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

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

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

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

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

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

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

RESERVATION OF LEADER TIME

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

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

The ACTING PRESIDENT pro tempore. Under the previous order, the Senate will resume consideration of S. 3167, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 3167) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Pending:

Durbin/Blumenthal amendment No. 2127, to require manufacturers of dietary supplements to test the safety and efficacy of new 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. 2148, to amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease states of 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. 111. 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 and use prescription drugs (other than a controlled substance as defined in section 102 of the Controlled Substances Act) that—

(1) is purchased from an approved Canadian pharmacy;

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

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

(4) is purchased 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 section 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 subsection and has a purpose other than to participate in the program established under this section;

"(2) complies 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) commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure 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 which 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 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 forumulation 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 many 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. The emails have at least one optimistic reference to release more details in the coming weeks.

What the hell? White House Deputy Chief of Staff Jim Messina, now Obama’s campaign manager, complained to a lobbyist for the Pharmaceutical Research and Manufacturers of America (PhRMA) in January 15, 2009, saying that then-Senator Obama had said “I love to see the administration weigh in and take the same position that I would love to see the administration weigh in and take the same position.”

At the time Billy Tauzin was president and CEO of PhRMA—Mr. President, this is 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.

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.

“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 for this agreement were kept from both the public and the House of Representatives,” the committee’s Republican members wrote in a memo.

On June 20, 2009, Obama released a terse 296-word statement announcing a deal between pharmaceutical companies and the Health and Human Services Department. This reference to “our deal” came two months before the final passage of ObamaCare in an email with the subject line, “FW: TAUZIN EMAIL.”

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 Emanuel, was actively engaged in these negotiations as early as January 2009. The negotiations, according to sources familiar with the agreement were kept from both the White House and the House of Representatives, the committee’s Republican members wrote in a memo.

That is Mr. Tauzin—promised Messina, “we will deliver a final yes to you by Tuesday, June 22nd.”

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? Was it the worst, or best, of the unregulated self-interest 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 drugs 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 companies today 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. consumers have access to 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 in no worse condition than as U.S. approved drugs. To protect U.S. patients against rogue 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. If half of the bill is 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. And I have no doubt that many Americans whose health care 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 are 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 health care at less cost there being no official program to import medications from Canada, approximately 1 million U.S. consumers use

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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 pharmacies 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 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 pharmacy other than to participate in the U.S.-Canadian safe drug distribution 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 agrees to return 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 get under this program. The answer is no unless they can be safely imported under the provisions of the amendment and regulations issued by the Secretary. The amendment doesn’t discriminate against the type of conditions or medicines that patients should be able to safely import under this program. Not all biologics are the same. Some biologic medicines are available in capsules; others are injectable 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 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 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.

Mr. BINGAMAN. Mr. President, I ask unanimous consent that the order for business be suspended for the purpose of taking up 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 my colleagues to please stand 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.

The Acting President pro tempore.

Mr. HARKIN. Mr. President, I ask for the yeas and nays to be ordered on the amendment; is that correct?

The Acting President pro tempore. The leader is correct.

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

The Acting President pro tempore. The Senate has that right.

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 want to continue 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

There appears to be a sufficient second.

The yeas and nays were ordered.

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

The Acting President pro tempore. The clerk will call the roll.

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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 huddied behind closed doors, out of sight of the public and the press, and produced the tax hike instead of letting the committee actually do its work.

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

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

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

But let’s be clear about something. The real issue isn’t the fact that certain students are going to see an interest rate hike because we will address that concern; it is that so many young people today can’t find a job that will enable them to pay off their loans in the first place. That is the much larger problem. The solution is a pro-growth 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 to issues, 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 now lost interest in 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 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. 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 hope you will permit me to inform 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 in injuries sustained that day at an ammunition supply point in Kandahar Province, Afghanistan. He was 20 years old.

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

After his tragic death at entirely too young an age, one of Specialist Taylor’s colleagues, 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 in injuries sustained that day at an ammunition supply point in Kandahar Province, Afghanistan. He was 20 years old.

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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 1st Class Alex W. Taylor in the highest regard for his friend David W. Taylor in the highest regard for his service on behalf of our country. We are here today, 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, Mr. 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, ensuring that 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 the needed tools to the prescription drug supply chain and increases the accountability and transparency of the Food and Drug Administration.

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

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

It seems that, once again, despite the countless times—the Senate has rejected the policy my friend from Arizona pursues, he has brought us an amendment that I believe puts Americans at risk, undermines FDA’s authority, and would have a devastating ripple effect throughout our country’s drug supply by allowing untraceable, unaccountable drugs from all over the globe into the U.S. market without any FDA oversight whatsoever.

This amendment does not provide the FDA with any additional resources to monitor the drugs coming from Canada. It would allow drugs 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 for bringing counterfeit and dangerous products into our country. 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.

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 biopharmaceutical 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, life-saving, life-enhancing drugs, and I take issue with this amendment. This is 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 your mother—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 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 come 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 $32 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, a written law to prosecute those who commit fraud. But ultimately taking away the incentives we have in place to attract investment in this important research, especially when the penalties could be triggered by a minor, unrelated offense—the way the amendment’s written law 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.

The sooner we can get to voting, the sooner we can get to a better life for all of us.

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.

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 amendment in the nature of a substitute be printed in the record and be debated and voted upon.

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.

Again, I 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 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.

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 Importation and Drug Safety Act, a bill I have worked on for many years with Senator SNOE and Senator MCCAIN.

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

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

In 2005, I combined that bill with the proposal sponsored by then-Senator Dorgan and Senator SNOWE. And in 2007, 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 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, it also establishes 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
A letter from Assistant Deputy Minister of Health, Canada, to the U.S. Surgeon General again said that Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to change the future.

The pending amendment would allow importation from Canadian Internet pharmacies. Canadian Internet pharmacies openly acknowledge they obtain most of their drugs from other countries, contrary to the definitions of the HHS secretary. 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 require Canadian wholesalers that would be involved in the importation to be licensed in the same 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 all the risks? FDA advises consumers that some imported drugs, including those that bear the name of U.S.-approved products, may, in fact, be counterfeit versions that are unsafe or completely ineffective. You know, they can have all of the ingredients to it, but if it is not put together the right way, it will not even dissolve as it goes through the body, and therefore there would be no benefit from that drug, even though it looked like the real thing. It tasted like the real thing, it went down like the real thing. But if it is not the real thing, it can cause some real trouble with people’s health.

This 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.
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 generics 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 valid. In fact, 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, we 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 through the litigation, the patent law will change. The Sanders amendment would introduce even greater uncertainty into the R&D process. The Sanders amendment would create a disincentive to invest in drug development, the National Venture Capital Association has already expressed concerns. One critic has stated that the Sanders amendment ‘‘is subject to considerable penalties 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.

Mr. 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 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 departments 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.

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 pharmacies. I support 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 prescription drugs 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. First of all, American consumers 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. I think it is 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 is that American consumers are increasingly choosing to risk living without taking critical medications. According to the Commonwealth Fund, in 2010, 48 million Americans did not fill a prescription due to cost. That represents an increase of 66 percent since 2001.

If the Senate and the overall Congress were to adopt the McCain amendment, it would allow Americans to purchase safe medications at a lower price than 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. As Canadians do.

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

So for patients who are already trying to make ends meet in this very difficult economy by rationing their medications, splitting their pills, or even skipping medications entirely, why would we deny them access to safe drug products at these dramatically lower prices? I have co-sponsored Senator McCain’s amendment. It would allow Americans to import medication from accredited Canadian pharmacies from a list approved by the Secretary of Health and Human Services. U.S. 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 reputable before and after study. The late 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 these 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 low prices. Why shouldn’t we be discouraging price competition, as this study illustrates. That is one of the points I have been arguing over the years; that the real problem in this country with respect to prices for prescriptions is that we don’t have competition within the industry and competition for those medications.

Americans have learned that citizens in other countries use the same medications as we do. They are made in the same country. 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, communication, 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 products. 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 2001, 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.

According to former Pfizer CEO Hank McKinnell, the industry is only 19 percent and 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.

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

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

The amendment that is offered by the Senator from Arizona is allowing importation solely from Canada, and it is for online pharmacies based on a list that has been drafted by the Department of Health and Human Services. That is a very prescribed, targeted, limited approach to allowing American consumers to benefit from those lower priced drugs that are offered in Canada. It is a very important step that we must take this step. It is not paying for American consumers who otherwise are not going to be able to afford these medications when they are paying two to three times more than their counterparts in Canada, for example. The prices are rising five times more than the inflation rate year after year, so the compounding effect is significant and overwhelming for most American consumers and families. So what I hope is that we will allow the amendment that has been drafted by the Senator from Arizona.

Some have suggested that providing support for the McCann amendment will hinder efforts to quickly move on the underlying legislation for the FDA. That concern is certainly not persuasive because the McCann amendment is a very narrowly focused approach. It represents a good-faith effort to find a solution that would allow us to support the interoperability of State prescription drug monitoring programs under subsection (c)(1) and (c)(2), as modified, and (c)(3), and (c)(4).

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 HEALTH 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 subsection (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 cease to 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 disclose or to authorize the disclosure of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States."

"(4) PURPOSES.—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)."

Amendments, as modified, are as follows:

AMENDMENT NO. 2142, 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.

(b) REQUIREMENTS.—The Attorney General and the Secretary of Health and Human Services shall consider 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-State and direct State-to-State communication;

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary and the Committee on the Judiciary and the Committee on Energy and Commerce and the Committee on Energy and Commerce and 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) 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 cooperation with other relevant technologies 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

SEC. 1141. SHORT TITLE.

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

SEC. 1142. ADDING OTHER 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:

``(37) 5-(1,1-dimethylheptyl)-2-(1H,3H)-3-hydroxyxyclohexyl)phenol (CP-47,497);

(38) 5-(1,1-dimethylethyl)-2-(1H,3H)-3-hydroxyxyclohexyl)phenol (cannabicyclobutanol or CP-47,497 CB-homolog);

(39) 1-pentyl-3-(1-naphthoyl)indoledione (JWH-018 and AM678);

(40) 1-butyryl-3-(1-naphthoyl)indoledione (JWH-073);

(41) 1-hexyl-3-(1-naphthoyl)indoledione (JWH-019);

(42) 1-[2-(4-morpholinyl)ethyl]3-(1-naphthoyl)indoledione (JWH-200);

(43) 1-pentyl-3-(2-methoxyphenylacetyl)indoledione (JWH-250);

(44) 1-pentyl-3-(3-methoxyphenylacetyl)indoledione (JWH-981);

(45) 1-pentyl-3-(4-methyl-1-naphthoyl)indoledione (JWH-322);

(46) 1-pentyl-3-(4-chloro-1-naphthoyl)indoledione (JWH-398);

(47) 1-(5-fluoropentyl)-3-(1-naphthoyl)indoledione (AM2201);

(48) 1-(5-fluoropentyl)-3-iodobenzoylindoledione (AM694);

(49) 1-(5-fluoropentyl)-3-(4-methoxybenzoyl)indoledione (SR-19 and RCS-4);

(50) 1-cyclohexyl-3-(2-methoxyphenylacetyl)indoledione (SR-18 and RCS-8); and

(51) 1-pentyl-3-(2-chlorophenylacetyl)indoledione (JWH-263).

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (b) 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-ido-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 IMPELLING ORDERS TO PUBLIC SAFETY EXPANSION.

Section 201(b)(2) of the Controlled Substances Act (21 U.S.C. 812(b)(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) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) is amended by adding at the end the following: ‘‘Any mandatory minimum term of imprisonment required to be imposed under this subparagraph shall not apply with respect to any controlled substance added to schedule I by the Synthetic Drug Abuse Prevention Act of 2012.’’

SYNTHETIC DRUGS

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

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

Mr. HARKIN. Amendment 2146, as modified, filed by Senator PORTMAN, provides a number of new 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 it is important 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. 2153; and that the Coburn amendment No. 2153 be withdrawn.

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

AMENDMENT NO. 2142, AS MODIFIED

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

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

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

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

AMENDMENT NO. 2146, AS MODIFIED

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

The PRESIDING OFFICER. Is there further debate on the amendment? If there is no further debate, the question is on the adoption of the amendment. The amendment (No. 2146), as modified, was agreed to.

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

The PRESIDING OFFICER. The 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, 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, anticonsument 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 pharmaceutical companies and generic manufacturers 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. The actually received these savings, consumers have to have access to these generic drugs and have access to them in a timely manner.

In 1984, Congress passed the bipartisan Hatch-Waxman Act to create market-based incentives for generic pharmaceutical companies to bring their drugs to market as quickly as possible. The purpose of the law was to incentivize the early generic drug competition while preserving incentives for pharmaceutical 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 body knows about Lipitor. It is a cholesterol-lowering drug. It is familiar to everybody.

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

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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.

A relevant 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 name-brand 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 of course 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 prof- lifacy, health insurers and health care say there is a strong effort under way to bring medical costs under control.”

I was struck by that phrase “self-ac- knowledged proflligacy 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 sup- port 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 that the time 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. The sen- ator from New York addressed the Chair.

Mr. SCHUMER. Mr. President, I am going to speak for a brief moment on the Bingaman amendment.

The PRESIDING OFFICER. On the Bingaman amendment.

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

The PRESIDING OFFICER. The sen- ator from New York is recognized.

AMENDMENT NO. 2166

Mr. SCHUMER. Mr. President, I am going to speak for a brief moment on the Bingaman amendment. I am speaking on the Bingaman amendment. I am about to introduce the Bingaman amendment, as well as Chairman FEINSTEIN and Senator CASEY have proposed a Bingaman amendment.

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 slyers 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 would like to thank Senator HARKIN and ENZI particularly for getting us this package and Senator PORTMAN for working with us on this amendment.

