment.

Mr. DURBIN. Mr. President, I ask unanimous consent to have the same amount of time given on the other side.

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

Mr. DURBIN. Mr. President, the FDA asked for this knowledge and information. What am I asking them to disclose? The name of the product, the ingredients of it, and a copy of the label. If a Chinese manufacturer wants to sell a dietary supplement in Des Moines, IA, shouldn't they have to report to the FDA the name of the product and its ingredients? It is not required by law now. Let's give the FDA this extra information to keep Americans safe.

Mr. HARKIN. Madam President, I move to table the Durbin amendment, and I ask for the yeas and nays.

The PRESIDING OFFICER (Mrs. HAGAN). Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to the motion.

The clerk will call the roll.

The bill clerk called the roll.

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

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

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

The result was announced—yeas 77, nays 20, as follows:

[Rollcall Vote No. 110 Leg.]

YEAS—77

Akaka	Grassley	Moran
Alexander	Hagan	Murkowski
Ayotte	Harkin	Murray
Barrasso	Hatch	Nelson (NE)
Begich	Heller	Nelson (FL)
Bennet	Hoeven	Paul
Blunt	Inhofe	Portman
Boozman	Inouye	Risch
Brown (MA)	Isakson	Roberts
Brown (OH)	Johanns	Rubio
Burr	Johnson (SD)	Sessions
Cantwell	Johnson (WI)	Shaheen
Carper	Kerry	Shelby
Casey	Kohl	Snowe
Chambliss	Kyl	Stabenow
Coats	Landrieu	Tester
Coburn	Lee	Thune
Cochran	Levin	Toomey
Collins	Lieberman	Udall (CO)
Coons	Lugar	Udall (NM)
Corker	Manchin	Vitter
Cornyn	McCain	Warner
Crapo	McConnell	Whitehouse
DeMint	Menendez	Wicker
Enzi	Merkley	Wyden
Graham	Mikulski	

NAYS—20

Baucus	Franken	Reed
Bingaman	Gillibrand	Reid
Boxer	Klobuchar	Rockefeller
Cardin	Lautenberg	Sanders
Conrad	Leahy	Schumer
Durbin	McCaskill	Webb
Feinstein	Pryor	

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The motion was agreed to.

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

The motion to lay on the table was agreed to.

PRESCRIPTION DRUG INFORMATION

Mrs. GILLIBRAND. Madam President, earlier this week I introduced the Cody Miller Initiative for Safe Prescriptions Act. The legislation would require the Food and Drug Administration to issue regulations to ensure patients receive timely, consistent, and accurate information with their prescription drugs. The legislation would ensure patient medication information is regularly updated as new information becomes available and ensure that common information is applied consistently across similar products. Most importantly, the legislation would ensure patients are kept up to date about potential adverse side effects and dangerous drug interactions.

Mr. HARKIN. I applaud the work of the Senator from New York on this legislation and share her commitment to

ensuring patients receive standardized and accurate information about their prescription drugs. While verbal counseling by a pharmacist is still critical, the patient medication information is also an important resource to help patients use medications safely.

Mrs. GILLIBRAND. I appreciate the Chairman's support and hope to work with him to advance this legislation. I also hope he will join me in calling on the FDA to use its existing authority to ensure patient medication information is uniform, accurate, and up-to-date. The FDA is currently engaged in efforts to revise the patient education materials that are distributed to patients. However, the FDA's current plan falls short of ensuring that consumers will receive unbiased and accurate information about their prescription drugs. It also fails to ensure that patient medication information is consistent for identical or similar products.

Mr. HARKIN. I agree we need to take steps to improve the information patients receive and look forward to working with the Senator on this issue.

ACCELERATED PATIENT ACCESS

Mrs. HAGAN. Section 901 of the managers' amendment to S. 3187, Enhancement of Accelerated Patient Access to New Medical Treatments states that an accelerated approval under section 506(b) of the Federal Food, Drug, and Cosmetic Act is subject to certain limitations, including the requirement that the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit. Does the lack of an explicit reference to postapproval validation of surrogate endpoints, as described in current law, in any way restrict the Secretary's existing authority to require such validation postapproval?

Mr. HARKIN. The managers' amendment to 3187 revises section 506(b), removing the explicit language in current law requiring postapproval validation of surrogate endpoints. However, this is not intended to restrict the Secretary's current ability to require such validation postapproval, if appropriate. Equally important, the change likewise is not intended to suggest that any such validation should now occur prior to approval under section 506(b). Rather, in keeping with current practice, the bill's new language continues to permit the Secretary to require postapproval studies to verify the effect on the surrogate endpoint or predicted clinical outcome, i.e., verification of the predicted clinical benefit. In addition, it continues to allow the Secretary to withdraw an accelerated approval if the required studies fail to verify and describe the predicted effect.

Mr. ENZI. To receive accelerated approval, the managers' amendment requires that FDA determine that a surrogate or clinical endpoint is reasonably likely to be predictive of an effect on clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality as of the time of granting accelerated approval and the standards under section 505(c) of the FDCA or section 351(a) of the Public Health Service Act are met. In meeting such a requirement, it is appropriate for the Secretary to seek data and information to show that the surrogate or clinical endpoint is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

I would just like to reiterate that nothing in these amendments to section 506(b) is intended to alter the FDA's historical practice of utilizing unvalidated surrogates to grant accelerated approval in appropriate cases or its practice of granting traditional approval under section 505(b) based on validated surrogates in appropriate cases.

Mr. LEAHY. Madam President, Senator MANCHIN's amendment, amendment 2151 to the Food and Drug Administration Safety and Innovation Act, seeks to address the problem of prescription opiate drugs by tightening restrictions on hydrocodone. Opiate prescription drugs like hydrocodone have been a tremendous and growing problem in Vermont, as they have in West Virginia. I thank Senator MANCHIN for working with me to make the amendment better.

The scourge of prescription drug abuse has had a devastating effect in communities across the country. I heard about the lives destroyed by this epidemic and the violence and other ills it has brought with it in several hearings in Vermont in recent years. Senator MANCHIN's amendment seeks to make it more difficult for prescription drugs to get into the hands of those who would abuse them by requiring prescriptions more comprehensively and by restricting storage and transportation. I hope these steps will be helpful.

I am glad Senator MANCHIN was willing to work with me to modify the amendment so that it did not cause as many sentencing increases, and particularly to eliminate what would have been a new mandatory minimum sentence. Those who work on the problem of prescription drugs every day have not identified a lack of adequate criminal sentences to be part of the problem, so a significant change in the sentencing scheme was not needed or intended.

Indeed, the proliferation of severe sentences for drug offenses and of mandatory minimum sentences in particular is a large part of what has led to the serious problem we face now in having too many people in prison for too long. These sentences have contributed to the runaway prison costs that are so crippling to Federal and State budgets.

Overwhelming prison costs take resources away from programs focusing on drug prevention, drug treatment, and strong law enforcement, all of which are more effective in helping communities take on prescription drug problems than are lengthy sentences. I am glad that we could work to ensure that this amendment would help to address our prescription drug problem without contributing to the overincarceration of drug offenders.

I know some doctors in Vermont and elsewhere continue to have concerns about the effect this amendment will have on getting prescriptions to those who need them. I hope we can continue working together to ensure that we tackle the difficult problem of prescription drug addiction without hindering crucial medical care.

I thank Senator MANCHIN for his leadership on this issue.

Mr. REED. Madam President, I am pleased that last night, my amendment, No. 2126, which would ensure that there are no future delays on the implementation of new sunscreen labeling and testing standards, was adopted as part of the Food and Drug Administration Safety and Innovation Act.

Because sunscreens have been considered a cosmetic, they have largely avoided government oversight and the FDA hasn't changed its recommendations for sunscreen standards in over 30 years.

However, last June, after years of prodding by our former colleague Senator Dodd, me, and others, the FDA finally acted.

The agency finalized comprehensive new sunscreen regulations that were scheduled to go into effect on June 18, just a few weeks from now and in time for summer. Indeed, this was considered a victory for families across the country that spend more time outdoors and under the sun's harmful UVA and UVB rays during the summer months.

But just 2 weeks ago, the FDA announced it is now giving the industry an extra 6 months to make changes, meaning the standards will take effect in mid-December instead of this summer.

For too long the FDA has allowed manufacturers to get away with inaccurate claims about sun protection. My amendment will protect against any future delays and ensure the new sunscreen safety and labeling standards go into effect no later than the end of this year.

I am pleased that the Environmental Working Group supports this amendment, and the Consumer Health Care Products Association, which represents sunscreen manufacturers, has agreed to the amendment's inclusion in this bill. Finally, the Congressional Budget Office has informed me that my amendment would not result in any additional cost to the Federal government.

I thank Chairman HARKIN and Senator ENZI for reviewing this amendment and including it in this FDA reauthorization bill.

Mr. LEVIN. Madam President, I will support final passage of the Food and Drug Administration Safety and Innovation Act which will reauthorize the user fee agreements that govern the fees paid by the pharmaceutical and medical device industries to the Food and Drug Administration, FDA, to expedite the drug and device approval process.

These fees are an important funding source that provides the FDA with resources necessary to ensure potentially lifesaving drugs and medical devices can be reviewed and ultimately brought to market quickly and safely. I understand this legislation is the product of a tremendous amount of work by the chairman and ranking member of the HELP Committee, in conjunction with various stakeholders, and enjoys broad support from industry, the FDA, and consumer groups.

For the first time, this bill will also create new user fee agreements for generic drug manufacturers; manufacturers of biologics; and would make permanent the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. These two laws together help improve the safety and efficacy of pharmaceuticals for children.

Of particular interest, the bill aims to address drug shortages by requiring all manufactures of certain drugs to provide advance notification of possible supply disruptions and any permanent discontinuance of these products to the Health and Human Services Secretary. In addition, it will also require HHS to establish a task force to address possible drug shortages and will grant the secretary the authority to expedite the inspection and review process of substitute products that could mitigate a shortage.

The bill will allow the FDA to continue to collect fees from pharmaceutical manufacturers and medical device manufacturers through 2017. I am pleased to join with colleagues from both sides of the aisle in voting in favor of this important legislation.

Ms. MIKULSKI. Madam President, I applaud the effort underway between the FDA and industry to develop a transitional pathway for the regulation of emerging diagnostic tests. In addition, I am pleased that the FDA expressed its commitment to work with industry on this important initiative in the MDUFA III commitment letter.

Many new diagnostic tests serve as the missing link to improved health care through better detection, treatment, and monitoring of disease. Thus, it is critical for public health that FDA's premarket review system for diagnostics be modernized in a manner that supports advances in the sciences and promotes patient access.

I look forward to developments with respect to the agency's plans to develop a transitional in vitro diagnostics pathway and steps taken related to its implementation.

I also wish to talk about two massively important laws that work to ensure that medications used in children are tested and labeled correctly—the Best Pharmaceuticals for Children Act, known as BPCA, and the Pediatric Research Equity Act, known as PREA.

Taken together, these two laws encourage and require drug companies to study their products in children. They have been hugely successful in ensuring that physicians and parents have information needed to best treat our Nation's children.

Most drugs on the market have never been tested in children, largely because manufacturers face economic, mechanical, ethical, and legal obstacles that work to discourage pediatric testing.

With respect to economic obstacles, the pediatric drug marketplace is generally small, with little economic incentive for manufacturers to commit resources to testing in children when they could just test in the much larger adult population.

With respect to mechanical obstacles, young children often cannot swallow pills. This presents a challenge for drug manufacturers, who often then have to develop alternate formulations, such as liquids or chewable tablets. Finally, even for adults, ethical and legal requirements for participation in a clinical trial are incredibly complex and challenging. Trying to recruit children for trials is even more difficult. Parents don't want their kids used in experiments, and drug companies face added liability concerns.

We understand these challenges, but doctors still must treat children—many with serious and life-threatening conditions. And, too often, doctors are forced to prescribe drugs that have never been studied in kids. So in 2002 and 2003 Congress passed laws that serve as a carrot and stick to generate more pediatric drug information. We passed the Pediatric Research Equity Act, which requires safety and efficacy studies in children for all new drugs. For drugs that were on the market before PREA was enacted, the law allows FDA to go back and mandate child studies where appropriate.

We also passed the Best Pharmaceuticals for Children Act, which rewards drug companies with 6 months additional exclusivity if they complete additional pediatric testing requested by FDA.