EDUARDO SAVERIN

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

It is a modest proposal, made in response to the regrettable effort by a person named Eduardo Saverin, who renounced his American citizenship to avoid paying even the historically low level of 15 percent on capital gains for the several billion dollars in windfall 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 benefited 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—the worth of 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 and paid for by the right.

And they found a government that invests in research and development, in things like 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 forget, a non-corrupt legal system, which decided a case in the American taxpayer.

Our proposal targets no single race, no single religion, or political party. It is the act of renouncing one's U.S. citizenship—echoes that—''punishing Saverin for tax dodging is un-American.''

Really? Silly me. I thought that renouncing your citizenship now qualifies as heroic for the hard right wing? George Washington was heroic. Navy SEALs are heroic. Eduardo Saverin is not.

And let's not forget, a non-corrupt legal system, which decided a case in the American taxpayer. And when people do well in America, . . . .''I'm sorry. 15 percent capital gains rate on several billion dollars is so onerous that it is chasing him out of America that 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 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 for a better tax haven 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 Taxpayer to the Daily Caller—say our nation's fair share of Saverin for tax dodging is un-American."

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That is why it is baffling that ex-Mr. 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 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 célebre, defending his decision to purposely leave to purposely avoid paying your fair share, then we will attach a consequence to that dodge.

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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 toatten 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 are engaging a "Berlin Wall."

And in the Examiner they are accused say we are "totalitarian."

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

The law Mr. Norquist references in Nazi Germany was purely—discriminatory. It targeted a particular race of people—the Jewish people—and—punished them for nothing other than being Jewish and exercising freedom of movement. It was meant to constrain individuals from exercising their 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 offends 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 fleeing the country to avoid 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 Nazis did to 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.

Right wing blog after blog—from the American Thinker to the Daily Caller—are engaged in "class warfare to vilify people that create wealth—just like the Nazis did to 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.

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

Unbelievably, the far right prioritized millionaire tax breaks over our Nation’s full faith and credit. Despite that unreasonableness, we thought we had finally figured out a way to force the far right to come to grips with the need to deal with revenues. We came up with a mechanism called the sequester that would trigger harsh defense cuts if the Republicans continued to refuse any new revenues.

Surely, if there was one thing conservatives prized as much as tax cuts, it was defense spending, right? Wrong. As we speak, the far right remains unwilling to cede an inch on revenues, no matter what it means for the Pentagon. The deficit; the Nation’s creditworthiness; National security—all of these have taken a backseat to the far right’s idolatry on taxes. Now they have gone so far, they have taken 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 lionized an inheritor of wealth who renounced his citizenship to escape his tax 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 our narrow self-interest. 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 spaws. But there are also responsibilities and duties, such as patriotism, service, contributing your fair share, and commitment to community and family. As we approach critical debates on the matters of taxation and fairness and job creation so critical to keeping America, the greatest Nation on the face of the Earth, I certainly hope it is these values and others like it, that drowns out all other values that guide our actions.

Thank you. I yield the floor.

The PRESIDING OFFICER. The senior Senator from 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.

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. 211, Murkowski amendment No. 212 and Paul amendment No. 214.

The PRESIDING OFFICER. Is there objection?

Mr. VITTER addressed the Chair.

The PRESIDING OFFICER. The Senator from Louisiana.

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

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

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

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

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

The PRESIDING OFFICER. Is there objection?

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

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

The assistant majority leader.

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. 217

Mr. DURBIN. Mr. President, today we are considering a bill that will improve the FDA’s ability to assure the
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, the 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 can prevent patients with long-term health challenges from being able to access 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 FDA new authority to collect user fees for generic and biosimilar drugs. Currently, the FDA does not collect user fees to support the review of generic drugs, and it takes about 30 months for the agency to review generic drug applications. This extra time reduces access to safe, affordable generic drugs and leaves patients and taxpayers paying the tab for brand-name drugs that lack competition from generics.

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

Chairman HARKIN and Senator ENZI have put together a bill that responds to many of these challenges, including one that is of particular interest to me—the national shortage of critical drugs. Between 2006 and 2010 the drug shortage percentage increased from 56 to 178 drugs. Currently the drug shortage includes over 200 drugs, like intravenous nutrition supplements, cancer 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 responsible for treating patients, 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 a few 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 it isn’t 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 also too familiar with the drug shortage. She is a smart and hard-working woman who has been taking Concerta to treat her ADHD since she was 14. Like most people with severe ADD, she must take her medicine at a certain time every day 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 worked up early and walk to anotherv 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. Over time, she grew accustomed to going between these two CVS pharmacies to fill her prescription.

By the end of day 3, she was out of her supply that a drug is expensive 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 KLOBUCAR’s bill with key provisions to curb the national drug shortage. First, the bill requires drug manufacturers to notify the FDA of 6-month drug shortages in 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 anti- inflammatory. The FDA collaborated with Illinois-based generic drug manufacturer, Hospira, to increase production of this life-saving drug when another company halted production. Requiring 6 months advance notice of a shortage will help the FDA to work with companies to avoid shortages of critical drugs.

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

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

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

Since the heparin incident, the global nature of the drug supply chain has only grown. Today 80 percent of active pharmaceutical ingredients are manufactured outside of the United States. This bill improves the safety of our supply chain, both domestically and internationally by requiring foreign drug 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. Adulterated drugs and counterfeit drugs can have deadly consequences, yet the penalty for committing these crimes is less than the penalty for selling a counterfeit designer designer pill.

Currently, the penalty for intentionally counterfeit or adulterating a drug is no more than 3 years in prison or a $100,000 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 medicinal 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; 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. When they move back to the vitamin counter, all bets are off. Those are called dietary supplements. They are not subject to the same level of scrutiny, inspection, testing or regulation. It is an entirely different world.

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

There are between 55,000 and 75,000 dietary supplements in America. We don’t know the exact number. They include vitamins, minerals and other substances, but they also go further. They include energy drinks. Ever heard of the 5-Hour Energy Drink, Monster Energy Drink? Those are not sold as dietary supplements. 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 downtown, 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 product 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 what is in our products before we 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 voluntarily inform the information, so be it. But we don’t want to be required to disclose the information.

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

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


Dear Senator Durbin:

The Center for Science in the Public Interest is pleased to support your proposed amendment to the Food, Drug, and Cosmetic Act that would 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,

Washington, DC.

Chuck Bell,
Programs Director
Consumers Union

Joana Rusu,
Regulatory Counsel
Consumers Union

Mr. DURBIN. I ask my colleagues when this vote comes before us, before the other debate, that we once again introduce 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 ingredients look like?

The FDA has asked for this information. They asked expressly for this information. To say it is a burden on them, they already asked for it.
I ask my colleagues when this amendment comes up later this afternoon that they support this in the best interest of protecting American families and consumers.

I yield the floor.

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

The PRESIDING OFFICER. There are now 2 minutes of debate equally divided on the Bingaman amendment. The Senator from New Mexico.

Mr. BINGAMAN. Madam President, first I thank Senator Vitter for his comments and for his strong support of this amendment. I thank all of the 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_rand 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.

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 and do not lead to higher costs. In fact, some settlements can actually expedite generic drugs coming to market. According to

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 but for successfully challenging and invalidating a patent. So we would move the first filing exclusivity to a reward for filing and a use-it-or-lose-it statute for the brand.

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. If we don’t do something we will 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 restriction 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 incentivizes the companies remaining.

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 won, it would access.

This solution provides more litigation certainty. We propose basically a use-it-or-lose-it statute for the brand name to sue the generic within the Hatch-Waxman 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 a 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 pay 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 Big Pharma. We are going to preserve your exclusivity for developing a drug, but we are not going to let you buy off generics and unfairly extend that time period. We are going to let generics come to market in a reason-
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 to lead to 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 $390 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 proposed changes 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.
Mr. HARKIN. There is a lot of motion going on. I want to know where the time is coming from for the Senator from Tennessee.

The PRESIDING OFFICIAL. The Senator said he was speaking on the bill. Mr. HARKIN. Madam President, how much time is left on the bill?

The PRESIDING OFFICIAL. 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 be discovered in order to stay ahead of the growing trend of drug resistance. Drug discoveries do not happen overnight, so we must act now to ensure that we have lifesaving medications when we need them.

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

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

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

I thank Senator BLUMENTHAL from Connecticut for his leadership on this bill. I especially thank Senators HAR-kin 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 OFFICIAL. Who yields time?

The Senator from Wyoming.

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

The PRESIDING OFFICIAL. 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 WURZMANN for his partnership on this important bill.

In the last decade, unfortunately, prescription drug abuse has reached epidemic proportions in States such as Ohio, and in so many other States around the country. It is an issue that 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 bud-gets. 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 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 traffickers know this weakness in the system. 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 toward that end in order to bolster the monitoring system 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’ intergovernmental relationships.

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 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 prescription drug abuse.

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

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

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

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

Mrs. HAGAN. I would request 6 minutes.

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

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

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

I am particularly proud to support this bill because of what it 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 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, there are 30,000 children born every year, millions of Americans suffering from rare diseases, and I have had the honor to meet a number of them. Their stories are both heartbreaking and inspiring.

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

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

For the families and patients like these, suffering from these rare diseases for which there are no approved medications, medical advances cannot come fast enough. There are so many rare diseases, but over 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.

This amendment is the 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. This 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 was supported by patient advocates, including the National Organization of Rare Diseases, Us Against Alzheimer’s, 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 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 ensuring that global leaders work together on 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 amendment No. 2107. I appreciate the rise in opposition to the McCain leagues to join in supporting the FDA and flexibility required to maintain the technological resources 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 bio-equivalent to the FDA-approved drug. How can you 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 130 people. Then there was cough syrup made from antifreeze instead of glycerin. Seventy-eight people died. There are also the ineffective drugs that may not kill you but certainly won’t improve your health. I could list more, but I urge my colleagues to go talk to the FDA, FBI, and Customs and Border Protection and hear firsthand what they have experienced.

Counterfeiting is a real threat. It is a matter of public health and consumer safety. It is a matter of public health and consumer safety. 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 an 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 on both sides.

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

AMENDMENT NO. 2331

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 gentleman named Abner Kremschuke. He had 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 he 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 longer than we have been doing. We have been working 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 protection—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. That was your idea.

Also provided in the same legislation are the resources needed in the Patent Office to more expeditiously process patent applications. 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, agreement 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 piece 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 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 their jobs.

Other examples of bipartisan legislation we worked on, in one case the Transportation bill—land transportation: roads, highways, bridges, 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 get paid 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—to confer too, 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 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 give help to the farmers 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, 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 will 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. Business needs pharmaceutical businesses 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 I am the Chairman 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 success of current user fee programs. For a number of years, the companies have paid a user fee if they want the FDA to approve a drug or medical device, and we are making progress actually have more resources for the FDA to do their job. We 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, 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 and medical device 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 contami-
inate our country’s supply of prescription
drugs and put our patients and our health care providers at risk.
Some of my colleagues have proposed to inclu-
ded 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 Sen-
ator’s time has expired.

Mr. CARPER. I ask unanimous con-
sent for 3 more minutes equally di-
vided.

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

Mr. CARPER. Unfortunately, it
would open our borders to increased
numbers of contaminated and adulter-
ated drugs.
The proposal to import drugs from
Canada would allow drugs to be im-
ported wholesale, often from illegal
Internet pharmacies with no protection
against abuse or contamination.
Also, the measure is sup-
posed 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 polic-
ing 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 abil-
ity 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 larg-
er 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 filled in this coun-
try were generic drugs. This year, 80
percent of the medicines or prescrip-
tions that are being filled are generic.
One of the well-intentioned amend-
ments 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 per-
cent. I would suggest that we should
declare victory, and as time goes by,
even that 80 percent will become 85 per-
cent 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 to-
gether. We are in a whole host of
ways— including under the great
leadership of Senator HARKIN and Senator
Enzvi— working to make sure our phar-
aceutical industry is vibrant,
strong, the medical device industry is
vitaly strong, but also that patients
are not disadvantaged, that they are
actually advantaged by all of that.

So proceeding 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 pro-
posals that do what: help us to create
a more competitive 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
Enzvi have done. I ask unanimous con-
sent to follow their leadership here
today.

The PRESIDING OFFICER. Madam
President, is there any time
remaining on the Burr amend-
ment?

The PRESIDING OFFICER. There is
no time remaining on the Burr amend-
ment.

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

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

AMENDMENT NO. 2107

Mr. LAUTENBERG. Madam Presi-
dent, I rise to speak against amend-
ment No. 2107, the one that talks about
pharmaceutical products, medicines.
We know how important the prescrip-
tion drugs are to the health and
well-being of each and every person
in this country and the need to make
sure those drugs are safe and afford-
able. 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 insignif-
ican—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 end, more expensive, more intrusive
treatments. Americans buy medicine
to lower their cholesterol, fight cancer,
prevent heart disease. Some of these
have had remarkable effects. Heart dis-
ese 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 amend-
ment 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 pa-
tients, this amendment could bring po-
tentially dangerous and ineffective
drugs from Canada. I say that because,
the Canadian drug supply is not al-
ways safe. An FDA investigation found
that 85 percent of drugs imported from
Canadian 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 Depart-
ment 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.

Another observation, I find it kind of amusing to watch Re-
publican 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
collagies were decrying the Can-
adian system as a horrible socialist
experiment. My colleagues need not
to make up their minds. Do they prefer
socialized medicine? If so, it comes
with a price.

I am proud that many of our coun-
try’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 un-
dercut the hard work of these trained
New Jerseyans, only to put Americans
in danger.

Right now the drugs in our country
are fresh and effective as well. We are
seen by the results. Thanks to Senator HARKIN and Senator Enzvi, this bill will
even make our drugs more safe. Ameri-
cans 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 wish to say to the chairman that I appreciate his hard work on this bill, a very important piece of legislation.

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 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 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 yield the floor.
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 McCaskill's amendment, Senator Sanders' amendment, Senator Durbin's amendment, and then final passage.

By an earlier consent, all of those votes will be 16-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 on both sides in moving this legislation forward here on the floor. We have had good debates. They have not been drawn out endlessly, but we have had good debates and a good airing of the amendment. I thank all the 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 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 Memorial Day so that 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. And 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 Iowa.

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

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

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. 243

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 it. 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 diets and 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 deals with 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 billboards in this bill, this kind of turns food law on its head. It would allow supplements to be sold with claims to cure any disease, such as AIDS or cancer, without any kind of FDA review whatsoever. I take a 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 repugnant to every single aspect of 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 say 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 floor to no one in terms of my support for the amendment. I believe the FDA 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 due process, they need to know this. If Congress is going to accuse a person of the mens rea, they need to know that. If the government 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 due process, and 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 overzealous in 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? If there appears to be a sufficient second.

The question is agreeing to the motion.
Amendment No. 2107

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.

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 misdeed. In addition, such liability may not reflect fraud. The amendment would discourage the development of new cures for patients. If manufacturers know they could lose exclusivity for even minor infractions, they will not invest the millions of dollars necessary to create new lifesaving therapies for patients.

I ask that the Senate oppose the amendment.

I yield the floor.

The PRESIDING OFFICER. All time has expired.

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

The question is on agreeing to the amendment.

Mr. KYL. The following Senators are necessarily absent: the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Senator from Illinois (Mr. KIRK).

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

Mr. DURBIN. Mr. President, I ask unanimous consent to have the same.

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

The PRESIDING OFFICER. 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. 227

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 real 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 large set 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 strip 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.

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. The Senator from Connecticut (Mrs. HAGAN). Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to the motion.

The clerk will call the roll.

Mr. HATCH. The bill clerk called the roll.

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

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

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

The result was announced—yeas 77, nays 20, as follows:

[Rollcall Vote No. 110 Leg.]

YEAS—77

Akaka

Barrasso

Ayotte

Bennet

Brown (OH)

Brown (MA)

Baucus

Alexander

Bennet

Burr

Brown (MA)

Burr

Johnson (SD)

Johnson (WI)

Carson

Eskimo

Collins

Collins

Conrad

Coons

Corker

Cornyn

Crapo

DeMint

Enzi

Feinstein

Gilibrand

NOT VOTING—3

Blumenthal

Hutchison

Kirk

[Rollcall Vote No. 110 Leg.]

YEAS—9

Bennet

Brown (OH)

Durbin

NAYS—88

Akaka

Alexander

Ayotte

Barrasso

Baucus

Begich

Bingaman

Blunt

Boozman

Boxer

Boozman

Brown (MA)

Burr

Cantwell

Cardin

Carper

Coats

Coons

Collins

Conrad

Corker

Cornyn

Crapo

DeMint

Enzi

Feinstein

Gilibrand

Hutchison

Kirk

[Rollcall Vote No. 109 Leg.]
The motion was agreed to.

Mr. HARKIN. I must object to the Senator from New York on this legislation and share her commitment to working with me to make the amendment better.

I commend 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 sentencing increase 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. 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.

I would like to reiterate that 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 sentencing increase in the sentencing scheme was not needed or intended.

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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 non-sterile drug, 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 during the industry’s annual meeting 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 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 enjoy broad support from industry, the FDA, and consumer groups.

For the first time, this bill will also create new user fee agreements for generic drug manufacturers; manufacturers of biologics; and would make permanent the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. These two laws together help improve the safety and efficacy of pharmaceuticals for children.

Of particular interest, the bill aims to address the problem of requiring all manufacturers of certain drugs to provide advance notification of possible supply disruptions and any permanent discontinuation of these products to the Health and Human Services Secretary. It will also require the 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 emergency pediatric exclusivity. 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 first line to improve 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 it.”
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 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 more challenges and obstacles facing our families—from trying to find or keep a job, to figuring out how to pay for 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 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 mishandling 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 thousands of pets in the United States. Melamine and acid was added to infant formula in China, poisoning and killing six babies and sickening 300,000 others.

In 2008, contaminated Heparin from China killed and sickened hundreds across the United States.

In 2008, more than $20 million in illegally imported and counterfeit Lipitor was sold throughout the United States.

In 2009, an estimated 46 drug cargo thefts occurred, valued at $184 million. Many 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 would like to point out the bill before us today. The FDA Safety and Innovation Act takes a number of important steps to improve the safety of our Nation’s drug supply. For instance, this legislation requires every foreign manufacturer engaged in the manufacture of a drug or device imported into the United States, to electronically register with the FDA.

Under current law, there are no requirements governing how often FDA must inspect foreign facilities. The bill before us requires FDA to set up a risk-based inspection frequency to ensure that we are getting in there and inspecting facilities that pose the greatest risks. This legislation gives the Secretary of Homeland Security the authority to refuse admission into the United States any drug or ingredient if it was manufactured, processed, packed, or held at an establishment that has refused 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, the bill increases penalties for bad actors who knowingly adulterate or counterfeit drugs.

In developing this legislation, the question we had to ask was this: Does the Federal agency tasked with ensuring the safety of our Nation’s drugs have the resources and authorities necessary to do their job and protect the public health? The answer was no. But I believe the new authorities contained in this legislation 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, the 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 patients the burden of paying 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 in-venous nutrition supplements, cancer treating drugs, and anesthesia.

Over the past few months, I have held three roundtable discussions at hospital pharmacies to learn about the drug shortage and how it is affecting providers and patients. From these discus-sions 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 ac-cess to drugs and safe treatments.

At Advocate Hospital in Litchfield, a doctor shared that patients don’t want to repeat their treatment, an entity that 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 hos-pital in that drug is not on the supplied.

Pharmacies now spend part of each day scrambling to find drugs or an alter-native treatment.

I recently learned that a young woman who works here in DC is still too familiar with the drug shortage. She is a smart and hardworking woman who has been taking Concerta to treat her ADHD since she was 14. Like most people who have the condition, she usual-ly has her prescription filled 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 phar-macies to fill her prescription until one month when she could not fill her prescription with her from 3 days and was unable to find a pharmacy with enough 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 pre-scribed time to take the drug.

The shortage of ADD drugs impacts children, adults, parents, and employ-ees 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 na-tional drug shortage.

First, the bill requires drug manu-facturers 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 pa-tients.

This winter, thanks to open communica-tion between the FDA and drug companies, the FDA successfully avoid-ed 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 short-ages 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 cruci blood thinning drug heparin. The source of the contamination was a facility in China that intentionally contaminated the drug. This was a hor-rIBLE 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 our overall manufactur-ing practices of drugs and drug in-gredients 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 manu-factured 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 facili-ties with the FDA.

This bill also places greater responsi-bility on U.S. drug manufacturers to know their international suppliers and increases penalties for intentionally contamination 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 counterfeiting or counterfeiting a drug is no more than 3 years in prison or a $10,000 fine or both. This bill raises the penal-ty 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 or 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 fear for patients and de-vices and drugs, improves the pipeline for antibiotics and pediatric drugs, and helps secure the supply chain for pre-scription drugs.

I thank Chairman Harkin and Senator Enzi for their extraordinary leader-ship 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 bene-fited greatly by the constructive ideas and efforts of all the Members of this body. I sincerely thank all my col-leagues, especially Senator Enzi, for their hard work on this must-pass leg-islation.

This excellent bill is a shining exam-ple 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 reau-thorize 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 Sen-ator from Wyoming.

Mr. ENZI. Madam President, the chairmain has said it well. We appreci-ate 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 this bill.

I yield the floor.

The PRESIDING OFFICER. The question is, Shall the bill pass?

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient sec-ond.
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Sec. 1126. Optimizing global clinical trials.

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Sec. 1135. Medical device and device errors.

Sec. 1136. Compliance provision.

Sec. 1137. Ensuring adequate information regarding pharmaceuticals for all populations, including racial and underrepresented subpopulations, including racial subgroups.

Sec. 1138. Recommendations on interoperability standards.

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

Sec. 1140. Recommendations on clinical trial registration; GAO Study of clinical trial registration and reporting requirements.

Sec. 1141. Proposed amendment.

Sec. 1142. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.

Sec. 1143. Recommendations on interoperability standards.

Subtitle D—Synthetic Drugs

Sec. 1151. Short title.

Sec. 1152. Addition of synthetic drugs to schedule I of the Controlled Substances Act.

Sec. 1153. Temporary scheduling to avoid imminent hazards to public safety.

Sec. 1154. Prohibition on imposing mandatory minimum sentences.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act of 1938, as amended.

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 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 “insured” and inserting “insurer”.

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

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

(1) in subsection (a)—

(A) in the preceding paragraph (1), by striking “fiscal year 2006” 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 following clause (i) in paragraph (2)(A)—

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

(ii) by striking “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) by striking “in subparagraph (A)—”;

(ii) by striking “section 507 (as in effect prior to the implementation of the Food and Drug Administration Modernization Act of 1997)” and inserting “section 505(j)(7)”;

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

“(B) the average annual percent change in the Federal Price Index for all items; Annual Index) for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

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 applied 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) shall be adjusted by the Secretary by notice, published in the Federal Register, for fiscal year by the amount equal to the sum of—

(A) one;

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

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 fiscal 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 applied 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) shall be adjusted for a fiscal year for a fee year in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload for the 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 fee schedule 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 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.

(2) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted under paragraph (4).

(3) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment, and report the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the first fiscal year for which fees are set under this section) and, if the Secretary determines that the methodology warrants, adopt appropriate changes to the methodology.

(4) After review of the reports and receipt of comments, the Secretary shall, not later than 60 days before the start of the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

SEC. 104. REPORTING AND REPORTING REQUIREMENTS.

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

(a) by adding 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 performance of the Food and Drug Administration in achieving the goals 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 prepared a complete response on all human drug applications and supplementations in the cohort.

(b) in subsection (b), by striking "2008" and inserting "2013"

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

SEC. 105. SUNSET DATES.


(c) 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 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.


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, fees under 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 date) that are filed on or after October 1, 2007, but before such fees 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 directed 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.

(a) T YPES OF FEES.— Section 737 (21 U.S.C. 379j) is amended—

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

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

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

(b) A UTHORITY TO USE DEVICES AND FEES.

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

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

(2) 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";

(iii) by striking "section 510(c)" and inserting "section 510(c) and (i)";

(iv) by striking "subparagraph (B)" and inserting "subparagraph (C)";

(v) in clause (vii), by striking "1.84" and inserting "1.84";

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

(C) in subsection (3), by striking "2008 and inserting "2013";

(D) in subsection (4), by striking "2008 and inserting "2013";

(b) in paragraph (5)—

(A) in subparagraph (A)—

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

(ii) by striking "600 and inserting "1,500";

(B) in clause (viii), by striking "1,84" and inserting "2";

(C) in paragraph (6)—

(i) by striking "initial registration" and all that follows through the end of paragraph (6) and inserting "2008 registration for a device";

(ii) by adding paragraph (7) to read as follows:

"(i) the initial or annual registration (as applicable) of the establishment under section 510(f); 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 purposes under this section.

(c) FEES AMOUNTS.—

(1) in general.—Subject to subsections (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 (3).

(2) in paragraph (3) —

(A) in subparagraph (A)—

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

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

(B) in subparagraph (C), by striking "initial registration" and all that follows through the end of paragraph (3) and inserting "2008 registration for a device";

(C) in paragraph (4), by striking "600 and inserting "1,500";

(D) in paragraph (5)—

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

(ii) by striking "600 and inserting "1,500";

(E) in paragraph (6)—

(i) by striking "initial registration" and all that follows through the end of paragraph (6) and inserting "2008 registration for a device";

(ii) by adding paragraph (7) to read as follows:

"(i) the initial or annual registration (as applicable) of the establishment under section 510(f); 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 purposes under this section.

(C) in paragraph (7) —

(A) in subparagraph (A)—

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

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

(B) in subparagraph (C), by striking "initial registration" and all that follows through the end of paragraph (7) and inserting "2008 registration for a device";

(C) in paragraph (8), by striking paragraph (9) and inserting the following:

"(i) the initial or annual registration (as applicable) of the establishment under section 510(f); 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 purposes under this section.

(T) in paragraph (9) —

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“(a) AUTHORIZATIONS.—Sections 737 and 738 of title VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j et seq.), as in effect on 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 (21 U.S.C. 379j-1 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. 207. SUNSET DATES.

(a) AUTHORIZATIONS.—Sections 737 and 738 (21 U.S.C. 379j; 793) shall cease to be effective October 1, 2017.

(b) REPORTS.—Section 738A (21 U.S.C. 739j–1) shall cease to be effective January 3, 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. 298. STREAMLINING HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

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

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

"(b) Activities Described.—The activities described in this subsection are activities under this Act related to the review of device applications (as defined in section 738(b)).

"(c) Objectives Specified.—The objectives specified in this subsection 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 day before the date of enactment of the Omnibus Appropriations Act, 2013.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE.

(a) Short Title.—This title may be cited as the "Generic Drug User Fee Amendments of 2012".

(b) Finding.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 1 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. AUTHORITY TO 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. 741A. Definitions.

For purposes of this part:

"(1) The term ‘abbreviated new drug application’ means—

"(A) an application submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Modernization Act of 1997, and

"(B) an application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

"(2) The term ‘active pharmaceutical ingredient’ means—

"(A) a substance, or a mixture when the substance is unstable or cannot be transported as a single entity, that—

"(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 ratio of 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, of a drug product described in subparagraph (A) of such section shall not apply.