As a result of BPCA and PREA, over 425 drug labels have been revised with important pediatric information. Before BPCA and PREA, more than 80 percent of drugs used in kids were used off-label without data on safety and efficacy. Today, that number has been reduced to approximately 50 percent. New pediatric studies conducted as result of BPCA and PREA have resulted in new dosing information, new indications of use, new safety information, and new data on effectiveness in children.

The Food and Drug Administration Safety and Innovation Act removes the 5-year sunsets for BPCA and PREA, giving biopharmaceutical companies a more predictable regulatory path and providing certainty that these programs will still be up and running when companies complete their pediatric trials.

This bill also makes important pediatric information publicly available. The last reauthorization of BPCA and PREA ensured that certain pediatric studies were made publicly available but did not ensure the availability of pre-2007 studies. This bill ensures that pediatric studies conducted between 2002 and 2007, which resulted in a labeling change, are made publicly available for physicians, researchers, and parents.

Finally, this bill gives FDA new tools to ensure that studies required by PREA are completed on time, unless there is an appropriate reason for delay.

Children are not small adults. They have different medical needs. The only way to improve the health of current and future generations of children is to better understand how drugs work in pediatric populations. We need to help doctors by getting them more information so that treatment of pediatric diseases is less of a guessing game and more of an informed practice. I believe these two pediatric programs have been incredibly successful, and I am very encouraged by the improvements we make in the bill before us today.

Finally Madam President, I wish to talk about the safety of our Nation's prescription drug supply. Today, there are many challenges and obstacles facing our families—from trying to find or keep a job, to figuring out how to pay off crushing student loans, to obtaining affordable health insurance. One thing that our families shouldn't have to worry about is whether the drug they are taking or whether the drug their loved one is taking to cure or treat an illness is going to harm them instead of help them.

When the modern FDA was first established in 1938, most of our medical products were developed and manufactured within our own borders. That is no longer the case. Nearly 40 percent of drugs Americans rely upon are made outside our borders. About 80 percent of the active ingredients used in drugs made in the United States come from 150 other countries. The increased globalization of our drug industry, coupled with the fact that we have not given our Federal agencies additional authorities to keep pace, has created great challenges for FDA and industry and great danger to patients in need.

Where there is need, there is greed. Where there is greed, there is scam and schemes. In this case, we know that increased globalization and insufficient authorities to regulate at a Federal level has created a dangerous opportunity for bad actors to take advantage. And they have taken advantage—from adulteration, to counterfeiting, to cargo theft, to manufacturing drugs in unsanitary conditions, to mislabeled products. We have seen it all in recent years and the consequences have been deadly.

In recent years, a highly toxic solvent, known as DEG, added to fever medicine, cough syrup, and teething products resulted in the deaths of children and adults in Panama, Haiti, and Nigeria.

In 2007, pet food adulterated with melamine and acid sickened several thousand pets in the United States. Melamine and acid was added to infant formula in China, poisoning and killing six babies and sickening 300,000 others.

In 2008, contaminated Heparin from China killed and sickened hundreds across the United States.

In 2003, more than $20 million in illegally imported and counterfeit Lipitor was sold throughout the United States.

In 2009, an estimated 46 drug cargo thefts occurred, valued at $184 million.

Many stolen drugs are then improperly stored or handled before being sold back to consumers, putting patients at risk. For instance, stolen insulin was reintroduced into the drug supply and caused adverse events in patients because it had not been refrigerated. I could go on and on with examples of how counterfeit, adulterated, and stolen drugs have sickened and killed people and animals worldwide.

But, I am encouraged by the bill before us today. The FDA Safety and Innovation Act takes a number of important steps to improve the safety of our Nation's drug supply. For instance, this legislation requires every foreign establishment engaged in the manufacture of a drug or device imported into the United States, to electronically register with the FDA.

Under current law, there are no requirements governing how often FDA must inspect foreign facilities. The bill before us requires FDA to set up a risk-based inspection frequency to ensure that we are getting in there and inspecting facilities that pose the greatest risks.

This legislation gives the Secretary of Homeland Security the authority to refuse admission into the United States any drug or ingredient if it was manufactured, processed, packed, or held at an establishment that has refused or delayed inspection by FDA.

This bill requires drug manufacturers and wholesalers to notify the FDA if they become aware that their drug has been counterfeited or has been stolen or lost in substantial quantities.

Finally, this bill increases penalties for bad actors who knowingly adulterate or counterfeit drugs.

In developing this legislation, the question we had to ask was this: Does the Federal agency tasked with ensuring the safety of our Nation's drugs have the resources and authorities necessary to do their job and protect the public health? The answer was no. But I believe the new authorities contained in the FDA Safety and Innovation Act—which we developed on a bipartisan basis in the Senate HELP committee—will help us ensure that the next time we ask this question, the answer will be yes.

Mr. DURBIN. Madam President, today, we are considering a bill that will improve the FDA's ability to assure the safety of drugs in our medicine cabinets and medical devices in our hospitals.

The FDA is an essential guardian of the public's health and safety.

In the past few years, FDA has faced obstacles that call on the agency to adapt and respond to the evolving nature of reviewing, manufacturing, and distributing drugs and devices.

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

Last fall, I visited Cook Medical's medical device plant in Canton, IL, and representatives expressed concern about the amount of time it takes medical devices to be reviewed.

FDA needs sufficient time to review medical devices in order to ensure their safety and effectiveness. However, inefficiencies and insufficient resources can result in longer review times, which means patients have to wait longer to benefit from new medical devices.

This bill makes key changes to maintain the safety of devices and preserve our country's leadership in biomedical innovation.

The bill will authorize the FDA to collect almost $600 million in user fees over 5 years. FDA can use these additional resources to help hire and train staff.

Furthermore, the bill makes important improvements by streamlining the review process for devices and increasing communication between the FDA and device manufacturers throughout the review process.

These changes to the review of medical devices will not only help innovative device companies get their product to market faster but will prevent patients from having to wait extra weeks and months to benefit from a new device.

In addition to reauthorizing the Prescription Drug and Medical Device User Fee Acts, this bill also establishes the Generic Drug User Fee Act and Biosimilar User Fee Act, which give FDA new authority to collect user fees for generic and biosimilar drugs.

Currently the FDA does not collect user fees to support the review of generic drugs, and it takes about 30 months for the agency to review generic drug applications. This extra time reduces access to safe, affordable generic drugs and leaves patients and taxpayers paying the tab for brand-name drugs that lack competition from generics.

Since the first Prescription Drug User Fee Act was enacted in 1992, the FDA began collecting user fees to support the review of applications.

FDA has cut the review time for new drugs by 60 percent, from 2 years to a little over 1 year.

Similarly, the Generic Drug User Fee Act will give FDA the support it needs to cut the current 30-month review time for generic drugs down to 10 months.

This improvement will promote competition in the marketplace and save money by reducing the amount of time patients have to wait for less expensive generic alternatives to brand-name drugs.

The process of negotiating and drafting this legislation started 18 months ago, and the result is a comprehensive bill that improves the safety and quality of drugs and medical devices.

Chairman HARKIN and Senator ENZI have put together a bill that responds to many of these challenges, including one that is of particular interest to me—the national shortage of critical drugs.

Between 2006 and 2010 the drug shortage increased 200 percent—from 56 to 178 drugs. Currently the drug shortage includes over 200 drugs, such as intravenous nutrition supplements, cancer treating drugs, and anesthesia.

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

At Advocate Hospital in Libertyville, a doctor shared that he learned just days before starting a patient on chemotherapy that the drug was not available. Unfortunately, this is a common scenario across the country as doctors learn days before starting a treatment or even once the patient is on the hospital bed that a drug is not available.

Pharmacists now spend part of each day scrambling to find drugs or an alternative treatment.

I recently learned that a young woman on my staff here in DC is all too familiar with the drug shortage. She is a smart and hardworking woman

who has been taking Concerta to treat her ADD since she was 14. Like most people with severe ADD, she must take her medicine at a certain time every day in order to keep their ADD symptoms from impeding basic life and work responsibilities. And while there are several ADD drugs on the market, each drug works differently and can have different side effects, so switching to a new prescription is not without risk.

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

Over time, she grew accustomed to going between these two CVS pharmacies to fill her prescription until one month when she carried her prescription with her for 3 days and was unable to find a pharmacy with enough Concerta to fill her 30-day prescription. By the end of day 3, she was out of her supply. She woke up early and rode her bike to four or five CVS pharmacies until she was able to find a pharmacy that could fill her prescription. But by then it was 12 o'clock and past the prescribed time to take the drug.

The shortage of ADD drugs impacts children, adults, parents, and employees across the country.

Congress must take action to address the drug shortage.

The FDA Safety and Innovation Act builds on Senator KLOBUCHAR's bill, with key provisions to curb the national drug shortage.

First, the bill requires drug manufacturers to notify the FDA 6 months in advance for certain drug shortages.

With this much notice, the FDA can work with manufacturers to try to avoid a shortage and, when necessary, identify alternative sources of the drug to ensure we maintain a supply for patients.

This winter, thanks to open communication between the FDA and drug companies, the FDA successfully avoided a shortage of methotrexate, a vital drug to treat leukemia with children.

FDA collaborated with Illinois-based generic drug manufacturer Hospira to increase production of this lifesaving drug when another company halted production.

Requiring 6 months' advance notice of a drug shortage will help the FDA to work with companies to avoid shortages of critical drugs.

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

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

In 2008, serious injuries and 81 deaths were linked to contamination of the crucial blood thinning drug heparin. The source of the contamination was a facility in China that intentionally adulterated the drug. This was a horrible illustration of what happens when adulterated and counterfeit drugs make their way into the drug supply chain and ultimately to patients.

This case has also raised serious questions about the global manufacturing practices of drugs and drug ingredients and the FDA's responsibility to protect the drug supply chain. Since the heparin incident, the global nature of the drug supply chain has only grown. Today, 80 percent of active pharmaceutical ingredients are manufactured outside of the United States.

This bill improves the safety of our supply chain both domestically and internationally by requiring foreign manufacturers to register their facilities with the FDA.

The bill also places greater responsibility on U.S. drug manufacturers to know their international suppliers and increases penalties for intentionally contaminating or counterfeiting drugs.

Counterfeit and adulterated drugs can have deadly consequences, yet the penalty for committing these crimes is less than the penalty for selling a counterfeit designer purse. Currently, the penalty for intentionally counterfeiting or adulterating a drug is no more than 3 ears in prison or a $10,000 fine or both. This bill raises the penalty for intentionally adulterating a drug to no more than 20 years in prison or a $1 million fine or both. And the penalty for intentionally counterfeiting drugs is raised to no more than 20 years in prison or a $4 million fine or both.

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

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

The PRESIDING OFFICER. The question is on the engrossment and the third reading of the bill.

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

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote on passage of the bill, as amended.

The Senator from Iowa.

Mr. HARKIN. Madam President, we have all put in a lot of work and benefited greatly by the constructive ideas and efforts of all the Members of this body. I sincerely thank all my colleagues, especially Senator ENZI, for their hard work on this must-pass legislation.

This excellent bill is a shining example of what we can achieve when we all work together. Now we must keep our promise to patients and the biomedical industry and pass this critical bill.

Today, with one vote, we can reauthorize the essential FDA's user fee agreements, systematically modernize FDA's medical product authority, and help to boost American innovation and ensure that patients have access to the therapies they need.

So I urge my colleagues to join in this bipartisan spirit of cooperation and pass this important legislation, the FDA Safety and Innovation Act.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, the chairman has said it well. We appreciate the bipartisan spirit in which people have participated, especially in committee for a year and a half, working out amendments, working out ideas, and coming up with a bill that had a good consensus.

I appreciate the action on the Senate floor, the people who were willing to do time limits on their amendments, and how quickly we have gotten through the votes.

I particularly want to thank the chairman for the way he has handled this in committee and the process since then. We had a couple of issues that were outstanding and those got worked out.

I also want to thank the staffs on both sides. Their dedication for a year and a half is what made this happen, and we have some outstanding staff on both sides. Every member of the committee and every committee member's staff helped on this one, and that makes a difference. So I ask everyone to support the bill.

I yield the floor.

The PRESIDING OFFICER. The question is, Shall the bill pass?

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The assistant bill clerk called the roll.

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

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

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

The result was announced—yeas 96, nays 1, as follows:

[Rollcall Vote No. 111 Leg.]