"(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.

"(B) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the 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 ‘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 these 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 databases.

"(iv) Implementing and enforcing section 506(c) (relating to postapproval studies and clinical trials and labeling changes) and section 506(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 ‘postison emission tomography drug’ has the meaning given to the term ‘postison emission tomography drug’ in section 2019(i), 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; and

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

"(C) monitoring, 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
amount of the drug master file fee for fiscal
year 2013, the Secretary shall assess and col-
mect fees in accordance with this section as
authorized to a Type II active pharma-
cutical ingredient at a facility by
the Secretary, in accordance with criteria to be pub-
lished by the Secretary.

(3) GENERIC DRUG FACILITY FEE AND ACTIVE
PHARMACEUTICAL INGREDIENT DRUG MASTER
FILE.—An applicant that submits a generic
drug application shall be subject to a fee for
the information to support approval of a ge-

eral drug submission applicant.

(b)(2) Amounts due after October 1, 2012, in a generic drug sub-
mission following the applicant’s with-
drawal of the application, be subject to a full
fee under subparagraph (A).

(c) Filing of a notice.—A drug master file is subsequently referenced
in at least one generic drug submission that
includes by reference to Type II active
pharmaceutical ingredient drug master
file numbers that cor-
derly available on the Internet Web site of
the Secretary.

(1)(A) IN GENERAL.—Facilities identified, or in-
cluded by reference to Type II active
pharmaceutical ingredient at a facility by
the Secretary, in accordance with criteria to be pub-
lished by the Secretary.

(4) ADDITIONAL FEE FOR ACTIVE PHARMA-
CEUTICAL INGREDIENTS AND FINISHED
PRODUCTS.—Each person that owns a fa-
cility which is identified or in-
cluded by reference to 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.

(IV) 30 calendar days after the date of en-
closure of the notice under subparagraph (B); or

(III) 30 calendar days after publication of
the information to support approval of a ge-

eral drug submission applicant.

(II) 30 calendar days after the date of en-
closure of the notice under subparagraph (B);

(III) 30 calendar days after publication of
the information to support approval of a ge-

eral drug submission applicant.

(1) IN GENERAL.—Each person that owns a
facility which is identified or in-
cluded by reference to 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.

(c) Filing of a notice.—An applicant that submits a generic
drug application shall be subject to a fee for
the information to support approval of a ge-

eral drug submission applicant.

Army, and shall pay a fee, in the amount determined
by the Secretary, in accordance with criteria to be pub-
lished by the Secretary.

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PHARMACEUTICAL INGREDIENT DRUG MASTER
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drug application shall be subject to a fee for
the information to support approval of a ge-

eral drug submission applicant.

(3) GENERIC DRUG FACILITY FEE AND ACTIVE
PHARMACEUTICAL INGREDIENT DRUG MASTER
FILE.—An applicant that submits a generic
drug application shall be subject to a fee for
the information to support approval of a ge-

eral drug submission applicant.
‘(D) 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 paragraph (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) at the time of submission of such information.

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

‘(A) if it is submitted via a Food and Drug Administration electronic gateway, on the date 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 receives such a submission is closed, the day that such submission is received shall be deemed to be submitted on the next day when that office is open for business; or

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

‘(b) FEE REVENUE AMOUNTS.—

‘(1) IN GENERAL.—For fiscal year 2013—

‘(A) 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) IN ESTABLISHING FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(i) 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)(4)(A)(i) (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)(ii) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall not be 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 and 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 (b) (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 not be 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 and its territories and possessions.

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

‘(f) IDENTIFICATION OF FACILITIES.—

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

‘(A) the Secretary shall establish, by October 31, 2013, 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 the date to comply with the requirement for identification of facilities under 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).

‘(g) REMARKS.—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 for such submission.

‘(h) 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.

‘(i) 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 format and content 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 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 notice 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 prescription drugs only, drugs solely, or in addition to other drugs; and

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

‘(B) CERTAIN PROVISIONS AND ORGANIZATIONS.—

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

"(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 reviewed within the meaning of section 506(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 subpart (a)(2)(D) of subsection (l)) 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 506(j)(5)(A) unless the condition specified in clause (ii) is met.

"(ii) 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.

"(C) NONRECEIVABLE FOR NONPAYMENT.—(i) If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a Type II active pharmaceutical ingredient drug master file that has not been paid or the facility is removed from all governmental references such a facility shall not be received, the Secretary shall notify the sponsor of the abbreviated new drug submission not being received, and any prior approval supplement to the abbreviated new drug application not being received within the meaning of section 506(j)(5)(A) until such outstanding fee is paid.

"(D) IN CONCLUSION.—(a) within 30 calendar days after it is due, the amount of fees appropriated for such fiscal year (excluding fees authorized by this section—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts, subject to paragraph (2). Such fees are authorized to remain available until expended.

"(2) LIMITATION.—In any fiscal year not more than 10 percent below the level specified in such subparagraph.

"(C) 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 appropriated for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

"(D) 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.

"(2) 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 subject to paragraph (a)(2) be reduced to offset the number of officers, employees, and advisory committees so engaged.
(1) **POSITRON EMISSION TOMOGRAPHY DRUGS.**

(2) **EXEMPTION FROM FEES.**—Submission of an application for a positron emission tomography drug 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 (d)(1) 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, 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 performance 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, the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for 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) **CONGRESSIONAL RECONCILIATION.**

(1) **CONSULTATION.**—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting these goals, 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 after 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 and present them to the congressional committees specified in such paragraph.

(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 and any significant controversy 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:

"(a) If it is a drug containing a pharmaceutical ingredient that was manufactured, prepared, propagated, compound, 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, compound, 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) by striking "are activities" and inserting "are activities;"

(2) in subsection (c) by adding at the end the following: "(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 306 of the Generic Drug User Fee Amendments of 2012."

**TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS**

**SEC. 401. SHORT TITLE; FINDING.**

(a) **SHORT TITLE.**—This title may be cited as the "Biosimilar User Fee Act of 2012."

(b) **FINDING.**—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of Subchapter C of chapter 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 Appropriations. Such fees are in addition to the cost of the programs the Secretary is authorized to carry out in such letters and the cost of the studies and services to the Chairman of the Committee on Appropriations; and

**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 particular product that is in the Consumer Price Index for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) of the preceding fiscal year, as divided by such Index for September 2011.

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

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

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

(3) The term 'biosimilar biological product' means a product for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term 'biosimilar biological product application' means an application for licensure of a biosimilar 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 an approved reference product; a biological product for topical application licensed before September 1, 1992, or a large volume parenteral drug approved before such date;

(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

(I) the 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;

(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) The term 'biosimilar biological product development meeting' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term 'biosimilar biological product development program' means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7)(A) The term 'biosimilar biological product establishment' means a foreign or domestic business entity that—

(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) For purposes of subparagraph (A)(ii), the term 'manufactured' does not include packaging.

(8) The term 'biosimilar initial advisory meeting' means—

(A) means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure of a product 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 results.

(9) The term 'costs of resources allocated' for the process for the review of biosimilar biological product applications means the expenses incurred in the process in the review of biosimilar biological product applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers and employees and 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 a supplement requesting that the Secretary approve a change in the review of a biosimilar biological product application; 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 processing such as lyophilized products before reconstitution.

(11) The term 'financial hold' means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is not consistent with the provisions of section 351(k), including any regulations promulgated under section 351(k)(4) of the Public Health Service Act.

(12) The term 'person' includes an affiliate of such person.

(13) The term 'postmarket safety activities' includes the following activities of the Secretary: reviewing of adverse-event reports and postmarket safety information on biosimilar biological products, including the following activities:

(A) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

(B) 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 applying 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(c)(1) (relating to risk evaluation and mitigation strategies).

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

(14) The term 'permit' means a request to the Secretary to approve a change in a biosimilar biological product application which approve biosimilar biological product development, biosimilar biological product development, biosimilar biological product applications, and supplements.

(15) The term 'pending biosimilar biological product application'—

(A) initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(II) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.

(B) meeting request described in this clause is a request for a biosimilar biological product development fee by the earlier of the following:

(i) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(ii) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.

(C) meeting request described in this clause is a request for a biosimilar biological product development fee by the earlier of the following:

(i) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(ii) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.

(D) meeting request described in this clause is a request for a biosimilar biological product development fee by the earlier of the following:

(i) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(ii) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.

(E) meeting request described in this clause is a request for a biosimilar biological product development fee by the earlier of the following:

(i) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(ii) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.

(F) meeting request described in this clause is a request for a biosimilar biological product development fee by the earlier of the following:

(i) Not later than 60 days after the date of receipt by the Secretary of a meeting request described in this clause; or

(ii) The date of submission of an investigational new drug application describing an investigation that is intended to support a meeting request described in this clause.
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 or meeting.

"(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

"(I) IN GENERAL.—A person that pays an initial or annual 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 fees, referred to in this section as "annual biosimilar biological product development fee".

"(II) DUE DATE.—The annual biosimilar biological product development 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 biological product development program fee for each fiscal year will be due on the date specified in clause (ii), unless the Secretary—

(i) submitted a marketing application for the biological product that was accepted for filing;

(ii) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C);

(iii) discontinuation of fee obligation.—A person may discontinue participation in the biosimilar biological product development program for the product for which fees are required under subparagraph (A) or (B), or a reactivation fee paid under subparagraph (D) 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), a reactivation fee as required under subparagraph (D), or a payment due or payable under subparagraph (E).

"(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), the Secretary shall not accept for filing, and shall not be subject to a fee under subparagraph (A), (B), or (D) of paragraph (1) for that product.

"(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.

"(E) Exceptions for previously filed applications.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for the application or supplement when it 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 by the same person by the same person (or the person’s licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A), (B), or (D) of paragraph (1) for that product.

"(D) Application fee for filing or withdrawn before filing.—A biosimilar biological product application or supplement that was submitted but was not approved 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 for filing, 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 establishment fee of—

(i) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

(II) a fee for a biosimilar biological product establishment that is listed in the approved biosimilar biological product application that includes the establishment fee for a 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 biosimilar biological product establishment—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) Establishment fee—The establishment fee 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 began, 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 APPLICANT .—

(A) REQUIREMENTS.—The biosimilar biological product application fee for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a prescription drug product establishment for that fiscal year.

(B) USE OF FEES AND LIMITATION.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be reduced to offset the number of officers, not engaged in the process of the review of human drug applications, the initial biosimilar biological product application fee described in section 736(a)(1)(A)(i) for that fiscal year.

(C) 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 began, 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.

(5) DNAXIC RESOLUTION REQUIREMENTS.—The biosimilar biological product application fee for a fiscal year shall be equal to 20 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(E) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product establishment for that fiscal year.

(F) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the processing of biosimilar biological product applications.

(C) Application Fee Waiver for Small Businesses.—

(1) Waiver of Application Fee.—The Secretary shall grant to a person who is named as the applicant in a biosimilar biological product application a waiver from the application fee assessed under the section (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 supplement applications 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 gross sales revenue of $20 million or more for the fiscal year, as defined in section 744G(4)) and introduced or delivered for interstate commerce.

(4) 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) Credit 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. Such sums transferred shall be available solely for the process of the review of biosimilar biological product applications.

(2) Collections and Appropriation Acts.

(A) In General.—Subject to subparagaphs (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 in 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 for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent officers, employees, and advisory committees to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (expressed as a percentage of the fees authorized 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 Fiscal 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, may be collected if such fees are assessed for such fiscal year.

(E) Authorization of Appropriations.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount assessed for such fiscal year under this section.

(F) Collection of Unpaid Fees.—In any case where the Secretary does not receive payment in full of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be deemed to be 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 for fees collected under subsection (a), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee 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 be reduced to offset the number of officers, employees, 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. 744L. 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 and objectives 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 reviewed comments and recommendations 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 fees associated with the process for the review of biosimilar biological product applications.

(2) INTERIM RESULTS.—Not later than June 30, 2012, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

(3) FINAL RESULTS.—Not later than September 30, 2012, 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) academic experts; 

(D) health care professionals; 

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

(F) 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; and 

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

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

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than 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 this 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) S Belmont REQUIREMENTS.—The amendment made by section 403 shall cease to be effective January 31, 2018.

SEC. 405. EFFECTIVE DATE.

(a) In General.—Notwithstanding the amendments made by this title, the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of 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 collected 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 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 BIOLOGICAL PRODUCTS

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 “or on or before October 1, 2012.”; and 

(3) in paragraph (2), by striking “or on or before October 1, 2012.”.

(b) Research Into Pediatric Uses for Drugs and Biological Products.—Section 505B (21 U.S.C. 355b) 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) Amendments 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 paragraph (2) or (3) of section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) or for the submission of such information as is necessary to carry out 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 request. 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 clause (ii) or (III) of subparagraph (A)(i) continue to be met; and

(ii) the applicant submits a new timeline under subparagraph (A)(iii) and any significant updates to the information required under subparagraph (A)(iii).

“(ii) Timing and Information.—If the deferral extension under subparagraph (A) is requested by the applicant, the Secretary 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 request. The Secretary may grant an extension of a deferral extension that has expired prior to the date of submission for such required studies has passed or if the request for an extension is pending. For a deferral extension 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, the 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 such request or studies. If any recommendations of such study or studies are late or delayed:

(1) 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:

“(i) in clause (i)—

“(1) by inserting ‘‘, as well as the date of each deferral or deferral extension, as applicable,’’ after ‘‘such deferral,’’; and

“(ii) by inserting ‘‘not later than 90 days after submission to the Secretary or with the next routine quarterly update after ‘‘Administrative STUDY PLAN’’; and

“(2) in subsection (f)—

“(A) in the subsection heading, by inserting ‘‘DEFERRAL EXTENSIONS’’, after ‘‘DEFERRALS’’; ‘‘PEDIATRIC STUDY PLAN’’, and ‘‘PEDIATRIC PLANS’’; and

“(B) in paragraph (1), by inserting ‘‘, deferral extension,’’ after ‘‘deferral’’; and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS’’, after ‘‘DEFERRALS’’, and ‘‘PEDIATRIC STUDY PLANS’’, and ‘‘PEDIATRIC PLANS’’.