YEAS—96

Akaka	Begich	Boxer
Alexander	Bennet	Brown (MA)
Ayotte	Bingaman	Brown (OH)
Barrasso	Blunt	Burr
Baucus	Boozman	Cantwell

Cardin	Inouye	Nelson (FL)
Carper	Isakson	Paul
Casey	Johanns	Portman
Chambliss	Johnson (SD)	Pryor
Coats	Johnson (WI)	Reed
Coburn	Kerry	Reid
Cochran	Klobuchar	Risch
Collins	Kohl	Roberts
Conrad	Kyl	Rockefeller
Coons	Landrieu	Rubio
Corker	Lautenberg	Schumer
Cornyn	Leahy	Sessions
Crapo	Lee	Shaheen
DeMint	Levin	Shelby
Durbin	Lieberman	Snowe
Enzi	Lugar	Stabenow
Feinstein	Manchin	Tester
Franken	McCain	Thune
Gillibrand	McCaskill	Toomey
Graham	McConnell	Udall (CO)
Grassley	Menendez	Udall (NM)
Hagan	Merkley	Vitter
Harkin	Mikulski	Warner
Hatch	Moran	Webb
Heller	Murkowski	Whitehouse
Hoeven	Murray	Wicker
Inhofe	Nelson (NE)	Wyden

NAYS—1

Sanders

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The bill (S. 3187), as amended, was passed, as follows:

S. 3187

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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

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

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

(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 OBTAINED FROM FOREIGN GOVERNMENTS.—

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

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

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

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

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

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

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner.

''(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

''(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1)

and that has executed a written agreement under paragraph (2) information referenced in section 301(j) in the following circumstances:

''(A) Information concerning the inspection of a facility may be provided if—

''(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

''(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

''(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.''.

SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

''For purposes of subsection (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.''.

SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

''SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

''(a) DEFINITIONS.—In this section:

''(1) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

''(2) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor (which may be an individual) accredited by an accreditation body to conduct drug safety and quality audits.

''(3) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct drug safety and quality audits on behalf of an accredited third-party auditor.

''(4) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity intended for internal purposes only to determine whether an establishment is in compliance with the provisions of this Act and applicable industry practices, or any other such service.

''(5) DRUG SAFETY AND QUALITY AUDIT.—The term 'drug safety and quality audit'—

''(A) means an audit of an eligible entity to certify that the eligible entity meets the requirements of this Act applicable to drugs, including the requirements of section 501 with respect to drugs; and

''(B) is not a consultative audit.

''(6) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity, including a foreign drug establishment registered under section 510(c), in the drug supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

''(7) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government or any other third party (which may be an individual), as the Secretary determines appropriate in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for accreditation to conduct drug safety and quality audits.

''(b) ACCREDITATION SYSTEM.—

''(1) RECOGNITION OF ACCREDITATION BODIES.—

''(A) IN GENERAL.—Not later than 2 years after date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

''(B) DIRECT ACCREDITATION.—

''(i) IN GENERAL.—If, by the date that is 2 years after the date of establishment of the system described in subparagraph (A), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

''(ii) CERTAIN DIRECT ACCREDITATIONS.—Notwithstanding subparagraph (A) or clause (i), the Secretary may directly accredit any foreign government or any agency of a foreign government as a third-party auditor at any time after the date of enactment of the Food and Drug Administration Safety and Innovation Act.

''(2) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary—

''(A) a list of all accredited third-party auditors accredited by such body (including the name, contact information, and scope and duration of accreditation for each such auditor), and the audit agents of such auditors; and

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

''(3) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(4) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

''(5) MODEL ACCREDITATION STANDARDS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall develop model standards, including standards for drug safety and quality audit results, reports, and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section.

''(B) CONTENT.—The standards developed under subparagraph (A) may—

''(i) include a description of required standards relating to the training procedures, competency, management responsibilities, quality control, and conflict of interest requirements of accredited third-party auditors; and

''(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

''(C) REQUIREMENT TO PROVIDE RESULTS AND REPORTS TO THE SECRETARY.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to provide to the Secretary, upon request, the results and reports of any drug safety and quality audit conducted pursuant to the accreditation provided under this section.

''(6) DISCLOSURE.—The Secretary shall maintain on the Internet Web site of the Food and Drug Administration a list of recognized accreditation bodies and accredited third-party auditors under this section.

''(c) ACCREDITED THIRD-PARTY AUDITORS.—

''(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

''(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of drug safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or drugs certified by such government or agency meet the requirements of this Act.

''(B) OTHER THIRD PARTIES.—Prior to accrediting any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that party and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the third-party auditor is capable of adequately ensuring that an eligible entity or drug certified by such third-party auditor meets the requirements of this Act.

''(2) USE OF AUDIT AGENTS.—An accredited third-party auditor may conduct drug safety and quality audits and may employ or use audit agents to conduct drug safety and quality audits, but must ensure that such audit agents comply with all requirements the Secretary deems necessary, including requirements under paragraph (1) and subsection (b)(5).

''(3) REVOCATION OF ACCREDITATION.—

''(A) IN GENERAL.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the accreditation of an accredited third-party auditor—

''(i) if, following an evaluation, the Secretary finds that the accredited third-party auditor is not in compliance with the requirements of this section; or

''(ii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to determine compliance with the requirements set forth in this section.

''(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party

auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(3) is revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

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

''(A) if the Secretary determines, based on evidence presented, that—

''(i) the third-party auditor satisfies the requirements of this section; and

''(ii) adequate grounds for revocation no longer exist; and

''(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3)—

''(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (3), through direct accreditation under subsection (b)(1)(B), or by an accreditation body in good standing; or

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

''(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

''(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic, document or certification, as the Secretary may require under this Act, regarding compliance with section 501. The Secretary may consider any such document or certification to satisfy requirements under section 801(r) and to target inspection resources under section 510(h).

''(B) REQUIREMENTS FOR ISSUING CERTIFICATION.—

''(i) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) only after conducting a drug safety and quality audit and such other activities that may be necessary to establish compliance with the provisions of section 501.

''(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a drug certification described in subparagraph (A).

''(C) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor or any audit agent of such auditor to submit to the Secretary a drug safety and quality audit report and such other reports or documents required as part of the drug safety and quality audit process, for any eligible entity for which the accredited third-party auditor or audit agent of such auditor performed a drug safety and quality audit. The Secretary may require documentation that the eligible entity is in compliance with any applicable registration requirements.

''(D) LIMITATION.—The requirement under subparagraph (C) shall not include any report or other documents resulting from a consultative audit, except that the Secretary may access the results of a consultative audit in accordance with section 704.

''(E) DECLARATION OF AUDIT TYPE.—Before an accredited third-party auditor begins any audit or provides any consultative service to an eligible entity, both the accredited third-party auditor and eligible entity shall establish in writing whether the audit is intended to be a drug safety and quality audit. Any audit, inspection, or consultative service of any type provided by an accredited third-party auditor on behalf of an eligible entity shall be presumed to be a drug safety and quality audit in the absence of such a written agreement. Once a drug safety and quality audit is initiated, it shall be subject to the requirements of this section, and no person may withhold from the Secretary any document subject to subparagraph (C) on the grounds that the audit was a consultative audit or otherwise not a drug safety and quality audit.

''(F) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary under section 704.

''(6) REQUIREMENTS REGARDING SERIOUS RISKS TO THE PUBLIC HEALTH.—If, at any time during a drug safety and quality audit, an accredited third-party auditor or an audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

''(A) the identity and location of the eligible entity subject to the drug safety and quality audit; and

''(B) such condition.

''(7) LIMITATIONS.—

''(A) IN GENERAL.—An audit agent of an accredited third-party auditor may not perform a drug safety and quality audit of an eligible entity if such audit agent has performed a drug safety and quality audit or consultative audit of such eligible entity during the previous 13-month period.

''(B) WAIVER.—The Secretary may waive the application of subparagraph (A) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region or that the use of the same audit agent or accredited third-party auditor is otherwise necessary.

''(8) CONFLICTS OF INTEREST.—

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

''(i) not be owned, managed, or controlled by any person that owns or operates a third-party auditor to be accredited by such body;

''(ii) in carrying out accreditation of third-party auditors under this section, have procedures to ensure against the use of any officer or employee of such body that has a financial conflict of interest regarding a third-party auditor to be accredited by such body; and

''(iii) annually make available to the Secretary disclosures of the extent to which such body and the officers and employees of such body have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(B) ACCREDITED THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

''(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

''(ii) in carrying out drug safety and quality audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

''(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(C) AUDIT AGENTS.—An audit agent shall—

''(i) not own or operate an eligible entity to be audited by such agent;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

''(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(d) FALSE STATEMENTS.—Any statement or representation made—

''(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

''(2) by an accreditation body, accredited third-party auditor, or audit agent of such auditor to the Secretary, shall be subject to section 1001 of title 18, United States Code.

''(e) MONITORING.—To ensure compliance with the requirements of this section, the Secretary—

''(1) shall periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

''(2) shall periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

''(3) may at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

''(4) shall take any other measures deemed necessary by the Secretary.

''(f) EFFECT OF AUDIT.—The results of a drug safety and quality audit by an accredited third-party auditor under this section—

''(1) may be used by the eligible entity—

''(A) as documentation of compliance with section 501(a)(2)(B) or section 801(r); and

''(B) for other purposes as determined appropriate by the Secretary; and

''(2) shall be used by the Secretary in establishing the risk-based inspection schedules under section 510(h).

''(g) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—The Secretary may assess fees on accreditation bodies and accredited third-party auditors in such an amount necessary to establish and administer the recognition and accreditation program under this section. The Secretary may require accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to carry out this section. The Secretary shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

''(2) AUTHORIZED FEES FOR RECOGNIZED ACCREDITATION BODIES.—An accreditation body recognized by the Secretary under subsection (b) may assess a reasonable fee to accredit third-party auditors.

''(h) LIMITATIONS.—

''(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The drug safety and quality audits performed under this section shall not be considered inspections under section 704.

''(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.

''(i) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and

Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating the regulations implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) CONTENT.—Such regulations shall include—

''(A) requirements that, to the extent practicable, drug safety and quality audits performed under this section be unannounced;

''(B) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

''(C) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).

''(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).''.

(b) REPORT ON ACCREDITED THIRD-PARTY AUDITORS.—Not later than January 20, 2017, the Comptroller General of the United States shall submit to Congress a report that addresses the following, with respect to the period beginning on the date of implementation of section 809 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and ending on the date of such report:

(1) The extent to which drug safety and quality audits completed by accredited third-party auditors under such section 809 are being used by the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') in establishing or applying the risk-based inspection schedules under section 510(h) of such Act (as amended by section 705).

(2) The extent to which drug safety and quality audits completed by accredited third-party auditors or agents are assisting the Food and Drug Administration in evaluating compliance with sections 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B)) and 801(r) of such Act (as added by section 711).

(3) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under such section 809.

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

(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors to ensure compliance with the requirements of such section 809.

(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.

(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.

(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue, modify, or terminate the program.

SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

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

(2) by adding at the end the following:

''(r)(1) The Secretary may require, as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

''(2) The information described under paragraph (1) may include—

''(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

''(B) facility information, such as proof of registration and the unique facility identifier;

''(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

''(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

''(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

''(A) by certifications from accredited third parties, as described under section 809;

''(B) through representation by a foreign government, if such inspection is conducted using standards and practices as determined appropriate by the Secretary; or

''(C) other appropriate documentation or evidence as described by the Secretary.

''(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

''(B) In promulgating the regulations implementing this subsection, the Secretary shall—

''(i) issue a notice of proposed rulemaking that includes the proposed regulation;

''(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

''(iii) publish the final regulation not less than 30 days before the effective date of the regulation.

''(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).''.

SEC. 712. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(aaa) The failure to notify the Secretary in violation of section 568.''.

(b) NOTIFICATION.—

(1) IN GENERAL.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a covered person if the covered person knows—

''(1) of a substantial loss or theft of such drug; or

''(2) that such drug—

''(A) has been or is being counterfeited; and

''(B)(i) is a counterfeit product in commerce in the United States; or

''(ii) is offered for import into the United States.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in a reasonable time, in such reasonable manner, and by such reasonable means as the Secretary may require by regulation or specify in guidance.

''(c) DEFINITION.—In this section, the term 'covered person' means—

''(1) a person who is required to register under section 510 with respect to an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug; or

''(2) a person engaged in the wholesale distribution (as defined in section 503(e)(3)(B)) of a drug.''.

(2) APPLICABILITY.—Notifications under section 568 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) apply to losses, thefts, or counterfeiting, as described in subsection (a) of such section 568, that occur on or after the date of enactment of this Act.

SEC. 713. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 714. ENHANCED CRIMINAL PENALTY FOR COUNTERFEITING DRUGS.