“(V) Tracking of Letters—Annual Information. Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) 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 in 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:

“(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design group, relevant endpoints, and statistical approach);

“(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

“(iii) other information specified in the regulations promulgated under paragraph (4).

“(C) MEETING. —The Secretary—

“(1) shall meet with the applicant to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A); and

“(ii) shall determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting is necessary.

“(iii) if the Secretary determines that no meeting is necessary, shall notify the applicant and provide written comments of the Secretary as to whether such request meets the requirements of this section, 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 the deferral or deferral extension under subsection (a).

“(3) AGREED INITIAL PEDIATRIC STUDY PLAN. —

“(1) PEDIATRIC STUDY PLANS. —Subsection (e)

“(A) in the subsection heading, by striking ‘‘p pediatric plans’’, and inserting ‘‘PEDIATRIC STUDY PLANS’’; and

“(B) in paragraph (1), by striking ‘‘all pediatric plans’’ and inserting ‘‘initial pediatric study plans, agreed initial pediatric study plans’’.

“(C) in paragraph (4)—

“(1) in the paragraph heading, by striking ‘‘PEDIATRIC PLANS’’, and inserting ‘‘PEDIATRIC STUDY PLANS’’;

“(2) by striking ‘‘all pediatric plans’’ and inserting ‘‘initial pediatric study plans, agreed initial pediatric study plans’’.

“(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 subsection (a)(2) of section 505B, as amended by section 12(2) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m) note) is amended by striking ‘‘for the duration of the Best Pharmaceuticals for Children Act of 2007’’ and inserting ‘‘for the duration of the Best Pharmaceuticals for Children Act of 2017’’.

“(2) in subsection (k) of section 505B, as amended by section 1(4) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m) note), by striking ‘‘the date of enactment of the Best Pharmaceuticals for Children Act of 2007’’ and inserting ‘‘the date of the enactment of the Best Pharmaceuticals for Children Act of 2007’’.

“(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. 509. 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 2007 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 ‘‘Notwithstanding section 14 of the Federal Advisory Committee Act, the 2007 advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Federal Advisory Committee Act and shall meet at least once a year’’.

“(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 Best Pharmaceuticals for Children Act of 2007’’.


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"360j(m)(6)(A)(iv)) is amended by striking ‘‘(D) aggregated on an annual basis—

“(1) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for such each deferral or deferral extension;

“(ii) the timeline for completion of the assessments in paragraph (1); and

“(iii) the number of assessments completed and pending;—

“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) ISSUANCE OF LETTER.—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 (b)(1), or 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.

“(2) REQUIREMENTS.—If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

“(1) 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 (as determined under such deferral or deferral extension). In such case, and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 305), but subject there shall not be the basis for a proceedings—

“(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.”
PEDIATRIC DEVICE AVAILABILITY.—Section (a) in paragraph (7), including—
(A) the number of labeling changes made to drugs and biological products pursuant to such sections since the date of enactment of this Act; and
(B) the importance of such drugs and biological products in the improvement of the health of children;
(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section, including—
(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted; and
(B) the number of waivers and partial waivers granted; and
(C) the number of letters issued under subsection (d) of such section 505B;
(3) in subsection (g) —
(1) in the first sentence, by inserting “partial’’ before ‘‘waiver is granted’’; and
(2) in the second sentence, by striking ‘‘either a full or’’ and inserting ‘‘such a’’;
(iv) in the matter following subparagraph (A), by inserting ‘‘or section 351(m) of this Act,’’; and
(m)(3) of section 351 of the Public Health Service Act apply,’’; and
(4) in subsection (h)—
(A) by inserting ‘‘an application (or supplement to an application) that contains’’ after ‘‘date of submission of’’; and
(B) by inserting ‘‘or the date of the submission of an application that contains’’ after ‘‘studies), the’’ and inserting ‘‘The’’;
(5) in paragraph (1) —
(A) by inserting ‘‘or section 351(m) of this Act’’ after ‘‘date of submission of’’; and
(B) by inserting ‘‘, including, with respect to a drug, an application (or supplement to an application)’’ for ‘‘a’’;
(iv) in the following paragraphs—
(A) in paragraph (1)(A), by inserting ‘‘(or supplement)’’ after ‘‘a’’ and inserting ‘‘, including, with respect to a drug, an application (or supplement to an application)’’ for ‘‘a’’;
(B) in paragraph (1)(B), by inserting ‘‘(or supplement)’’ after ‘‘a’’ and inserting ‘‘, including, with respect to a drug, an application (or supplement to an application)’’ for ‘‘a’’;
(c) CONSULTATION ON RECOMMENDATIONS.—At least 180 days before the report is due under subsection (a), the Secretary shall provide notice of the recommendations of the Committee to the programs described in subsection (b)(7), including suggestions for modifications to such programs.
SEC. 509. TECHNICAL AMENDMENTS.
(a) PEDIATRIC STUDIES OF DRUGS IN FFDDCA.—Section 505A (21 U.S.C. 355a) is amended—
(1) in subsection (b) —
(A) by inserting ‘‘and deferral extensions’’ after ‘‘deferrals’’; and
(B) by inserting ‘‘, including, with respect to a drug, an application (or supplement to an application)’’ for ‘‘a’’;
(c) INTERNAL REVIEW COMMITTEE.—The heading of section 505C (21 U.S.C. 355c) is amended by inserting ‘‘AND DEFERRAL EXTENSIONS’’ after ‘‘DEFERRALS’’; and
(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS EXPIRED LISTED PATENTS.—Section 355(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 ‘‘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’’;
(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)(4)(E)(ii), (iii), and (v) or (j)(5)(F)(ii), (iii), or (v) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 513(k)(7) of the Federal Food, Drug, and Cosmetic 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 or device.

(2) by redesigning paragraphs (1) and (2) as subparagraphs (A) and (B) and moving clause (iii) of subsection (b)(1)(A) as so redesignated, 2 ems to the right; and

(3) by adding at the end following:

‘‘(2) 3-YEAR EXCLUSIVITY PERIOD. —The 3-year period referred to in subsection (a) of this section shall begin on the date of the enactment of this Act and shall extend to the end of the 3-year period under subparagraph (A) of section 505(j)(5) or shall extend to the 360-day period under section 505(j)(5) that the Secretary identifies in the notice of exclusivity period as the 3-year period for purposes of this subsection if the Secretary determines that this subsection applies to such drug or device. As used in this subsection, the term ‘date of the enactment of this Act’ means the date of the enactment of this Act as defined in subsection (b) of section 505(j), as amended by the Patient Protection and Affordable Care Act.’’

(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 ‘‘and an order issued’’.

(B) Section 513(e)(3) (21 U.S.C. 360c(e)(3)) is amended by striking ‘‘under regulation promulgated or under any order issued under subsection (e) of section 505(b) of such Act’’ and inserting ‘‘or an order issued under section 505(b) of such Act’’.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this section shall take 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 but such regulation shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 513(e) applies to an administrative order issued with respect to a device reclassified after 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 514(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act as if such regulation promulgated under section 513(e) of such Act were an order issued under section 514(a)(1) of the Federal Food, Drug, and Cosmetic Act but such order shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 514(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ‘‘(2) The Secretary may, after notice and opportunity for public hearing, by regulation promulgated under the authority of this section, reclassify a device from class II to class III if the Secretary finds that the device is appropriate for such classification and that such classification is in the interest of public health’’;

(B) in subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of this Act).

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(a)(1) (21 U.S.C. 360a(a)(1)) is amended by striking ‘‘regulation promulgated’’.

(B) Section 513(a)(2) (21 U.S.C. 360a(a)(2)) is amended by striking ‘‘under regulation promulgated or under any order issued under subsection (e) of section 505(b) of such Act’’.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this section shall take 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 but such regulation shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 513(e) applies to an administrative order issued with respect to a device reclassified after 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 514(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act as if such regulation promulgated under section 513(e) of such Act were an order issued under section 514(a)(1) of the Federal Food, Drug, and Cosmetic Act but such order shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 514(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ‘‘(2) The Secretary may, after notice and opportunity for public hearing, by regulation promulgated under the authority of this section, reclassify a device from class II to class III if the Secretary finds that the device is appropriate for such classification and that such classification is in the interest of public health’’;

(B) in subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of this Act).

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(a)(1) (21 U.S.C. 360a(a)(1)) is amended by striking ‘‘regulation promulgated’’.

(B) Section 513(a)(2) (21 U.S.C. 360a(a)(2)) is amended by striking ‘‘under regulation promulgated or under any order issued under subsection (e) of section 505(b) of such Act’’.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this section shall take 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 but such regulation shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 513(e) applies to an administrative order issued with respect to a device reclassified after 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 514(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act as if such regulation promulgated under section 513(e) of such Act were an order issued under section 514(a)(1) of the Federal Food, Drug, and Cosmetic Act but such order shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 514(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ‘‘(2) The Secretary may, after notice and opportunity for public hearing, by regulation promulgated under the authority of this section, reclassify a device from class II to class III if the Secretary finds that the device is appropriate for such classification and that such classification is in the interest of public health’’;

(B) in subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of this Act).

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(a)(1) (21 U.S.C. 360a(a)(1)) is amended by striking ‘‘regulation promulgated’’.

(B) Section 513(a)(2) (21 U.S.C. 360a(a)(2)) is amended by striking ‘‘under regulation promulgated or under any order issued under subsection (e) of section 505(b) of such Act’’.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this section shall take 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 but such regulation shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 513(e) applies to an administrative order issued with respect to a device reclassified after 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 514(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act as if such regulation promulgated under section 513(e) of such Act were an order issued under section 514(a)(1) of the Federal Food, Drug, and Cosmetic Act but such order shall not apply to any regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 514(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.
"Authority to issue such administrative order shall not be delegated below the Commission. 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, determines 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 subsection (b); and
(ii) by striking paragraph (2)(A) and inserting—
"(A) by striking "regulation promulgated" and inserting "order requiring"; and
"(B) by striking "proposed order under paragraph (1) shall take effect"; and
(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":
(II) in paragraph (3)—
(i) by striking "proposed regulation" each place such term appears and inserting "proposed order";
(II) by striking "and" after "order" and inserting "order;";
(iii) by striking 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)(i) and inserting —
"(A) the number and type of class I and class II devices reclassified as class I or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosme tic Act (21 U.S.C. 360c(e)(1));
(II) in subparagraph (2)(B)—
(i) by striking "(ii)" and inserting "(i)(I)";
(ii) 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 described in subparagraph (A);"
SEC. 602. CONDITION OF APPROVAL STUDIES.
"(C) CLARIFICATION.—With respect to devices cleared under such section 515(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. 603. 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 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)); and
(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 510(k) of such Act (21 U.S.C. 355(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 frequently recalled;
(C) the causes of device recalls; and
(D) any other information as the Secretary determines appropriate.
(b) AUDIT CH CPROCEDURES.—The Secretary shall clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.
(c) ASSESSMENT CRITERIA.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) or to a requirement under section 515(g) of such Act (21 U.S.C. 360(g)) has performed an effective recall, or under such section 515(k)(3)(C)(i) shall not apply to devices.

"(1) IN GENERAL.—
"(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (1), (ii), (iii), and (iv) of section 515(a) of such Act to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.
(1) EXECUTION.—Section 519(g)(3)(C) of such Act is amended—
(iii) by adding at the end the following:
"(8) INCLUSION OF DEVICES IN THE POSTMARKET SURVEILLANCE AND ANALYSIS SYSTEM.—
"(1) IN GENERAL.—
"(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (1), (ii), (iii), and (iv) of section 515(a) of such Act to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.
"(1) EXECUTION.—Section 519(g)(3)(C) of such Act is amended—
(iii) by adding at the end the following:
"(8) INCLUSION OF DEVICES IN THE POSTMARKET SURVEILLANCE AND ANALYSIS SYSTEM.—
(d) TERMINATION OF RECALL.—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. 360(e)); and

(2) any correction or removal action for which a report is required to be submitted to the Secretary under section 519(g) of such Act (21 U.S.C. 360(g)).

SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360(g)) is amended by adding at the end the following:

“(b) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(1) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigations, 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

(2) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

(3) the Secretary may authorize the removal of such 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—

(1) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigations, 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

(2) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

(3) the Secretary may authorize the removal of such 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.

“(C) Any written request to the Secretary from a 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. 360(f)) is amended—

(1) by striking “The Secretary shall promulgate” and inserting “Not later than December 31, 2013, the Secretary shall issue final guidance on the regulations are finalized.”;

(2) by amending subparagraph (A) to read as follows:

“(A) IN GENERAL.—A person who has submitted a request for an exemption under section 513(i) or for whom the Secretary disapproves an application for an investigational 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 pursuant to 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.—Exempt 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 supervisory 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 involving 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(b)(1) (21 U.S.C. 371(b)(1)) is amended—

(1) by striking “(C) For guidance documents” and inserting “(C)(i) For guidance documents”; 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. 360(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

(ii) Apply for premarket approval under section 515, or

(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, at such time as the Secretary to the classification for the device. Any such request shall describe the device and provide detailed information and reasons for the 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 at 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 will provide such assurance. Requests under this clause shall be subject to the electronic copy requirements of section 764(a)(b).