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

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

(b) TITLE 18.—Section 2320(b) of title 18, United States Code, is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by inserting after paragraph (1) the following:

''(2) COUNTERFEIT DRUGS.—

''(A) IN GENERAL.—Whoever commits an offense under subsection (a) with respect to a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) shall—

''(i) if an individual, be fined not more than $4,000,000, imprisoned not more than 20 years, or both; and

''(ii) if a person other than an individual, be fined not more than $10,000,000.

''(B) MULTIPLE OFFENSES.—In the case of an offense by a person under this paragraph that occurs after that person is convicted of another offense under this paragraph, the person convicted—

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

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

(c) SENTENCING.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to its authority under section 994(p) of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and amend, if appropriate, its guidelines and its policy statements applicable to persons convicted of an offense described in section 2320(b)(2) of title 18, United States Code, as amended by subsection (b), in order to reflect the intent of Congress that such penalties be increased in comparison to those currently provided by the guidelines and policy statements.

(2) REQUIREMENTS.—In carrying out this subsection, the Commission shall—

(A) ensure that the sentencing guidelines and policy statements reflect the intent of Congress that the guidelines and policy statements reflect the serious nature of the offenses described in paragraph (1) and the need for an effective deterrent and appropriate punishment to prevent such offenses;

(B) consider the extent to which the guidelines may or may not appropriately account for the potential and actual harm to the public resulting from the offense;

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

(D) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

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

(F) assure that the guidelines adequately meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.

SEC. 715. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

SEC. 716. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this title (or an amendment made by this title) shall be construed in a manner inconsistent with the obligations of the United States under the Agreement Establishing the World Trade Organization, or any other treaty or international agreement to which the United States is a party.

Subtitle B—Pharmaceutical Distribution Integrity

SEC. 721. SHORT TITLE.

This subtitle may be referred to as the ''Securing Pharmaceutical Distribution Integrity to Protect the Public Health Act of 2012'' or the ''Securing Pharmaceutical Distribution Integrity Act of 2012''.

SEC. 722. SECURING THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter H—Pharmaceutical Distribution Integrity

''SEC. 581. DEFINITIONS.

''In this subchapter:

''(1) DATA CARRIER.—The term 'data carrier' means a machine-readable graphic that is intended to be affixed to, or imprinted upon, an individual saleable unit and a homogeneous case of product. The data carrier shall comply with a form and format developed by a widely recognized international standards development organization to ensure interoperability among distribution chain participants.

''(2) INDIVIDUAL SALEABLE UNIT.—The term 'individual saleable unit' means the smallest container of product put into interstate commerce by the manufacturer that is intended by the manufacturer for individual sale to a pharmacy or other dispenser of such product.

''(3) PRODUCT.—The term 'product' means a finished drug subject to section 503(b)(1).

''(4) PRODUCT TRACING.—The term 'product tracing' means—

''(A) identifying the immediate previous source and immediate subsequent recipient of a product in wholesale distribution at the lot level where a change of ownership of such product has occurred between non-affiliated entities, except as otherwise described in this subchapter;

''(B) identifying the immediate subsequent recipient of the product at the lot level when a manufacturer or repackager introduces such product into interstate commerce;

''(C) identifying that manufacturer and dispenser of a product at the lot level when a manufacturer ships a product at the lot level, without regard to the change in ownership involving the wholesale distributor; and

''(D) identifying the immediate previous source of a product at the lot level for dispensers.

''(5) RXTEC.—The term 'RxTEC' means a data carrier that includes the standardized numerical identifier (SNI), the lot number, and the expiration date of a product. The standard data carrier RxTEC shall be a 2D data matrix barcode affixed to each individual saleable unit of a product and a linear or 2D data matrix barcode on a homogenous case of a product. Such information shall be both machine readable and human readable.

''(6) SUSPECT PRODUCT.—The term 'suspect product' means a product that, based on credible evidence—

''(A) is potentially counterfeit, diverted, or stolen;

''(B) is reasonably likely to be intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; or

''(C) appears otherwise unfit for distribution such that the product would result in serious adverse health consequence or death to humans.

''(7) VERIFICATION.—The term 'verification' means the process of determining whether a product has the standardized numerical identifier or lot number, consistent with section 582, and expiration date assigned by the manufacturer, or the repackager as applicable, and identifying whether a product has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution. Verification of the RxTEC data may occur by using either a human-readable, machine-readable, or other method such as through purchase records or invoices.

''SEC. 582. ENSURING THE SAFETY OF THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN THROUGH THE ESTABLISHMENT OF AN RXTEC SYSTEM.

''(a) MANUFACTURER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable units and homogeneous case of all products intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in interstate commerce; and

''(C) maintain, where a change of ownership has occurred between non-affiliated entities or, in the case of a return from the immediate previous source, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

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

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(D) provide the following change of ownership and trans action information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the manufacturer did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(E) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (C) and (D) necessary to identify the immediate previous source or immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of a suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the manufacturer, and checking inventory for a suspect product at the request of a trading partner or the Secretary in case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, or theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of the counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered repackager, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION OF PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a manufacturer, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the manufacturer, in consultation with the Secretary, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

''(b) REPACKAGER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable unit and the homogenous case of all product intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and each homogenous case of product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC;

''(C) receive only products encoded with RxTEC data from a licensed or registered manufacturer or wholesaler;

''(D) maintain, where a change of ownership has occurred between non-affiliated entities in wholesale distribution, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(E) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the repackager—

''(I) is licensed or registered;

''(II) received the product from a manufacturer that is licensed or registered;

''(III) received a signed statement from the manufacturer of such product consistent with subsection (a)(1)(D)(vi); and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(F) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, or as determined necessary by the Secretary or such other Federal or State official to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraph (C) or (E) necessary to identify the immediate previous source or the immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include—

''(I) responding to alerts regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the repackager; and

''(II) checking inventory for a suspect product at the request of a trading partner or the Secretary in the case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered manufacturer, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a repackager, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that it would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the repackager, in consultation with the Secretary, and manufacturer as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a repackager to aggregate unit level data to cases or pallets.

''(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive only products encoded with RxTEC from a licensed or registered manufacturer, wholesaler, or repackager;

''(B) maintain, in wholesale distribution where a change of ownership has occurred between non-affiliated entities, change of ownership and transaction information, including—

''(i) RxTEC data by lot;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(C) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product;

''(vi) the date of the transaction; and

''(vii) a signed statement that the wholesale distributor—

''(I) is licensed or registered;

''(II) received the product from a registered or licensed manufacturer, repackager, or wholesale distributor, as applicable;

''(III) received a signed statement from the immediate subsequent recipient of such

product that such trading partner did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(D) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, return, or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (B) and (C), as necessary to identify the immediate previous source or the immediate subsequent recipient of such product.

''(2) VERIFICATION REQUIREMENTS.—

''(A) IN GENERAL.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(i) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidence of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(I) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the wholesale distributor, and checking inventory for a suspect product at the request of a trading partner or the Secretary; and

''(II) shall take into consideration—

''(aa) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(bb) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(cc) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(dd) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(ee) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(ff) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of suspect product entering the pharmaceutical distribution supply chain;

''(ii) conduct lot-level verification in the event of a recall, including upon the request of a licensed or registered manufacturer, repackager, dispenser, or the Secretary, regarding such product and recall;

''(iii) conduct verification of a returned product to validate the return at the lot level for a sealed homogenous case of such product or at the individual saleable unit of such product if the unit is not in a sealed homogenous case; and

''(iv) conduct unit level verification of a suspect product—

''(I) upon the request of a licensed or registered manufacturer, repackager, wholesaler, dispenser, or the Secretary, regarding such product; or

''(II) upon the determination that a product is a suspect product.

''(B) LIMITATION.—Nothing in this paragraph shall require a wholesale distributor to verify product at the unit level except as required under clauses (iii) and (iv) of subparagraph (A).

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a wholesale distributor, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the wholesaler, in consultation with the Secretary, and manufacturer or repackager as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) CONFIDENTIAL DATA.—A wholesale distributor may confidentially maintain RxTEC data for a direct trading partner and provide access to such information to such trading partner in lieu of data transmission, if mutually agreed upon by such trading partners.

''(d) DISPENSER REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A dispenser, not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive product only from a licensed or registered manufacturer, repackager, or wholesale distributor;

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

''(C) maintain RxTEC lot level data or allow the wholesale distributor to confidentially maintain and store the RxTEC lot level data sufficient to identify the product provided to the dispenser from the immediate previous source where a change of ownership has occurred between non-affiliated entities (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor);

''(D) use the RxTEC lot level data maintained by the dispenser or maintained by the wholesale distributor on behalf of the dispenser (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor), as necessary to respond to a request from the Secretary in the event of a suspect product or recall;

''(E) maintain lot level data upon change of ownership between non-affiliated entities and for recalled product; and

''(F) for investigation purposes only, and upon request by the Secretary, other appropriate Federal official, or State official, for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or immediate subsequent receipt of the suspect or recalled product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—Not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a dispenser shall be required to conduct lot level verification of suspect product only.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a dispenser, upon confirming that a product is a suspect product or a product otherwise unfit for distribution, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this paragraph may not be redistributed as a saleable product unless the dispenser, in consultation with the Secretary, and manufacturer, repackager, or wholesaler as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) LIMITATIONS.—Nothing in this section shall—

''(i) require a dispenser to verify product at the unit level; or

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

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

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

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

''(3) not prescribe or proscribe specific technologies or systems for the maintenance and transmission of data other than the standard data carrier for RxTEC or specific methods of verification;

''(4) not require a record of the complete previous distribution history of the drug from the point of origin of such drug;

''(5) take into consideration whether the public health benefits of imposing any additional regulations outweigh the cost of compliance with such requirements;

''(6) be scale-appropriate and practicable for entities of varying sizes and capabilities;

''(7) with respect to cost and recordkeeping burdens, not require the creation and maintenance of duplicative records where the information is contained in other company records kept in the normal course of business;

''(8) to the extent practicable, not require specific business systems for compliance with such requirements;

''(9) include a process by which the Secretary may issue a waiver of such regulations for an individual entity if the Secretary determines that such requirements would result in an economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act; and

''(10) include a process by which the Secretary may determine exceptions to the standard data carrier RxTEC requirement if a drug is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section.

''(f) REGULATIONS AND GUIDANCE.—

''(1) IN GENERAL.—The Secretary may issue guidance consistent with this section regarding the circumstances surrounding suspect product and verification practices.

''(2) PROCEDURE.—The Secretary, in promulgating any regulation pursuant to this section, shall—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).

''(g) STANDARDS.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other supply chain stakeholders, prioritize and develop standards for the interoperable exchange of ownership and transaction information for tracking and tracing prescription drugs.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 712, is further amended by inserting at the end the following:

''(bbb) The violation of any requirement under section 582.''.

(c) SMALL ENTITY COMPLIANCE GUIDE.—Not later than 180 days after enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue a compliance guide setting forth in plain language the requirements under section 582 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in order to assist small entities in complying with such section.

(d) LIMITATIONS.—

(1) SAVINGS CLAUSE.—Nothing in this subtitle or the amendments made by this subtitle shall preempt any State or local law or regulation.

(2) EFFECT ON CALIFORNIA LAW.—Notwithstanding any other provision of Federal or State law, including any provision of this subtitle or of subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), such subchapter H shall not trigger California Business and Professions Code, section 4034.1.

(3) EFFECTIVE DATE.—Subsection (c) and the amendments made by subsections (a) and (b) shall take effect on January 1, 2022, or on the date on which Congress enacts a law providing for express preemption of any State law regulating the distribution of drugs, whichever is later.

SEC. 723. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

''(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

''(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

''(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

''(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

''(3) an application for a product that is not approved for the use for which it received a designation under subsection (d).

''(d) DESIGNATION.—

''(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

''(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

''(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

''(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary may designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection.

''(f) QUALIFYING PATHOGEN.—

''(1) DEFINITION.—In this section, the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

''(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

''(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; and

''(D) Clostridium difficile.

''(2) LIST OF QUALIFYING PATHOGENS.—

''(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

''(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section the Secretary shall—

''(i) consider—

''(I) the impact on the public health due to drug-resistant organisms in humans;

''(II) the rate of growth of drug-resistant organisms in humans;

''(III) the increase in resistance rates in humans; and

''(IV) the morbidity and mortality in humans; and

''(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

''(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 802. PRIORITY REVIEW.

(a) AMENDMENT.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 524 the following:

''SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''If the Secretary designates a drug under section 505E(d) as a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b).''.

(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 803. FAST TRACK PRODUCT.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b), is amended by inserting '', or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' before the period at the end of the first sentence.

SEC. 804. GAO STUDY.

(a) IN GENERAL.—The Comptroller General of the United States shall—

(1) conduct a study—

(A) on the need for, and public health impact of, incentives to encourage the research, development, and marketing of qualified infectious disease biological products and antifungal products; and

(B) consistent with trade and confidentiality data protections, assessing, for all antibacterial and antifungal drugs, including biological products, the average or aggregate—

(i) costs of all clinical trials for each phase;

(ii) percentage of success or failure at each phase of clinical trials; and

(iii) public versus private funding levels of the trials for each phase; and

(2) not later than 1 year after the date of enactment of this Act, submit a report to Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.

(b) CONTENTS.—The part of the study described in subsection (a)(1)(A) shall include—

(1) an assessment of any underlying regulatory issues related to qualified infectious disease products, including qualified infectious disease biological products;

(2) an assessment of the management by the Food and Drug Administration of the review of qualified infectious disease products, including qualified infectious disease biological products and the regulatory certainty of related regulatory pathways for such products;

(3) a description of any regulatory impediments to the clinical development of new qualified infectious disease products, including qualified infectious disease biological products, and the efforts of the Food and Drug Administration to address such impediments; and

(4) recommendations with respect to—

(A) improving the review and predictability of regulatory pathways for such products; and

(B) overcoming any regulatory impediments identified in paragraph (3).

(c) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''qualified infectious disease biological product'' means a biological product intended to treat a serious or life-threatening infection described in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

(3) The term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 805. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid micro-biological surrogate markers, the use of non-inferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for non-inferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise effect the guidance documents of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) GAO STUDY.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) regarding the review and revision of the clinical trial guidance documents required under subsection (a) and the impact such review and revision has had on the review and approval of qualified infectious disease products;

(2) assessing—

(A) the effectiveness of the results-oriented metrics managers employ to ensure that reviewers of such products are familiar with, and consistently applying, clinical trial guidance documents; and

(B) the predictability of related regulatory pathways and review;

(3) identifying any outstanding regulatory impediments to the clinical development of qualified infectious disease products;

(4) reporting on the progress the Food and Drug Administration has made in addressing the impediments identified under paragraph (3); and

(5) containing recommendations regarding how to improve the review of, and regulatory pathway for, such products.

(d) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section

505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.

(a) INITIAL STRATEGY AND IMPLEMENTATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategy and implementation plan with respect to the requirements of this Act. The strategy and implementation plan shall include—

(1) a description of the regulatory challenges to clinical development, approval, and licensure of qualified infectious disease products;

(2) the regulatory and scientific priorities of the Secretary with respect to such challenges; and

(3) the steps the Secretary will take to ensure regulatory certainty and predictability with respect to qualified infectious disease products, including steps the Secretary will take to ensure managers and reviewers are familiar with related regulatory pathways, requirements of the Food and Drug Administration, guidance documents related to such products, and applying such requirements consistently.

(b) SUBSEQUENT REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on—

(1) the progress made toward the priorities identified under subsection (a)(2);

(2) the number of qualified infectious disease products that have been submitted for approval or licensure on or after the date of enactment of this Act;

(3) a list of qualified infectious disease products with information on the types of exclusivity granted for each product, consistent with the information published under section 505(j)(7)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)(iii));

(4) the number of such qualified infectious disease products and that have been approved or licensed on or after the date of enactment of this Act; and

(5) the number of calendar days it took for the approval or licensure of the qualified infectious disease products approved or licensed on or after the date of enactment of this Act.

(c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.—Section 506 (21 U.S.C. 356) is amended to read as follows:

''SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

''(a) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—

''(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

''(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

''(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

''(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

''(B) That the sponsor submit copies of all promotional materials related to the product during the pre approval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

''(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

''(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

''(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may

commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

''(B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

''(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

''(e) CONSTRUCTION.—

''(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).''.

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

(4) NO EFFECT OF INACTION ON REQUESTS.—If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) INDEPENDENT REVIEW.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. 902. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 901, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) by redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—

''(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

''(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.'';

(4) in subsection (f)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval, and''; and

(5) by adding at the end the following:

''(g) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 712, is further amended by adding at the end the following:

''SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

''(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

''(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (c).

''(2) CONSULTATION WITH EXTERNAL EXPERTS.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (c), when such consultation is necessary because the Secretary lacks specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities and the necessary expertise can be provided by the external experts.

''(b) EXTERNAL EXPERTS.—For purposes of subsection (a)(2), external experts are those who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

''(c) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

''(1) rare diseases;

''(2) the severity of rare diseases;

''(3) the unmet medical need associated with rare diseases;

''(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

''(5) an assessment of the benefits and risks of therapies to treat rare diseases;

''(6) the general design of clinical trials for rare disease populations and subpopulations; and

''(7) demographics and the clinical description of patient populations.

''(d) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

''(e) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

''(f) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(g) NO RIGHT OR OBLIGATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.''.

SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

(a) ESTABLISHMENT OF WORKING GROUP.—

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the ''Access Board'') shall convene a stakeholder working group (referred to in this section as the ''working group'') to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired.

(2) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(3) BEST PRACTICES.—

(A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet websites of the working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities.

(C) LIMITATIONS.—The best practices developed under subparagraph (A) shall not be construed as accessibility guidelines or standards of the Access Board, and shall not confer any rights or impose any obligations on working group participants or other persons. Nothing in this section shall be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other Federal or State law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

(4) CONSIDERATIONS.—In developing and issuing the best practices under paragraph (3)(A), the working group shall consider—

(A) the use of—

(i) Braille;

(ii) auditory means, such as—

(I) ''talking bottles'' that provide audible container label information;

(II) digital voice recorders attached to the prescription drug container; and

(III) radio frequency identification tags;

(iii) enhanced visual means, such as—

(I) large font labels or large font ''duplicate'' labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serf font; and

(iv) other relevant alternatives as determined by the working group;

(B) whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices; and

(C) such other factors as the working group determines to be appropriate.

(5) INFORMATION CAMPAIGN.—Upon completion of development of the best practices under subsection (a)(3), the National Council on Disability, in consultation with the working group, shall conduct an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.

(6) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

(b) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations

about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.

(c) DEFINITIONS.—In this section—

(1) the term ''pharmacy'' includes a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet website or by mail;

(2) the term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(3) the term ''prescription drug container label'' means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispensed to the consumer.

SEC. 905. RISK-BENEFIT FRAMEWORK.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.''.

SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION INDUCEMENT MODEL.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies to provide expert consultation and conduct a study that evaluates the feasibility and possible consequences of the use of innovation inducement prizes to reward successful medical innovations. Under the agreement, the National Academies shall submit to the Secretary a report on such study not later than 15 months after the date of enactment of this Act.

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidate targets for the new incentive system and consider different medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;

(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and

(C) antibiotics.

(c) ELEMENTS.—The study conducted under subsection (a) shall include consideration of each of the following:

(1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly/patent-based system, as in effect on the date of enactment of this Act.

(2) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would be more or less expensive than the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act, calculated over different time periods.

(4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(5) The type of information and decision-making skills that would be necessary to manage end product prizes.

(6) Whether there would there be major advantages in rewarding the incremental impact of innovations, as benchmarked against existing products.

(7) How open-source dividend prizes could be managed, and whether such prizes would increase access to knowledge, materials, data and technologies.

(8) Whether a system of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes.

SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.

(a) REAUTHORIZATION OF PROGRAM.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

(b) HUMAN CLINICAL TESTING.—Section 5(b)(1)(A)(ii)) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking ''after the date such drug is designated under section 526 of such Act and''.

SEC. 908. REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS IN CLINICAL TRIALS AND DATA ANALYSIS IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall publish on the Internet website of the Food and Drug Administration a report, consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act, addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the Food and Drug Administration, and shall provide such publication to Congress.

(2) CONTENTS OF REPORT.—The report described in paragraph (1) shall contain the following:

(A) A description of existing tools to ensure that data to support demographic analyses are submitted in applications for drugs, biological products, and devices, and that these analyses are conducted by applicants consistent with applicable Food and Drug Administration requirements and Guidance for Industry. The report shall address how the Food and Drug Administration makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to healthcare providers, researchers, and patients.

(B) An analysis of the extent to which demographic data subset analyses on sex, age, race, and ethnicity is presented in applications for new drug applications for new molecular entities under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262), and in premarket approval applications under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) for products approved or licensed by the Food and Drug Administration, consistent with applicable requirements and Guidance for Industry, and consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act.

(C) An analysis of the extent to which demographic subgroups, including sex, age, racial, and ethnic subgroups, are represented in clinical studies to support applications for approved or licensed new molecular entities, biological products, and devices.

(D) An analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity is readily available to the public in a timely manner by means of the product labeling or the Food and Drug Administration's Internet website.

(b) ACTION PLAN.—

(1) IN GENERAL.—Not later than 1 year after the publication of the report described in subsection (a), the Secretary, acting through the Commissioner, shall publish an action plan on the Internet website of the Food and Drug Administration, and provide such publication to Congress.

(2) CONTENT OF ACTION PLAN.—The plan described in paragraph (1) shall include—

(A) recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling;

(B) recommendations, as appropriate, on the inclusion of such data, or the lack of availability of such data in labeling;

(C) recommendations, as appropriate, to otherwise improve the public availability of such data to patients, healthcare providers, and researchers; and

(D) a determination with respect to each recommendation identified in subparagraphs (A) through (C) that distinguishes between product types referenced in subsection (a)(2)(B) insofar as the applicability of each such recommendation to each type of product.

(c) DEFINITIONS.—In this section:

(1) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) The term ''device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) The term ''biological product'' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE X—DRUG SHORTAGES

SEC. 1001. DRUG SHORTAGES.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining;

''(C) intended for use in the prevention of a debilitating disease or condition;

''(D) a sterile injectable product; or

''(E) used in emergency medical care or during surgery; and

''(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a

recombinant product, a product derived from human plasma protein, or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that could lead to a meaningful disruption in the supply of that drug in the United States.

''(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

''(1) expedite the review of a supplement to a new drug application submitted under section 505(b), an abbreviated new drug application submitted under section 505(j), or a supplement to such an application submitted under section 505(j) that could help mitigate or prevent such shortage; or

''(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

''(d) COORDINATION.—

''(1) TASK FORCE AND STRATEGIC PLAN.—

''(A) IN GENERAL.—

''(i) TASK FORCE.—As soon as practicable after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a Task Force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

''(ii) STRATEGIC PLAN.—The strategic plan described in clause (i) shall include—

''(I) plans for enhanced interagency and intraagency coordination, communication, and decisionmaking;

''(II) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

''(III) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

''(IV) plans for considering the impact of drug shortages on research and clinical trials.

''(iii) CONSULTATION.—In carrying out this subparagraph, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

''(B) TIMING.—Not later than 1 year after the date of enactment Food and Drug Administration Safety and Innovation Act, the Task Force shall—

''(i) publish the strategic plan described in subparagraph (A); and

''(ii) submit such plan to Congress.

''(2) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under subsection (a), there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

''(3) ACTION.—If the Secretary determines, after the communication described in paragraph (2), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

''(4) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which healthcare providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

''(5) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this subsection shall—

''(A) be subject to judicial review; or

''(B) be construed to establish a defense to an enforcement action by the Secretary.

''(e) RECORDKEEPING AND REPORTING.—

''(1) RECORDKEEPING.—The Secretary shall maintain records related to drug shortages, including with respect to each of the following:

''(A) The number of manufacturers that submitted a notification to the Secretary under subsection (a) in each calendar year.

''(B) The number of drug shortages that occurred in each calendar year and a list of drug names, drug types, and classes that were the subject of such shortages.

''(C) A list of the known factors contributing to the drug shortages described in subparagraph (B).

''(D)(i) A list of major actions taken by the Secretary to prevent or mitigate the drug shortages described in subparagraph (B).

''(ii) The Secretary shall include in the list under clause (i) the following:

''(I) The number of applications for which the Secretary expedited review under subsection (c)(1) in each calendar year.

''(II) The number of establishment inspections or reinspections that the Secretary expedited under subsection (c)(2) in each calendar year.

''(E) The number of notifications submitted to the Secretary under subsection (a) in each calendar year.

''(F) The names of manufacturers that the Secretary has learned did not comply with the notification requirement under subsection (a) in each calendar year.