(3) In amending 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, in which case the Secretary may require 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),”; and

(B) in clause (ii), by inserting “or is classified in” after “remains in”.

(b) T HIRD PARTY INSPECTIONS.—Section 510(k) Device Modifications: Deciding When such guidance should be prepared and recommendations required for the report under subsection (b).

(2) REPRESENTATIVES.—The Secretary shall determine the number of representatives participating in the working group, and shall ensure that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, stakeholders with expertise in medical devices, including any favorable or adverse impact on pediatric device development;

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

(3) in paragraph (8), by striking “of all devices described in paragraph (6)(A)(i)”.

(b) APPLICABILITY TO EXISTING DEVICES.—A person may petition the Secretary—

(b) Third Party Inspections—Section 510(k) Device Modifications: Deciding When such guidance should be prepared and recommendations required for the report under subsection (b).
‘‘(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 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) by striking ‘‘in subsection (b)’’ and

(c) IDENTIFICATION OF DRUG EXCIPENT INFORMATION WITH PRODUCT LISTING.—Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amended—

SEC. 703. IDENTIFICATION OF DRUG EXCIPENT INFORMATION WITH PRODUCT LISTING. Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amended—

1. In paragraph (C), by striking ‘‘;’’ and

(1) in subparagraph (C), by striking ‘‘;’’ and

2. In subsection (b), by adding at the end the following:

3. In paragraph (1), in subparagraphs (A) and (B), by striking ‘‘in any State’’.

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS. (a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 332(o)) is amended by striking ‘‘in any State’’.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(b) (1) (21 U.S.C. 360(b)) 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, propaganda, compounding, or processing of a drug or device for, or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—’’;

‘‘(B) by amending subparagraph (A) to read as follows:

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

1. With respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address, the name of the United States agent for the 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 each 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

‘‘(B) 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. 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 date that is required to be registered with the Secretary that includes—

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

(b) the number of domestic and foreign establishments that the Secretary inspected in the previous fiscal year;

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

(7) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (6) available to the public at the official Web site of the Food and Drug Administration.’’.

SEC. 705. RISK-BASED INSPECTION FREQUENCY. Section 704(a) (21 U.S.C. 360(a)) is amended to read as follows:

(1) INSPECTIONS.—

‘‘(1) IN GENERAL.—Every establishment that is inspected under paragraph (1), 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, preparation, propaganda, compounding, or processing of a device, or drug, shall be inspected by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in every 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, propaganda, compounding, or processing of a drug or device (referred to in this provision as ‘‘drug (manufacturers or drug (manufacturers)’’ in accordance with a risk-based schedule established by the Secretary.

SEC. 706. RECORDS FOR INSPECTION. Section 706(a) (21 U.S.C. 361(a)) is amended by adding at the end the following:

‘‘(4) Any records or other information that the Secretary is entitled to inspect under this section shall be, on request from the Secretary, provided to the Secretary by the person within a reasonable time frame, within reasonable limits and in a reasonable manner, and in electronic form, at the expense of the person. The records or other information 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:

‘‘(4) Risk factors.—In determining the risk-based schedule established 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 drugs 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 described in section 503(b).

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

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

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

(7) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (6) available to the public at the official Web site of the Food and Drug Administration.’’.

SEC. 708. ADD ON BILLS 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 Act, the Secretary of Homeland Security shall, upon request from the Secretary of
Health and Human Services refuse to admit into the United States any article if the article was manufactured, prepared, compounded, processed, or held at an establishment that has been identified by 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 of title 21 is amended—

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

(a) CONTRACTORS.—The Secretary; and

(b) by adding at the end the following:

"(B) Information not described in subparagraph (A) may be provided to a foreign government or to any other foreign entity if the Secretary reasonably believes, or that the written agreement described in paragraph (2) establishes, that the government or entity 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.

(3) Effect of subsection.—Nothing in this subsection affects the ability of the Secretary to enter an agreement authorized by other provisions of law to share confidential information.

SEC. 709. ENHANCING THE SAFETY AND QUALITY OF DRUGS.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

"(A) mean an audit of an eligible entity to conduct drug safety and quality audits.

(5) Drug safety and quality audit.—The term "drug safety and quality audit"—

(i) include a description of required standards relating to the training procedures, competency, management responsibilities, control, and other requirements of accredited third-party auditors; and

(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) a list held by the Secretary under subsection (c)(1), that is eligible to be considered for accreditation 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 enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors at any time after the date of enactment of the Food and Drug Administration Safety and Innovation Act.

(ii) Certain direct accreditations.—Notwithstanding subparagraph (A) or clause (i), the Secretary may directly accredit any foreign government or any foreign entity 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 that 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 may promptly revoke, after the opportunity for an informal hearing, the recognition of any accreditation body that in good faith determined, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

(4) 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, as the Secretary determines, 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 this paragraph shall include a description of required standards relating to the training procedures, competency, management responsibilities, control, and other 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 REPORT 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 body 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 accredit- ing a foreign government or an agency of such 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 per- form such review of the capabilities of such foreign government or agency of the government as the Secretary deems necessary, including re- quirements under the standards developed under subsection (b)(5), to determine that the foreign government or agency of the for- eign government is capable of adequately en- suring that eligible entities or drugs cer- tified by such government or agency meet the requirements of this Act.

‘(B) OTHER THIRD PARTIES.—Prior to accredit- ing any other third party to be an ac- credited third-party auditor, the accredita- tion body (or, in the case of direct accredita- tion under subsection (b)(1)(B), the Secretary) shall perform such review of the capabilities of such third-party auditor as the Secretary deems necessary, including re- quirements 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 cer- tified 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 such other audit agents to conduct drug safety and quality audits, but must ensure that such audit agents comply with all requirements of this Act. The Secretary deems necessary, including re- quirements under paragraph (1) and sub- section (b)(5).

‘(3) REVOCATION OF ACCREDITATION.—

‘(A) IN GENERAL.—The Secretary shall promptly revoke, after an informal hearing, the accreditation of an accredited third-party auditor if the third-party auditor fails to comply with any applicable registration re- quirements of this Act.

‘(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party auditor if the third-party auditor is not in compliance with the requirements of this Act or if the third-party auditor fails to provide the results and reports of any drug safety and quality audit conducted pursuant to the accreditation body under this section.

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

‘(A) the Secretary determines, based on evi- dence presented, that—

‘(i) the third-party auditor satisfies the re- quirements of paragraph (1) and sub- section (b)(5); and

‘(ii) adequate grounds for revocation no longer exist; and

‘(B) in the case of a third-party auditor ac- credited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3)—

‘(i) the third-party auditor becomes ac- credited not later than 1 year after revoca- tion of accreditation under subsection (3), through direct accreditation under sub- section (b)(3), or by an accreditation body in good standing; or

‘(ii) the Secretary deems necessary, including re- quirements under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately en- suring that eligible entities or drugs cer- tified by such government or agency meet the requirements of this Act.

‘(2) OTHER THIRD PARTIES.—Prior to accredit- ing any other third party to be an ac- credited third-party auditor, the accredita- tion body (or, in the case of direct accredita- tion 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, a public, certificate of accreditation, as the Secretary may require under this Act, regarding compliance with the provisions of this section.

‘(C) RECORDS.—Following any accredita- tion of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary a drug safety and quality audit report and other documents as may be necessary to establish compliance with the provisions of this section.

‘(D) LIMITATION.—The requirement under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately en- suring that eligible entities or drugs cer- tified by such government or agency meet the requirements of this Act.

‘(ii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to deter- mine compliance with the requirements set forth in subparagraph (A) and subsection (b)(5).
“(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 audit reports and 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 510(h) of such Act (as added by subsection (a)) and ending on the date of such report:
(1) The extent to which drug safety and quality audits completed by accredited third-party auditors and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).
(2) The extent to which the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under section 809.
(4) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.
(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors 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 amended by section 711).
(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.
(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.
(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to fund the program.
“(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 establishment; and
“(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.
“(g) Costs.—
“(1) Authorized fees of Secretary.—The Secretary may require accredited third-party auditors to ensure drug safety and quality audits completed by accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809, including whether Congress should continue to fund the program.
“(2) may be used by the eligible entity—
“(A) as documentation of compliance with section 510(h) of such Act (as added by subsection (a)) and ending on the date of such report:
“(B) for other purposes as determined appropriate by the Secretary and
“(C) through establishing the risk-based inspection schedules under section 510(h).
“(h) Limitations.—
“(1) Effect of Audit.—The results of a drug safety and quality audit by an accredited third-party auditor under this section—
“(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 establishment; and
“(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.
“(2) No effect on inspection authority. —
“(ii) 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).
“(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 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 amended by section 711).
“(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.
“(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.
“(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to fund the program.
“(9) 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 and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).
“(2) the extent to which the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under such section 809.
“(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 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 amended by section 711).
“(6) the number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.
“(7) the number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.
“(8) recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to fund the program.
“(9) notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (b).”.
“(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:
“(aa) The failure to notify the Secretary in violation of section 58B.
“(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:
“(c) 58B. Notification.—
“(1) 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—
“(A) of a substantial loss or theft of such drug; or
“(B) 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.
“(ii) 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 by 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 described in paragraph (a) of section 588 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) apply to looses, thefts, or counterfeiting, as described in section 501 of such section 588, 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 PUNISHMENTS FOR COUNTERFEITING DRUGS.

(a) FDCA.—Section 303(b) (21 U.S.C. 333(b)) of section 113 is amended by adding at the end the following:

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

(b) TTRA.—Section 232(b) of title 18, United States Code, is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by inserting after paragraph (1) the following:

“(2) COUNTERFEIT DRUGS.—

“(A) IN GENERAL.—Whoever commits an offense under subsection (a) with respect to a counterfeit 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 $1,000,000, 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) IN GENERAL.—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—

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

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

(c) SENTENCING.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to section 3553(f) of title 18, 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 232(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 (a) and the need for an effective deterrent and appropriate punishment to prevent such offenses;

(B) consider the extent to which the guidelines and policy statements adequately account for the potential and actual harm to the public resulting from the offense;

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

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

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

(F) assure that the product shall be a 2D drug data matrix barcode affixed to each individual saleable unit of a product and a linear or 2D data matrix barcode on a homogenous unit 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 sections 582 and 583, 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 transactions.

“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 this Act, shall—

(A) establish a system to determine the original source of a product at the lot level for the RxTEC data; and

(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) establish a system to determine the original source of a product at the lot level for the RxTEC data; and

“(D) provide the following change of ownership and transaction information to the

“SEC. 583. REQUIREMENTS TO ENSURE AUDITABILITY AND INTTEGRITY TO PROTECT THE PUBLIC HEALTH ACT OF 2012."
paragraph, not later than 4 1⁄2 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, 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, manufactured, or distributed by any less the manufacturer, in consultation with the Secretary, determines such product may reenter the pharmaceutical distribution supply chain.

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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, manufactured, or distributed by any

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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, manufactured, or distributed by any

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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, manufactured, or distributed by any

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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, manufactured, or distributed by any

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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, manufactured, or distributed by any

(C) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

(D) N ECESSARY TO IDENTIFY THE IMMEDIATE PREVIOUS SOURCE OR IMMEDIATE SUBSEQUENT RECIPIENT OF SUCH PRODUCT, AS APPLICABLE.

(2) VERIFICATION REQUIREMENTS.—A repackager, upon confirming that a product is in the possession of 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.
the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

(A) receive only products encoded with RxTEC lot level data from registered manufacturer, wholesaler, or repackager; and

(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)Proprietor name and address of the immediate previous source and the immediate subsequent recipient of the product;

(iii) the proprietary or established name or name 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; and

(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; and

(II) has received the product from a registered or licensed manufacturer, repackager, or wholesaler, 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) notify 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 appropriate Federal official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

(i) RxTEC data by lot; and

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

(i) receive 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 records for each such 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 chain at which the suspect product originated, 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, or the Secretary, regarding such product and recall;

(iii) meet 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;

(iv) conduct unit level verification of a suspect product—

(I) upon the request of a licensed or registered manufacturer, repackager, wholesaler, 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 6 months 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 is a suspect or recalled product, as applicable, 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 distributor, 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—

(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 licensed or registered 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, shall data upon change of ownership between non-affiliated entities and for recalled product; and

(F) for investigation purposes only, and upon request by the Secretary, other appropriate Federal official, or State official, for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or immediate subsequent receipt of the suspect or recalled product, as applicable.

(2) VERIFICATION REQUIREMENTS.—Not later than 7/2 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 is a suspect or recalled product, as applicable, 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, or 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—

(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 licensed or registered 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, shall data upon change of ownership between non-affiliated entities and for recalled product; and

(F) for investigation purposes only, and upon request by the Secretary, other appropriate Federal official, or State official, for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or immediate subsequent receipt of the suspect or recalled product, as applicable.

(2) VERIFICATION REQUIREMENTS.—Not later than 7/2 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 is a suspect or recalled product, as applicable, 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, or 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—

(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 licensed or registered 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, shall 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.
“(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 benefit contained in other company regulations outweigh the cost of compliance with such requirements;

“(6) be scale-appropriate and practicable for entities of varying sizes and capabilities; and

“(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 that 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 the required information are required for compliance with this section.

“(1) Regulations and Guidance.—

“(1) 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.

“(2) Restrictions.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).

“(3) Small Entity Compliance Guide.—Not later than 160 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.

“(4) Limitations.—

“(A) Savings Clause.—Nothing in this subsection or the amendments made by this subtitle shall preempt any State or local law or regulation.

“(B) Subject 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 Professional Code section 10140.

“(5) 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 public comment in any State law regulating the distribution of drugs, whichever is later.

**SEC. 5566. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

“(a) Extension.—If the Secretary approves an application pursuant to section 5565 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (ii) and (iv) of subsection (j)(5)(F) of section 505, and the 1-year period described in section 527, as applicable, shall be extended by 5 years.