''(G) The number of times in each calendar year that the Secretary determined under subsection (d)(3) that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), but did not evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter on the grounds that there was imminent risk of serious adverse health consequences or death to humans, and a summary of the determinations.

''(H) A summary of the communications made and actions taken under subsection (d) in each calendar year.

''(I) Any other information the Secretary deems appropriate to better prevent and mitigate drug shortages.

''(2) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

''(3) ANNUAL SUMMARY.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing, with respect to the 1-year period preceding such report, the information described in paragraph (1). Such report shall not include any information that is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(f) DEFINITIONS.—For purposes of this section—

''(1) the term 'drug'—

''(A) means a drug (as defined in section 201(g)) that is intended for human use; and

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (h);

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug; and

''(3) the term 'meaningful disruption'—

''(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and impacts the ability of the manufacturer to fill orders or meet expected demand for its product; and

''(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

''(g) DISTRIBUTION.—To the maximum extent practicable, the Secretary may distribute information on drug shortages and on the permanent discontinuation of the drugs described in this section to appropriate provider and patient organizations, except that any such distribution shall not include any information that is exempt from disclosure under section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(h) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt a final regulation implementing this section.

''(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—The Secretary may by regulation apply this section to biological products (as defined in section 351 of the Public Health Service Act) if the Secretary determines such inclusion would benefit the public health.

''(B) RULE FOR VACCINES.—If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

''(i) consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

''(ii) explain the determination made by the Secretary under clause (i) in the regulation.

''(3) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the regulation's effective date.

''(4) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (3).''.

(b) EFFECT OF NOTIFICATION.—The submission of a notification to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) shall not be construed—

(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

(c) INTERNAL REVIEW.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(1) analyze and review the regulations promulgated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the guidances or policies issued under such Act related to drugs intended for human use, and the practices of the Food and Drug Administration regarding enforcing such Act related to manufacturing of such drugs, to identify any such regulations, guidances, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)); and

(2) determine how regulations, guidances, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce or prevent such drug shortages, taking into consideration the effect of any changes on the public health.

(d) STUDY ON MARKET FACTORS CONTRIBUTING TO DRUG SHORTAGES AND STOCKPILING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary, the Department of Health and Human Services Office of the Inspector General, the Attorney General, and Chairman of the Federal Trade Commission, shall publish a report reviewing any findings that drug shortages (as so defined) have led market participants to stockpile affected drugs or sell them at significantly increased prices, the impact of such activities on Federal revenue, and any economic factors that have exacerbated or created a market for such actions.

(2) CONTENT.—The report under paragraph (1) shall include—

(A) an analysis of the incidence of any of the activities described in paragraph (1) and the effect of such activities on the public health;

(B) an evaluation of whether in such cases there is a correlation between drugs in shortage and—

(i) the number of manufacturers producing such drugs;

(ii) the pricing structure, including Federal reimbursements, for such drugs before such drugs were in shortage, and to the extent possible, revenue received by each such manufacturer of such drugs;

(iii) pricing structure and revenue, to the extent possible, for the same drugs when sold under the conditions described in paragraph (1); and

(iv) the impact of contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) on competition, access to drugs, and pricing of drugs;

(C) whether the activities described in paragraph (1) are consistent with applicable law; and

(D) recommendations to Congress on what, if any, additional reporting or enforcement actions are necessary.

(3) TRADE SECRET AND CONFIDENTIAL INFORMATION.—Nothing in this subsection alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5, United States Code.

(e) GUIDANCE REGARDING REPACKAGING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs among hospitals within a common health system during a drug shortage, as identified by the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) IN GENERAL.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

(b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting ''clinical'' after ''any''.

SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended by striking ''2012'' and inserting ''2017''.

Subtitle B—Medical Gas Product Regulation

SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.

(a) REGULATION.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Medical Gas Products

''SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas product' means any of the following:

''(A) Oxygen, that meets the standards set forth in an official compendium.

''(B) Nitrogen, that meets the standards set forth in an official compendium.

''(C) Nitrous oxide, that meets the standards set forth in an official compendium.

''(D) Carbon dioxide, that meets the standards set forth in an official compendium.

''(E) Helium, that meets the standards set forth in an official compendium.

''(F) Carbon monoxide, that meets the standards set forth in an official compendium.

''(G) Medical air, that meets the standards set forth in an official compendium.

''(H) Any other medical gas product deemed appropriate by the Secretary, unless any period of exclusivity under section 505(c)(3)(E)(ii) or 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas product has not expired.

''(2) The term 'medical gas product' means a drug that—

''(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

''(B) is administered as a gas.

''SEC. 576. REGULATION OF MEDICAL GAS PRODUCTS.

''(a) CERTIFICATION OF DESIGNATED MEDICAL GAS PRODUCTS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Beginning on the date of enactment of this section, any person may file with the Secretary a request for a certification of a designated medical gas product.

''(B) CONTENT.—A request under subparagraph (A) shall contain—

''(i) a description of the medical gas product;

''(ii) the name and address of the sponsor;

''(iii) the name and address of the facility or facilities where the gas product is or will be manufactured; and

''(iv) any other information deemed appropriate by the Secretary to determine whether the medical gas product is a designated medical gas product.

''(2) GRANT OF CERTIFICATION.—A certification described under paragraph (1)(A) shall be determined to have been granted unless, not later than 60 days after the filing of a request under paragraph (1), the Secretary finds that—

''(A) the medical gas product subject to the certification is not a designated medical gas product;

''(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the gas product is a designated medical gas product; or

''(C) granting the request would be contrary to public health.

''(3) EFFECT OF CERTIFICATION.—

''(A) IN GENERAL.—

''(i) APPROVED USES.—A designated medical gas product for which a certification is granted under paragraph (2) is deemed, alone or in combination with another designated gas product or products as medically appropriate, to have in effect an approved application under section 505 or 512, subject to all applicable postapproval requirements, for the following indications for use:

''(I) Oxygen for the treatment or prevention of hypoxemia or hypoxia.

''(II) Nitrogen for use in hypoxic challenge testing.

''(III) Nitrous oxide for analgesia.

''(IV) Carbon dioxide for use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

''(V) Helium for the treatment of upper airway obstruction or increased airway resistance.

''(VI) Medical air to reduce the risk of hyperoxia.

''(VII) Carbon monoxide for use in lung diffusion testing.

''(VIII) Any other indication for use for a designated medical gas product or combination of designated medical gas products deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), under clause (iii) or (iv) of section 505(j)(5)(F), or under section

527, or the extension of any such period under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

''(ii) LABELING.—The requirements established in sections 503(b)(4) and 502(f) shall be deemed to have been met for a designated medical gas product if the labeling on final use containers of such gas product bears the information required by section 503(b)(4) and a warning statement concerning the use of the gas product, as determined by the Secretary by regulation, as well as appropriate directions and warnings concerning storage and handling.

''(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

''(i) EFFECT ON INELIGIBILITY.—No designated medical gas product deemed under paragraph (3)(A)(i) to have in effect an approved application shall be eligible for any periods of exclusivity under sections 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

''(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under sections 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in paragraph (3)(A)(i)(VIII).

''(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

''(A) IN GENERAL.—Nothing in this subchapter limits the authority of the Secretary to withdraw or suspend approval of a drug, including a designated medical gas product deemed under this section to have in effect an approved application, under section 505 or section 512.

''(B) REVOCATION.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the request for certification contains any material omission or falsification.

''(b) PRESCRIPTION REQUIREMENT.—

''(1) IN GENERAL.—A designated medical gas product shall be subject to section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such gas product from the requirements of section 503(b)(1) or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

''(2) EXCEPTION FOR OXYGEN.—

''(A) IN GENERAL.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

''(i) The use in the event of depressurization or other environmental oxygen deficiency.

''(ii) The use in the event of oxygen deficiency or use in emergency resuscitation, when administered by properly trained personnel.

''(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 503(b)(4) shall be deemed to have been met if the labeling of the oxygen bears a warning that the medical gas product can be used for emergency use only and for all other medical applications a prescription is required.

''(c) INAPPLICABILITY OF DRUGS FEES TO DESIGNATED MEDICAL GAS PRODUCTS.—A designated medical gas product deemed under this section to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.''.

SEC. 1112. REGULATIONS.

(a) REVIEW OF REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, after obtaining input from medical gas product manufacturers, and any other interested members of the public, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding any changes to the Federal drug regulations in title 21, Code of Federal Regulations that the Secretary determines to be necessary.

(b) AMENDED REGULATIONS.—If the Secretary determines that changes to the Federal drug regulations in title 21, Code of Federal Regulations are necessary under subsection (a), the Secretary shall issue final regulations implementing such changes not later than 4 years after the date of enactment of this Act.

SEC. 1113. APPLICABILITY.

Nothing in this subtitle or the amendments made by this subtitle shall apply to—

(1) a drug that is covered by an application under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) approved prior to May 1, 2012; or

(2) any of the gases listed in subparagraphs (A) through (G) of section 575(1) of such Act (as added by section 1111), or any mixture of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(i) of such Act (as added by section 1111); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Miscellaneous Provisions

SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

Section 712 (21 U.S.C. 379d–1) is amended—

(1) in subsection (b)—

(A) by striking paragraph (2); and

(B) in paragraph (1)—

(i) by redesignating subparagraph (B) as paragraph (2) and moving such paragraph, as so redesignated, 2 ems to the left;

(ii) in subparagraph (A), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(iii) in subparagraph (A), as so redesignated, by inserting '', including strategies to increase the number of special Government employees across medical and scientific specialties in areas where the Secretary would benefit from specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities'' before the semicolon at the end;

(iv) by striking ''(1) RECRUITMENT.—'' and inserting ''(1) RECRUITMENT IN GENERAL.—The Secretary shall—'';

(v) by striking ''(A) IN GENERAL.—The Secretary shall—'';

(vi) by redesignating clauses (i) through (iii) of paragraph (2) (as so redesignated) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(vii) in paragraph (2) (as so redesignated), in the matter before subparagraph (A) (as so redesignated), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(viii) by adding at the end the following:

''(3) RECRUITMENT THROUGH REFERRALS.—In carrying out paragraph (1), the Secretary shall, in order to further the goal of including in advisory committees highly qualified and specialized experts in the specific diseases to be considered by such advisory committees, at least every 180 days, request referrals from a variety of stakeholders, such as the Institute of Medicine, the National Institutes of Health, product developers, patient groups, disease advocacy organizations, professional societies, medical societies, including the American Academy of Medical Colleges, and other governmental organizations.'';

(2) by amending subsection (c)(2)(C) to read as follows:

''(C) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination made under subparagraph (B) considers the type, nature, and magnitude of the financial interests at issue and the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.'';

(3) in subsection (e), by inserting '', and shall make publicly available,'' after ''House of Representatives''; and

(4) by adding at the end the following:

''(g) GUIDANCE ON REPORTED FINANCIAL INTEREST OR INVOLVEMENT.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are reported under subsection (c)(1) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18, United States Code for the purposes of participating in a particular matter.''.

SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.

Not later than 2 years after the date of enactment this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) DRUGS AND BIOLOGICS.—

''(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

''(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

''(b) DEVICES.—

''(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such

pre-submissions or submissions, shall include an electronic copy of such pre-submissions or submissions.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide standards for the electronic copy required under such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.''.

SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.

(a) IN GENERAL.—To combat the significant rise in prescription drug abuse and the consequences of such abuse, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and in coordination with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to ensuring the safe use and disposal of prescription drugs with the potential for abuse.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall post a report on the Internet website of the Food and Drug Administration on the findings of the review under subsection (a). Such report shall include findings and recommendations on—

(1) how best to leverage and build upon existing Federal and federally funded data sources, such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 505(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool;

(2) how best to develop and disseminate widely best practices models and suggested standard requirements to States for achieving greater interoperability and effectiveness of prescription drug monitoring programs, especially with respect to provider participation, producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider, pharmacist, and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of abuse-deterrent drug products.

(d) STUDY AND REPORT ON PRESCRIPTION DRUG ABUSE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall seek to enter into an agreement with the Institute of Medicine to conduct a study and report on prescription drug abuse. Such report shall evaluate trends in prescription drug abuse, assess opportunities to inform and educate the public, patients, and health care providers on issues related to prescription drug abuse and misuse, and identify potential barriers, if any, to prescription drug monitoring program participation and implementation.

SEC. 1125. TANNING BED LABELING.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements for sunlamp products to include specific requirements to more clearly and effectively convey the risks that such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 903, is further amended by adding at the end the following:

''SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.

''(a) IN GENERAL.—The Secretary shall—

''(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically-driven clinical trial standards with respect to medical products around the world; and

''(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

''(A) enhance medical product development;

''(B) facilitate the use of foreign data; and

''(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or non-clinical studies.

''(b) MEDICAL PRODUCT.—In this section, the term 'medical product' means a drug, as defined in subsection (g) of section 201, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

''(c) SAVINGS CLAUSE.—Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this Act.

''SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—In determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug or device in the United States.

''(b) NOTICE TO SPONSOR.—If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug or device pursuant to an application submitted under this chapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.''.

SEC. 1127. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration with respect to medical products;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards such regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) the adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports submitted to Congress under sections 736B(a) (as amended by section 104), 738A(a) (as amended by section 204), 744C(a) (as added by section 303), and 744I(a) (as added by section 403) of the Federal Food, Drug, and Cosmetic Act for each of fiscal years 2013 through 2017, the Secretary shall annually report on the progress made with respect to—

(1) advancing the regulatory science priorities identified under paragraph (2) of subsection (b) and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

(d) INDEPENDENT ASSESSMENT.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) detailing the progress made by the Food and Drug Administration in meeting the priorities and addressing the gaps identified in subsection (b), including any outstanding gaps; and

(2) containing recommendations, as appropriate, on how regulatory science initiatives for medical products can be strengthened and improved to promote the public health and advance innovation in regulatory decisionmaking.

(e) MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

SEC. 1128. INFORMATION TECHNOLOGY.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) report to Congress on—

(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and

(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A);

(2) the effectiveness of the comprehensive information technology strategic plan described in subsection (a)(1)(A), including the results-oriented goals and performance measures; and

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

SEC. 1129. REPORTING REQUIREMENTS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.), as amended by section 208, is further amended by adding at the end the following:

''SEC. 715. REPORTING REQUIREMENTS.

''(a) NEW DRUGS.—Beginning with fiscal year 2013 and ending with fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 2 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 2 of subchapter C in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

''(2) the percentage of such applications that were approved;

''(3) the percentage of such applications that were issued complete response letters;

''(4) the percentage of such applications that were subject to a refuse-to-file action;

''(5) the percentage of such applications that were withdrawn; and

''(6) the average total time to decision by the Secretary for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter.''.

''(b) GENERIC DRUGS.—Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 7 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 7 of subchapter C, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

''(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

''(3) the total number of applications under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on the date of enactment of the Food and Drug Administration Safety and Innovation Act; and

''(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.

''(c) BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under part 8 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

''(A) the number of applications for approval filed under section 351(k) of the Public Health Service Act; and

''(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

''(2) ADDITIONAL INFORMATION.—As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the Public Health Service Act.''.

SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.

(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

(1) identify strategic institutional goals and priorities for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health;

(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Food and Drug Administration; and

(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals and priorities identified

under paragraph (1) and the effectiveness of the actions identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including new requirements under parts 2, 3, 7, and 8 of subchapter C of title VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).

(b) REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic management plan described in subsection (a) and related actions carried out by the Food and Drug Administration. Such report shall—

(1) assess the effectiveness of the actions described in subsection (a)(2) in recruiting, retaining, training, and developing the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health in fulfilling the public health mission of the Food and Drug Administration;

(2) assess the effectiveness of the measures identified under subsection (a)(3) in gauging progress against the strategic goals and priorities identified under subsection (a)(1);

(3) assess the extent to which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are using the identified results-oriented set of performance measures in tracking their workload by strategic goals and the effectiveness of such measures;

(4) assess the extent to which performance information is collected, analyzed, and acted on by managers; and

(5) make recommendations, as appropriate, regarding how the strategic management plan and related actions of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health could be improved to fulfill the public health mission of the Food and Drug Administration in as efficient and effective manner as possible.

SEC. 1131. DRUG DEVELOPMENT AND TESTING.

(a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–1) is amended by adding at the end the following:

''(k) DRUG DEVELOPMENT AND TESTING.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act, if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has agreed to comply with the terms of the notice.

''(2) WRITTEN NOTICE.—For purposes of this subsection, the Secretary shall, within a reasonable period of time, consider and respond to a request by an eligible drug developer for a written notice authorizing the supply of a covered drug for purposes of testing as described in paragraph (1), and the Secretary shall issue a written notice to such eligible drug developer and the holder of an application for a covered drug authorizing the supply of such drug to such eligible drug developer for purposes of testing if—

''(A) the eligible drug developer has agreed to comply with any conditions the Secretary considers necessary;

''(B) in the event the eligible drug developer is conducting bioequivalence or other clinical testing, the eligible drug developer has submitted, and the Secretary has approved, a protocol that includes protections that the Secretary finds will provide assurance of safety comparable to the assurance of safety provided by the elements to ensure safe use in the risk evaluation and mitigation strategy for the covered drug as applicable to such testing; and

''(C) the eligible drug developer is in compliance with applicable laws and regulations related to such testing, including any applicable requirements related to Investigational New Drug Applications or informed consent.

''(3) ADDITIONAL REQUIRED ELEMENT.—The Secretary shall require as an element of each risk evaluation and mitigation strategy with elements to ensure safe use approved by the Secretary that the holder of an application for a covered drug shall not restrict the resale of the covered drug to an eligible drug developer that receives a written notice from the Secretary under paragraph (2) unless, at any time, the Secretary provides written notice to the holder of the application directing otherwise based on a shortage of such drug for patients, national security concerns related to access to such drug, or such other reason as the Secretary may specify.

''(4) VIOLATION AND PENALTIES.—For purposes of subsection (f)(8) and sections 301, 303(f)(4), 502(y), and 505(p), it shall be a violation of the risk evaluation and mitigation strategy for the holder of the application for a covered drug to violate the element described in paragraph (3), or in the case of a holder of an application that is a sole distributor or supplier of a covered drug, to prevent the sale thereof after receipt of a written notice by the Secretary issued under paragraph (2). The Secretary shall provide written notice to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives within 30 days of the Secretary becoming aware that a holder of an application of a covered drug has restricted the sale of such a covered drug to any eligible drug developer after receipt of written notice as provided in paragraph (2).

''(5) LIABILITY.—Unless the holder of the application for a covered drug and the eligible developer are the same entity, the holder of an application for a covered drug shall not be liable for any claim arising out of the eligible drug developer's testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for a drug obtained under this subsection. Nothing in this subsection shall be construed to expand or limit the liability of the eligible drug developer or the holder of an application for a covered drug for any other claim.

''(6) CERTIFICATION.—In any request for supply of a covered drug for purposes of testing as described in paragraph (1), an eligible drug developer shall certify to the Secretary that—

''(A) the eligible drug developer will comply with all conditions the Secretary considers necessary, any protocol approved by the Secretary, and all applicable laws and regulations pertaining to such testing; and

''(B) the eligible drug developer intends to submit an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for the drug for which it is requesting written notice pursuant to paragraph (2), and will use the covered drug only for the purpose of conducting testing to support such an application.

''(7) DEFINITIONS.—

''(A) COVERED DRUG.—Notwithstanding subsection (b)(2), for purposes of this subsection, the term 'covered drug' means a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to a risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, required to have a risk evaluation and mitigation strategy with elements to ensure safe use under section 909(b) of the Food and Drug Administration Amendments Act of 2007.

''(B) ELIGIBLE DRUG DEVELOPER.—For purposes of this subsection, the term 'eligible drug developer' means a sponsor that has submitted, or intends to submit, an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act to market a version of the covered drug in the United States.

''(8) EFFECT ON OTHER LAW.—Notwithstanding the provisions of this subsection, the antitrust statutes enforced by the Federal Trade Commission, including the Federal Trade Commission Act (15 U.S.C. 41–58), the Sherman Act (15 U.S.C. 1–7), and any other statute properly under such Commission's jurisdiction, shall apply to the conduct described in this subsection to the same extent as such statutes did on the day before the date of enactment of this subsection.''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 505–1(c)(2) (21 U.S.C. 355–1(c)(2)) is amended by striking ''(e) and (f)'' and inserting ''(e), (f), and (k)(3)''.

(2) Section 502(y) (21 U.S.C. 352(y)) is amended by striking '''(d), (e), or (f) of section 505–1'' and inserting ''(d), (e), (f), or (k)(3) of section 505–1''.

SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 1126, is further amended by adding at the end the following:

''SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.

''(a) IN GENERAL.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

''(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

''(2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

''(b) FINANCIAL INTEREST.—In this section, the term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.''.

SEC. 1133. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

(a) IN GENERAL.—Chapter X (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary, in consultation as appropriate with the Secretary of Agriculture, shall establish within the Food and Drug Administration a Nanotechnology Regulatory Science Program (referred to in this section as the 'program') to enhance scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under this Act or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems.

''(b) PROGRAM PURPOSES.—The purposes of the program established under subsection (a) may include—

''(1) assessing scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Administration;

''(2) in cooperation with other Federal agencies, developing and organizing information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

''(3) promoting Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

''(4) promoting and participating in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

''(5) collecting, synthesizing, interpreting, and disseminating scientific information and data related to the interactions of nanomaterials with biological systems;

''(6) building scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

''(7) ensuring ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

''(8) encouraging the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

''(9) carrying out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

''(c) PROGRAM ADMINISTRATION.—

''(1) DESIGNATED INDIVIDUAL.—In carrying out the program under this section, the Secretary, acting through the Commissioner of Food and Drugs, may designate an appropriately qualified individual who shall supervise the planning, management, and coordination of the program.

''(2) DUTIES.—The duties of the individual designated under paragraph (1) may include—

''(A) developing a detailed strategic plan for achieving specific short- and long-term technical goals for the program;

''(B) coordinating and integrating the strategic plan with activities by the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative; and

''(C) developing Food and Drug Administration programs, contracts, memoranda of agreement, joint funding agreements, and other cooperative arrangements necessary for meeting the long-term challenges and achieving the specific technical goals of the program.

''(d) REPORT.—Not later than March 15, 2015, the Secretary shall publish on the Internet Web site of the Food and Drug Administration a report on the program carried out under this section. Such report shall include—

''(1) a review of the specific short- and long-term goals of the program;

''(2) an assessment of current and proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities; and

''(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.

''(e) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary under any other provision of this Act or other statutes administered by the Food and Drug Administration.''.

(b) EFFECTIVE DATE; SUNSET.—The Nanotechnology Regulatory Science Program authorized under section 1013 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later. Such Program shall cease to be effective October 1, 2017.

SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes any problems posed by pharmacy Internet websites that violate Federal or State law, including—

(1) the methods by which Internet websites are used to sell prescription drugs in violation of Federal or State law or established industry standards;

(2) the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet websites;

(3) efforts by the Federal Government and State and local governments to investigate and prosecute the owners or operators of pharmacy Internet websites, to address the threats such websites pose, and to protect patients;

(4) the level of success that Federal, State, and local governments have experienced in investigating and prosecuting such cases;

(5) whether the law, as in effect on the date of the report, provides sufficient authorities to Federal, State, and local governments to investigate and prosecute the owners and operators of pharmacy Internet websites;

(6) additional authorities that could assist Federal, State, and local governments in investigating and prosecuting the owners and operators of pharmacy Internet websites;

(7) laws, policies, and activities that would educate consumers about how to distinguish pharmacy Internet websites that comply with Federal and State laws and established industry standards from those pharmacy Internet websites that do not comply with such laws and standards; and

(8) laws, policies, and activities that would encourage private sector actors to take steps to address the prevalence of illegitimate pharmacy Internet websites.

SEC. 1135. MEDICATION AND DEVICE ERRORS.

The Secretary of Health and Human Services shall continue and further coordinate activities of the Department of Health and Human Services related to the prevention of medication and device errors, including consideration of medication and device errors that affect the pediatric patient population. In developing initiatives to address medication and device errors, the Secretary shall consider the root causes of medication and device errors, including pediatric medication and device errors, in the clinical setting and consult with relevant stakeholders on effective strategies to reduce and prevent medication and device errors in the clinical setting.

SEC. 1136. COMPLIANCE PROVISION.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go-Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SEC. 1137. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act,

the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

SEC. 1138. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants, the amount of tax credits issued for clinical research, and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) with respect to waivers and reductions for small business under the Prescription Drug User Fee Act, the number of small businesses applying for and receiving waivers and reductions from drug user fees under subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(6) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process; and

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SEC. 1139. PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 221(a) of the Public Health Service Act (42 U.S.C. 213a(a)) is amended by adding at the end the following:

''(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.''.