“(b) Relate 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 at any time before the date of receipt of each set of recommendations 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 drug that has been designated 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 for the drug to be a qualified infectious disease product.

“(d) Limitations.—Except as provided in paragraph (3), a designation under subsection (d) shall not be without reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

“(e) 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.

(2) REGULATIONS.—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) REQUIREMENTS.—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) ISSUANCE.—The Secretary may designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations implementing this section.

(f) QUALIFYING PATHOGEN.—

(1) DEFINITION.—In this section, the term ‘qualifying pathogen’ means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococci;

(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; and

(D) Clostridium difficile.

(2) LIST OF QUALIFYING PATHOGENS.—

(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens with the objective of developing the methodology for developing such list.

(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under subparagraph (A), the Secretary shall—

(i) consider—

(I) the impact on the public health due to drug-resistant organisms in humans; and

(II) the rate of growth of drug-resistant organisms in humans;

(ii) the increase in resistance rates in humans; and

(iii) the morbidity and mortality in humans; and

(iv) 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.—

(1) DEFINITION.—The term ‘qualified infectious disease product’ means—

(A) an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

(i) an antibacterial or antifungal resistent pathogen, including novel or emerging infectious pathogens; or

(ii) 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 in 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.

(1) AMENDMENT.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 521 the following:

"SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

‘‘(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—

‘‘(a) REVIEW AND PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

‘‘(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term ‘qualified infectious disease 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.

‘‘(2) THE SECRETARY.—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—

(i) new scientific and medical information and technology; and

(ii) 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 include—

(A) 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.

(B) RULE OF CONSTRUCTION.—Except to the extent to which the term 'clinical trials' 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 under subsection (a) may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes are 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, or identifying the 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 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; and

(2) assessing—

(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.
(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 pathways for, such products.

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 that address 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;

(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 such products, consistent with the information published under section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355E(g));

(4) the number of such qualified infectious disease products that have been approved or licensed on or after the date of enactment of this Act; and

(5) the number of calendar days it took for the development 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 PRODUCTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the "FDA") serves a critical role in helping to ensure that new medicines are safe and effective.

(B) Regulatory hurdles impede the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(C) The development of qualified infectious disease products and that have been approved or licensed on or after the date of enactment of this Act;

(D) The progress made toward the priorities identified under subsection (a)(2);

(E) 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;

(F) The number of qualified infectious disease products with information on the types of exclusivity granted for such products, consistent with the information published under section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355E(g));

(G) The number of such qualified infectious disease products that have been approved or licensed on or after the date of enactment of this Act; and

(H) The number of calendar days it took for the development of the qualified infectious disease products approved or licensed on or after the date of enactment of this Act.

Title X—Drug Approval and Patient Access

SEC. 1001. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL PRODUCTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the "FDA") serves a critical role in helping to ensure that new medicines are safe and effective.

(B) Regulatory hurdles impede the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(2) 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.

(C) A new generation of modern, targeted medicines is under development to target a broad range of serious or life-threatening diseases, some approved by using disease metrics based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(D) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more flexible requirements for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening disease or conditions or for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development process.

(E) 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.

(F) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for 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. 355e), as amended by this section, to help expedite the development and review of treatments for patients with a broad range of serious or life-threatening diseases or conditions.

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

(1) IN GENERAL.—

(A) ACCELERATED APPROVAL.—The Secretary may approve an application for accelerated approval using expedited procedures (as defined in section 505E(g) of the Federal Food, Drug, and Cosmetic Act) if the Secretary determines that the drug is reasonably likely to predict clinical benefit, on the basis of an early clinical endpoint that is reasonably likely to predict effectiveness standards for such treatments.

(B) LIMITATION.—Approval of a product under this subsection is subject to the following limitations:

(i) That the sponsor conduct appropriate post-approval studies to study the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(ii) That the sponsor submit copies of all preclinical materials used to support the product during the preapproval review period and, following approval, 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;
product fails to verify and describe such ef- ects or treatment.

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

‘‘(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 that a preclinical evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate the 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 extended under section 506(c)(4) of the Federal Food, Drug, and Cosmetic 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) Awareness Efforts.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of the 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.

‘‘(f) Development Program.—The Secretary 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:

‘‘(a) Designation of a Drug as a Breakthrough Therapy.—

‘‘(i) in general.—The Secretary shall, at the request of a 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 measures, such as substantial treatment effects observed early in clinical development.

‘‘(ii) 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 or section 351(a)(3) of the Public Health Service Act.

‘‘(3) Designation.—

‘‘(A) in general.—Not later than 60 cal- endar days after the date of enactment of this Act, the Secretary shall, after a public comment period, approve such regulations as are necessary to implement the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

‘‘(B) Amendments.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

‘‘(i) amending regulations to include the application; and

‘‘(ii) providing timely advice to, and interac- tion between the review team and the sponsor; and

‘‘(iii) involving senior managers and ex- perienced review staff, as appropriate, in a col- laborative, cross-disciplinary review; and

‘‘(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

‘‘(v) taking steps to ensure that the design of the clinical trials is as efficient as prac- tical, such as through the use of innovative trial designs 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”.

‘‘(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 Appropriations, 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 (re-ferred to in this section as the “Secretary”) shall issue final guidance and implement the amendments made by this section. The Secretary shall also consider such regulations not later than 2 years after the date of enact- ment of this Act.

‘‘(B) Procedure.—In amending regulations under this title, 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.

(11) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate these regulations using as a basis any amendments made by section only as described in clause (ii).

(12) 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 the 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall access the manner by which the Food and Drug Administration prescribed the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended, 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 506(c)(2)(A) 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 INHERITED DISEASES.

Subchapter E of chapter V (21 U.S.C. 360bb et seq.), as amended by section 712, is further amended by adding at the end:

“SEC. 506. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC INHERITED DISEASES.

“(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 minimum, for consultation 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 and approval of biological product and rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (c), with the appropriate 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 subsections (a) and (c), external experts are those individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

“(c) TOPIC SPECIFIC 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 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 pursuant to this subsection shall be considered special government employees, as defined under section 202 of title 18, United States Code.

“(e) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of 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 regulations and policies may apply 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 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 (hereafter referred to 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, organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacy organizations as determined by such group to develop best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(b) REQUIREMENTS.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to information on prescription drug container labels.

(b) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (a) may be made publicly available 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 altering any federal 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.

(d) ADMINISTRATIONS.—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 or large font “duplicate” labels that are affixed or matched to a prescription drug container; and

(iii) radio frequency identification tags;

(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 such best practices; and

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

(e) 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.

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

(g) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the date of section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Comptroller General of the United States shall submit to Congress a report on the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the extent to which pharmacies are utilizing such best practices. Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals continuing to face difficulties 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. In any rule prescribing a prescription drug container label means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispenses on the basis of a prescription.

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 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 PRIZE DESIGN.

(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 to assess 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 market of the medical technologies market as candidate targets for the new incentive system and consider different medical innovation inducement prize design issue, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) Marked 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.

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

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

(2) Whether the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(4) Whether a system of large innovation inducement prices would be more or less expensive than the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

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

(d) Analysis of the extent to which demographic data by demographic subgroups including sex, age, race, and ethnicity is readily available by means of the product labeling or the Food and Drug Administration’s Internet website.

(b) ACTION PLAN.—

(1) IN GENERAL.—Not later than 1 year after the publication of the report described in subsection (a), the 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 506(c) (21 U.S.C. 356c) is amended to read as follows:

“SEC. 506(c). 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) an emergency medical care or during surgery; and

“(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a replacement product, a product derived from human plasma protein, or any other product as designated by the Secretary, shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that could lead to a meaningful disruption to the supply of that drug in the United States.

“(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary not later than—

“(1) at least 6 months prior to the date of the discontinuance or interruption; or

“(2) 30 days prior to the date of the discontinuance or interruption; or

“(3) 15 days prior to the date of the discontinuance or interruption; or

“(4) 7 days prior to the date of the discontinuance or interruption; or

“(5) 3 days prior to the date of the discontinuance or interruption.”
force to develop and implement a strategic Drug Administration Safety and Innovation after the date of enactment of the Food and or prevent such drug shortage.

under section 505(j) that could help mitigate or prevent such shortage; or

an abbreviated new drug application submitted under section 505(j), or a sup-

tion 505(b), an abbreviated new drug applica-

Secretary may—

is, or is likely to be, a drug shortage of a

in subsection (a) or any other relevant infor-

impact of such shortage upon patients and

those risks associated with the violation in-

volved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

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 deter-

mination, 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.—The Secretary shall maintain records related to drug shortages, including with respect to each of the follow-

(1) The number of manufacturers that submitted a notification to the Secretary under subsection (a) in each calendar year. (B) The number of applications for which the Secretary expedited review under subsection (c)(1) in each calendar year. (C) A list of major actions taken by the Secretary to prevent or mitigate the drug shortages described in subparagraph (B). (D) A list of major actions taken by the Secretary to prevent or mitigate the drug shortages described in subparagraph (B). (ii) The Secretary shall include in the list under clause (i) the following:

(1) The number of notifications submitted to the Secretary under subsection (a) in each calendar year.

(2) 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 the drug.

(3) 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 the drug.

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

(3) ANNUAL SUMMARY.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt a final regulation implementing this section.

(4) INCLUSION OF BIOLOGICAL PRODUCTS.—

(A) In general.—The Secretary may by regulation implement 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 ex-

tent practicable, the Secretary may dis-
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, including 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, and any economic factors that have exacerbated or created a market for such actions.

(2) determine how regulations, guidances, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded in order to prevent or reduce 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 STOCKPILE FILING.—

(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, and the Inspector General, the Attorney General, and the Chairman of the Federal Trade Commission, shall publish a report reviewing any finding or determination under subsection (a) that have led market participants to stockpile affected drugs or sell them at significantly increased prices, the impact of such actions 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 sections 301 of title 15, the United States Code, or section 552(b)(4) of title 5, United States Code.

(e) GUIDANCE REGARDING REPACKAGING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance that clarifies the policy of the Food and Drug Administration and hospital pharmacies repackaging and safely transferring repackaged drugs among hospitals within a common health system during a drug shortage, and the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSION OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) IN GENERAL.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ‘‘2012’’ and inserting ‘‘2017’’.


SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(c) (21 U.S.C. 360bb-5(c)) 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 505A, applicable to such medical gas product has not expired.

(2) As used in this subchapter, ‘‘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.

(3) EFFECT OF CERTIFICATION.—

(A) The term ‘medical gas product’ means any of the following:

(i) APPROVED USES.—A designated medical 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:

(II) Oxygen for the treatment or prevention of hypoxemia or hypoxia.

(III) Nitrogen for use in hypoxic challenge testing.

(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 (i) or (ii) of section 505(c)(3)(H), under clause (i) of section 505(c)(5)(F), or under section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

(B) Any other medical gas product established in sections 503(b)(4) and 505(b) shall be deemed to have been met for a designated medical gas product if the labeling on final containers of such medical gas product bears the information required by section 503(b)(4) and a warning statement concerning the use of gas product, as determined by the Secretary by regulation, as well as appropriate directions and warnings concerning storage and handling.

(C) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

(i) EFFECT ON INELIGIBILITY.—No designated medical gas product deemed under paragraph (3) shall be deemed to have been granted unless, not later than 60 days after the filing of a request for certification under paragraph (1), the Secretary finds that—

(A) the medical gas product subject to the certification is not a designated medical gas product; or

(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.

(ii) EFFECT OF CERTIFICATION.—

(A) IN GENERAL.—A designated medical gas product for which a certification is granted under paragraph (2) is deemed, alone or in combination with any other designated medical 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:

(1) Oxygen for the treatment or prevention of hypoxemia or hypoxia.

(2) 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 (i) or (ii) of section 505(c)(3)(H), under clause (i) of section 505(c)(5)(F), or under section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

(2) Amending section 505A—

(a) Addition of a new subsection—


(c)(1) be manufactured; and

(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) 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 sections 301 of title 15, the United States Code, or section 552(b)(4) of title 5, United States Code.
to withdraw or suspend approval of a drug, including a designated medical gas product deemed under this section to have in effect an approved application, under section 505 or section 512.

"(B) REVOCATION.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the requirements of this section or the certification contains any material omission or falsification.

"(ii) PRESCRIPTION REQUIREMENT.—

"(A) IN GENERAL.—A designated medical gas product shall be subject to section 503(b)(4) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such gas product from the requirements of section 503(b)(4). Such action is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

"(B) 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.

"(C) 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.

"(ii)visions of drugs to designated medical gas products.—A designated medical gas product deemed under this section to have in effect an approved application shall be exempt from the provisions of title 21, Code of Federal Regulations that the Secretary determines to be unnecessary.

"(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.

(a) In General.—Nothing in this subtitle or the amendments made by this subtitle shall apply to—

(i) 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;

(ii) any of the cases 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 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) was approved on May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

b. 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, to the left;

(ii) in subparagraph (A), as so redesignated, 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 paragraph (2) (as so redesignated), in the matter before subparagraph (A) (as so redesignated), by striking subparagraph (A)” and inserting “(1) RERECUITMENT IN GENERAL.—The Secretary shall—”;

(iv) by striking “(1) RERECUITMENT 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.”;

(b) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination made under paragraph (B) considers the type, nature, and magnitude of the financial interest in having the expertise of the member with respect to the particular matter before the advisory committee.

(c) in subsection (c) by inserting “, and shall make publicly available,” after “House of Representatives”; and

(d) by adding at the end the following:

"(g) GUIDANCE CONTENTS.—In the guidance documents, such information shall include—

(i) how best to leverage and build upon existing Federal and federally funded data sources to provide prescription drug monitoring program data and the sentinel initiatives of the Food and Drug Administration under section 566(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)) and any other Federal, State, or local database, as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data warehouse and early warning tool.