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

SEC. 1140. REGULATIONS ON CLINICAL TRIAL REGISTRATION; GAO STUDY OF CLINICAL TRIAL REGISTRATION AND REPORTING REQUIREMENTS.

(a) DEFINITIONS.—In this section—

(1) the term ''applicable clinical trial'' has the meaning given such term under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(2) the term ''Director'' means the Director of the National Institutes of Health;

(3) the term ''responsible party'' has the meaning given such term under such section 402(j); and

(4) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) REQUIRED REGULATIONS.—

(1) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) FINAL RULE.—Not later than 180 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue the final rule on the registration of applicable clinical trials by responsible parties under such section 402(j).

(3) LETTER TO CONGRESS.—If the final rule described in paragraph (2) is not issued by the date required under such paragraph, the Secretary shall submit to Congress a letter that describes the reasons why such final rule has not been issued.

(c) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 2 years after the issuance of the final rule under subsection (b), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the registration and reporting requirements for applicable drug and device clinical trials under section 402(j) the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) CONTENT.—The report under paragraph (1) shall include—

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of trial (phase II, III, or IV), whether the applicable clinical trial is conducted domestically, in foreign sites, or a combination of sites, and such other categories as the Comptroller General determines useful) with the requirements of—

(i) registering applicable clinical trials under such section 402(j);

(ii) reporting the results of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) information on the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Comptroller General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the implementation of registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Comptroller General shall, after consulting with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative or legislative actions to increase the compliance with the requirements of such section 402(j).

SEC. 1141. HYDROCODONE AMENDMENT.

The Controlled Substances Act is amended—

(1) in schedule III(d) in section 202(c) (21 U.S.C. 812(c)), by—

(A) striking paragraphs (3) and (4); and

(B) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively; and

(2) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

''(F) In the case of any material, compound, mixture, or preparation containing—

''(i) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; or

''(ii) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts,

subparagraph (C) shall not apply and such case shall be subject to subparagraph (E).''.

SEC. 1142. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

SEC. 1143. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—The Attorney General and the Secretary of Health and Human Services may collaborate to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(b) REQUIREMENTS.—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating the development of recommendations on interoperability of prescription drug monitoring programs under subsection (a)—

(1) open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;

(3) the support of transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that Protected Health Information and Personally Identifiable Information are not

compromised at any point during such transmission; and

(4) access control methodologies to share protected information solely in accordance with State laws and regulations.

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on the Judiciary and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

(2) CONTENTS.—The report required under paragraph (1) shall include—

(A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability;

(B) a discussion of how State prescription monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; and

(C) any recommendations for addressing challenges that impact interoperability of State prescription monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs.

Subtitle D—Synthetic Drugs

SEC. 1151. SHORT TITLE.

This subtitle may be cited as the ''Synthetic Drug Abuse Prevention Act of 2012''.

SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1):

''(A) The term 'cannabimimetic agents' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

''(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

''(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

''(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

''(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

''(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

''(B) Such term includes—

''(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

''(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

''(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

''(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

''(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

''(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

''(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

''(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

''(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

''(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

''(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

''(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

''(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

''(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

''(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).''.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

''(18) 4-methylmethcathinone (Mephedrone).

''(19) 3,4-methylenedioxypyrovalerone (MDPV).

''(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

''(21) 2–(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

''(22) 2–(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

''(23) 2–(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

''(24) 2-[4–(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

''(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

''(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

''(27) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

''(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).''.

SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking ''one year'' and inserting ''2 years''; and

(2) by striking ''six months'' and inserting ''1 year''.

SEC. 1154. PROHIBITION ON IMPOSING MANDATORY MINIMUM SENTENCES.

Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended by adding at the end the following: ''Any mandatory minimum term of imprisonment required to be imposed under this subparagraph shall not apply with respect to any controlled substance added to schedule I by the Synthetic Drug Abuse Prevention Act of 2012.''.

Mr. REID. Madam President, I move to reconsider the vote and move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The majority leader is recognized.

Mr. REID. Madam President, I know people are very anxious to move on. I am, too, but I have to say just a word. I have said in my own caucus how much I appreciate the cooperation of Senator ENZI. He is a fine Senator. He and Senator HARKIN have worked so well together. It is exemplary for what the rest of us should do. I appreciate very much the work they have done. I repeat, it is how we should get other work done.

This is an important piece of legislation, and we made it look simple; it was not. But because of these two fine Senators, we were able to get this done in a very short period of time and get good things done for the American people.

Mr. HARKIN. Madam President, today, with passage of the FDA Safety and Innovation Act and the reauthorization of the FDA user fee agreements, we have helped both the FDA and the biomedical industry ensure that they can get needed medical products to patients quickly and safely.

This legislation will ensure that the FDA can swiftly approve drugs and medical devices, save biomedical industry jobs, protect patient access to new therapies, and preserve America's global leadership in biomedical innovation. It will keep patients safer by modernizing FDA's inspection process for foreign manufacturing facilities, while also improving access to new and innovative medicines and devices. It will reduce drug costs for consumers by speeding the approval of lower cost generic drugs and help prevent and address drug shortages. Finally, by improving the way FDA does business, increasing accountability and transparency, U.S. companies will be better able to innovate and compete in the global marketplace.

By passing the FDA Safety and Innovation Act, we have taken an important step to improve American families' access to lifesaving drugs and medical devices.

As I have said throughout this debate, the bipartisan process that produced this excellent bill has been quite remarkable. I have worked closely with my colleagues on both sides of the aisle, as well as industry stakeholders, patient groups, and consumer groups to solicit ideas and improvements on the critical provisions in this bill. We have a better product thanks to everyone's input.

I extend a special thank-you to my colleague, Ranking Member ENZI. I have been working with Senator ENZI for over a year on this bill. It has been a wonderful and cooperative partnership and a trusting friendship. I can honestly say we would not have gotten this done without his excellent leadership and wise counsel. I thank him for that.

I also thank all of the HELP Committee members, as well as members off the committee, who were thoroughly engaged with this process from the beginning as part of the bipartisan working groups we established. Each of them has contributed significantly to this legislation, and I am sincerely grateful for all their contributions.

Madam President, I will submit for the RECORD a list of all staff members who were part of our bipartisan working groups throughout the past year. We all know we could not have achieved this without the tireless and diligent work of our loyal staffs. I extend my deep appreciation for their hard work and extraordinary efforts.

I ask unanimous consent that the list of staff members be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

HELP BIPARTISAN WORKING GROUPS

DRUG SHORTAGES

Rachel Pryor—Blumenthal;
Jessica McNiece, Christine Evans—Mikulski;
Deirdre Fruh—Casey;
Andrew Hu—Klobuchar;
Hannah Katch, Whitney Brown—Franken;
Jennifer DeAngelis—Whitehouse;
Sophie Kasimow—Sanders;
Rohini Kosoglu, Sally Mayes—Bennett;
Susan Lexer—Merkley;
Joshua Teitelbaum—Hagan;
Sandra Wilkniss—Bingaman;
Jennifer Boyer—Roberts;
Hayden Rhudy—Hatch;
MarySumpter Lipinski—Alexander;
Christopher Bowlin—McCain;
Anna Abram, Margaret Coulter—Burr;
Anne Oswalt—Corker;
Amanda Makki—Murkowski.

GENERATING ANTIBIOTIC INCENTIVES NOW

Rachel Pryor—Blumenthal;
Hannah Katch, Whitney Brown—Franken;
Sophie Kasimow—Sanders;
Susan Lexer—Merkley;
Rohini Kosoglu—Bennett;
Joshua Teitelbaum—Hagan;
Sandra Wilkniss—Bingaman;
Matt Prowler, Deirdre Fruh—Casey;
Christine Evans, Jessica McNiece—Mikulski;
Margaret Coulter/Anna Abram—Burr;
Amanda Makki—Murkowski;
Ashley Carson Cottingham—Sanders;
Michael Behan—Sanders;
Tyler Thompson, Francie Pastor—Isakson;
MarySumpter Lapinski—Alexander;
Jennifer Boyer—Roberts;
Shauna McCarthy—Kirk;
Hayden Rhudy—Hatch.

PEDIATRICS (BPCA/PREA)

Paula Berg—Murray;
Kate Mevis—Reed;
Rohini Kosoglu, Sally Mayes—Bennett;
Jessica McNiece, Christine Evans—Mikulski;
Deirdre Fruh, Matt Prowler—Casey;
Hannah Katch, Whitney Brown—Franken;
Sophie Kasimow—Sanders;
Anna Abram, Margaret Coulter—Burr;
MarySumpter Lapinski, Nicolas Magallanes—Alexander;
Jennifer Boyer—Roberts;
Tyler Thompson—Isakson;
Amanda Makki—Murkowski;
Hayden Rhudy, Paul Williams—Hatch.

DRUG SUPPLY CHAIN

Rohini Kosoglu—Bennett;
Jennifer DeAngelis, Justin Florence—Whitehouse;
Anna Abram—Burr;
Erika Smith—Grassley.

Mr. HARKIN. On that note, I specifically thank the staff of Ranking Member ENZI's office. I thank Frank Macchiarola, Chuck Clapton, Keith Flanagan, Melissa Pfaff, Grace Stuntz, Katy Spangler, and Riley Swinehart. I know they have developed a close working relationship with my staff throughout the year, and I am sincerely grateful for their dedicated efforts.

I thank my own staff on the HELP Committee, who have spent many a night, long days, and weekends with Senator ENZI's staff and other Members' offices working to come to consensus on the critical policy issues in this legislation.

I thank our staff director, Dan Smith; his assistant, Pam Smith, who, by the way, will be very shortly taking over as our new staff director. Dan Smith is leaving our staff and going into the private sector. Pam Smith will be taking over as our new staff director. I also thank Jenelle Krishnamoorthy, who heads our health division, for all of the tireless work she has put in. I can't thank her enough for all her hard work. I also thank Elizabeth Jungman, Bill McConagha, Kathleen Laird, Kathleen Wise, Dan Goldberg, Justine Sessions, Kate Frischmann, Elizabeth Donovan, Lory Yudin, Frank Zhang, and Evan Griffis. Each of them has done a remarkable job. I thank them from the bottom of my heart for getting this legislation through.

We would be remiss if we didn't also thank the Congressional Budget Office for their knowledgeable and capable team that was willing to work around the clock to estimate the budgetary effects of this legislation.

Finally, we owe an enormous debt of gratitude to the staff members in the Legislative Counsel's Office. They too worked long hours, nights and weekends, to assist my staff in drafting this critical legislation and working out technical issues.

This bill's passage is a victory for the millions of Americans who need medicines or medical devices—a victory that would not have been possible without the dedicated work of our Senate family. I thank all of you for your extraordinary public service.

STOP THE STUDENT LOAN INTEREST RATE HIKE ACT OF 2012

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to S. 2343, which the clerk will report.

The legislative clerk read as follows:

A bill (S. 2343) to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and for other purposes.

The PRESIDING OFFICER. Under the previous order, there will be 10 minutes of debate equally divided and controlled between the two leaders or their designees.

The Republican leader.

Mr. MCCONNELL. Madam President, we are in a rather ridiculous staring contest, waiting for our Democratic friends to offer a proposal that can actually pass when we already have one right in front of us. We have wasted actually 2 weeks on this student loan issue for no good reason. Neither I nor the ranking member has heard a word from the Democrats on how they propose to resolve the issue and actually prevent the interest rate from rising.

As we learned earlier this week, the President doesn't seem to even talk to his committee chairmen anymore. All of this suggests that the White House doesn't want to solve the problem; that it would rather allow these rates to double in a few weeks so he can run around all summer pointing the finger at those Republicans in the Senate.

I would still like to believe that is not the case. We had a chance to talk to the President about this and other issues last week down at the White House. I am convinced he would like to get a solution. Yet the fact is, all he would have to do is simply pick up the phone and tell the Democratic leadership that we would like to get this done, and I am pretty confident we could work it out. Unfortunately, we cannot just wait around hoping the President is going to pick up the phone. College students cannot wait either. They want us to resolve the issue now, and I know we can.

To move the ball forward, I would say to my colleague, the majority leader, if he agrees with me—Senator HARKIN and Senator ENZI just did a good job with coming up with a bipartisan solution to the FDA bill. I am confident they could do the same thing on the student loan issue. They are the chairman and the ranking member of the committee that oversees student loan legislation. I have a lot of confidence in their ability to do it.

I am going to proffer a consent agreement that I think would allow us to go forward. My colleague from Tennessee will take the balance of our time after I have concluded.