(ii) 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

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participation, producing standardized data on adverse events, patient safety, and patient outcomes; and
(3) how best to develop provider, pharmacy, and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON ABUSE-DIFFERENTIATED PRODUCTS.—Not later than 16 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of abuse-differentiated products.

(d) STUDY AND REPORT ON PRESCRIPTION DRUG ABUSE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements 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. 1125. TANNING BED LABELING.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 503, 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 a 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 biological product, as defined in subsection (d) of section 351(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), or a device, as defined in subsection (k) of section 201, a biological product, as defined in subsection (d) of section 351(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), or a device, as defined in subsection (k) of section 201, a medical product, as defined in section 553 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 this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, as part of the data submitted by the applicant if the Secretary finds that the 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 of the United States, including in the European Union, are inadequate for the purpose of making a finding of 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 to advance 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 programs under the Prescription Drug User Fee Act, the Generic Drug User Fee Act, the Medical Device User Fee Act, and the Biosimilar User Fee Act, and shall be conducted in coordination 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 uniform, scientifically-driven clinical trial standards with respect to medical products around the world; and shall—

"(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisionmaking 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 to 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 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 specific decision that impede advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner;

"(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science as described in paragraph (4) are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

"(A) development, updating, and consistent application of guidance documents that support regulatory science in drug and device development and approval;

"(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 738B(a) (as amended by section 104), 738A(a) (as amended by section 204), 744C(a) (as added by section 303), and 744E(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 in advancing 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 described 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, and the Bio-similar User Fee Agreement commitment letter, and the Bio-similar User Fee Agreement commitment letter, and the Bio-

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 goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures,

"(B) the efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information about each system, including its system function or purpose, status information, and incorporating the 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 an explanation of 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 the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines.
(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.
(3) the development and implementation of a 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 strategy plan described in subsection (a)(1)(A), including the results-oriented goals and performance measures; and
(3) extent to which the Food and Drug Administration has fulfilled its 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 206, 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 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:
"(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 new drug under section 505(a), amendments to such applications, and priority approval supplements with respect to such applications filed in the previous fiscal year, including 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 priority 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.
"(b) BIOSIMILAR BIOTECHNOLOGICAL 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 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:
"(A) 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 Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;
"(B) the percentage of such applications that were approved; and
"(C) the percentage of such applications that were issued complete response letters; or
"(D) the percentage of such applications that were subject to a refuse-to-file action; and
"(E) the percentage of such applications that were withdrawn; and
"(2) 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.

SEC. 1130. STRATEGIC INTEGRATED MANAGE
MENT PLAN.
(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, 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:
(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 attract, retain, train, and convert to 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 the effectiveness of the measures identified in paragraph (a)(3) in gauging progress against the strategic goals and priorities identified under subsection (a)(1); and
(4) the total 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:
"(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 noti-
ce.

"(2) WRITTEN NOTICE.—For purposes of this subsection, the Secretary shall, within a reason-
able time after the holder of an application submits to the Secretary a written notice to authorize the supply of a drug for purposes of testing, 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 the drug 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.

"(C) the eligible drug developer is in compliance with all applicable laws and regulations related to such testing, including any applicable laws and regulations related to investigational New Drug Applications or informed consent.

"(3) ADDITIONAL REQUIRED ELEMENT.—The Secretary shall require as an element of each risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, received on 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 pur-
poses of this subsection, the term "eligible drug developer" means a person, or a group of persons, 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 for the drug for which the 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 sub-
section (b)(2), for purposes of this subsection, the term "covered drug" means a drug, in-
cluding a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, received on 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 pur-
poses of this subsection, the term "eligible drug developer" means a person, or a group of persons, 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 for the drug for which the written notice pursuant to paragraph (2), and will use the covered drug only for the purpose of conducting testing to support such an application.

"(C) the eligible drug developer is in com-
pliance with all applicable laws and regulations related to such testing, including any applicable laws and regulations related to investigational New Drug Applications or informed consent.

"(4) VIOLATION AND PENALTIES.—For pur-
poses of subsection (f)(8) and sections 391, 303(i)(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, and the holder of an application for a covered drug shall not restrict the sale 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 no-
tice to the holder of the application direct-
ing otherwise based on a shortage of such drug for patients, national security concerns related to access to such drug, or such other reason as the Secretary may specify.

"(5) LIABILITY.—Unless the holder of the ap-
pliance the holder of an application for a covered drug is in compliance with the terms of the written notice as provided in paragraph (2), or in the case of a holder of an application that is a sole dis-
tribution, the holder of an application for a covered drug has restricted the sale of such a covered drug to any eligible drug developer after re-
cept of a written notice as provided in para-
graph (2).

"(6) CERTIFICATION.—In any request for

Supplemental E of chapter V (21 U.S.C. 360bb et seq.), as amended by section 1126, is fur-
ther amended by adding at the end the fol-
lowing:

"SEC. 1126. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

"(a) IN GENERAL.—The Secretary shall de-
velop and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Com-
mence of the House of Representatives with-
in 30 days of the date on which the Secretary becomes aware that a holder of an application for a covered drug has restricted the sale of such a covered drug to any eligible drug developer after re-
cept of a written notice as provided in para-
graph (2).

"(b) TECHNICAL AND CONFORMING AMEND-
MENTS.—

"(1) Section 506-1(b) (21 U.S.C. 351-1(c)(2)) is amend-
ed by striking "(e) and (f)" and in-
serting "(e), (f), and (k)".3

"(2) Section 502(y) (21 U.S.C. 352(y)) is amendent by striking "(d), (e), or (f) of sec-
tion 506-1" and inserting "(d), (e), (f), or (k) of section 505-1".

"SEC. 1127. 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 with the Committee on Agriculture, Nutrition, and Forestry, shall establish within the Food and Drug Ad-
mistration 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 that are admin-
istered by the Food and Drug Administra-
tion, to address issues relevant to the regula-
tion of those products, including the poten-
tial toxicity 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) Promoting and disseminating scientific and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Ad-
mistration;

"(2) In cooperation with other Federal agencies, developing and organizing informa-
tion for use in databases and models that will fac-
ilitate the identification of potential hazards and effects, consistent with principles and characteristics regarding the behavior of classes of nanomaterials with bi-
ological systems;

"(3) Promoting Food and Drug Administra-
tion programs and participate in collabora-
tive efforts, to further the understanding of the science of nanomaterials that might contribute to toxicity;

"(4) Promoting and participating in collab-
orative efforts to further the under-
standing of the science of nanomaterials that might contribute to toxicity;

"(5) Collecting, synthesizing, interpreting, and disseminating scientific information and data related to the interactions of nano-
materials with biological systems;

"(6) Building scientific expertise on nano-
materials within the Food and Drug Admini-
stration, including the development of expert-
pise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act, including as a result of new information dissemination of new information within the centers of the Food and Drug Administra-
tion, and more broadly across the Food and Drug Administration, to ensure timely, in-
formed consideration of the most current science pertaining to nanomaterials;

"(7) Building scientific expertise on nano-
materials within the Food and Drug Admini-
ration, including the development of expert-
pise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act, including as a result of new information dissemination of new information within the centers of the Food and Drug Administra-
tion, and more broadly across the Food and Drug Administration, to ensure timely, in-
formed consideration of the most current science pertaining to nanomaterials;

"(8) Developing and disseminating public education and training efforts, to further the under-
standing of the science of nanomaterials that might contribute to toxicity;
‘‘(B) coordinating and integrating the strategic plan with activities of the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative; and
‘‘(C) developing Food and Drug Administration programs, contracts, memoranda of agreement, joint funding agreements, and other cooperative arrangements necessary for meeting the long-term challenges and achieving the specific technical goals of the program.’’

(d) REPORT.—Not later than March 15, 2015, the Secretary shall publish on the Internet Web site of the Food and Drug Administration a report on the program carried out under this section. Such report shall include—
‘‘(1) a review of the specific short- and long-term goals of the program;
‘‘(2) an assessment of current and proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities;
‘‘(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.
‘‘(e) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary under any other provision of this Act or other statutes administered by the Food and Drug Administration.’’.

(b) EFFECTIVE DATE; SUNSET.—The Nano-technology Coordinating Committee is authorized under section 1031 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later. Such Program shall cease to be effective October 1, 2017.

SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes any problems posed by pharmacy Internet websites that violate Federal or State law, including—

(1) the methods by which Internet websites are used to sell prescription drugs in violation of Federal or State law or established industry standards;

(2) the health and safety effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet websites;

(3) acts by the Federal Government and State and local governments to investigate and prosecute the owners or operators of pharmacy Internet websites, to address the threats such websites pose, and to protect patients;

(4) the level of success that Federal, State, and local governments have experienced in investigating and prosecute the owners and operators of pharmacy Internet websites;

(5) the level of success that Federal, State, and local governments have experienced in investigating and prosecuting the owners or operators of pharmacy Internet websites;

(6) any other relevant information;

(7) laws, policies, and activities that would educate consumers about how to distinguish pharmacy websites that comply with Federal and State laws and established industry standards from those pharmacy Internet websites that do not comply with such laws and policies; 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 issue a report on the coordination and implementation of the Department of Health and Human Services related to the prevention of medication and device errors, including considerations for the design of interventions that address the pediatric patient population. In developing initiatives to address medication and device errors, the Secretary shall coordinate with the Food and Drug Administration’s efforts to prevent medication and device errors, in the clinical setting and consult with relevant stakeholders on effec- tive approaches to detect and prevent medication and device errors in the clinical setting.

SEC. 1136. COMPLIANCE PROVISION.

The budgetary effects of this Act, for the purposes of 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 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 of this Act.

SEC. 1137. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR TARGETED POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL MINORITY POPULATIONS

(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 the public on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) REQUIREMENTS.—The communication plan described in subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic 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 to the extent available information is 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; and

(C) the effects of medication and device errors, including considerations for the design of interventions that address medication and device errors in the clinical setting.

(2) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(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 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.

(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 Small Business Prevent Drug User Fee Act, 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 clinical trial of drugs for rare diseases and disorders;

(3) 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. 379 et seq.).

(4) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(5) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(6) barriers small businesses encounter in the drug and medical device approval process; and

(7) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SEC. 1139. PROTECTIONS FOR THE COMMISIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 103(a)(24) of the Public Health Service Act (42 U.S.C. 201a(a)) is amended by adding at the end the following:

‘‘(18) Section 103(c), Protected Communications; Prevention of Retaliatory Personnel Actions.’’.

(b) CONFORMING AMENDMENT.—Section 223(b) of the Public Health Service Act (42 U.S.C. 201a(b)) is amended by adding at the end the following: ‘‘For purposes of paragraph (18) of subsection (a), the term ‘Inspector General’ in section 103(c) shall mean the Inspector General of the Department of Health and Human Services.’’.

SEC. 1140. REGULATIONS ON CLINICAL TRIAL REGISTRATION.

(a) DEFINITIONS.—In this section—

(1) the term ‘‘applicable clinical trial’’ has the meaning given such term under section 402(j); and

(2) the term ‘‘Director’’ means the Director of the National Institutes of Health.

(b) REQUIRED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall issue rules to implement this section.

(c) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall issue rules to implement this section.

May 24, 2012
Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j).

2 Equally, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue a notice of proposed rulemaking under paragraph (4), and the Controller 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 I(d) in section 292(c) (21 U.S.C. 812(c)), by—

(A) in paragraphs (3) and (4); and

(B) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively; and

2 in section 280(d) (21 U.S.C. 812(b)), by adding at the end the following:

"(F) In the case of any material, compound, mixture, or preparation containing—

1 not more than 20 milligrams of dihydromorphine 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

2 not more than 300 milligrams of dihydromorphine per 100 milliliters or not more than one and one-half times the dosage of an opioid, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts, paragraph (C) shall not apply and such compound, mixture, or preparation shall be considered Schedule II in accordance with 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 such rule shall not later than—

1 December 17, 2013, for products subject to such rule with annual sales of less than $25,000, and

2 December 17, 2012, for all other products subject to such rule.

SEC. 1142A. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(A) IN GENERAL.—The Attorney General and the Secretary of Health and Human Services shall require 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 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 3390 of the Public Health Service Act (42 U.S.C. 284–3).

(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 standards for prescription drug monitoring programs under subsection (a)—

1 the use of unique identifiers, or hubs, as necessary to facilitate interoperability by accommodating State-to-State interoperability

2 the support of transmissions that are facilitated by telecommunications; and

3 the use of electronic prescriptions that are fully secured as required, using industry standard methods of encryption, to ensure the protection of prescription sensitive information and Personally Identifiable Information are not compromised at any point during such transmission.

(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 Energy and Commerce of the House of Representaives a report on the implementation of the registration and reporting requirements for applicable drug and device clinical trials under section 402(j) for applicable drug and device clinical trials conducted within applicable clinical trial sites, and such other categories as the Attorney General determines useful (with the requirements of—

1 registering applicable clinical trials under such section 402(j);

2 reporting the results of such trials under such section; and

3 the completeness of the reporting of the required data under such section; and

3 the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section; and

2) In paragraph (1):—

(A) the term ‘‘cannabinimimetic 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:

1 2-(3-(hydroxycyclohexyl)phenyl) with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, benzyl, methyl, ethyl, or further substituted on the cyclohexyl ring to any extent;

2 3-(1-naphthyl)indenol or 3-(1-naphthylmethyl)indenol by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthyl or naphthyl ring to any extent;

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

4 1-(naphthylmethylene)indenol 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;

5 3-phenylacetylindenol or 3-benzoylindenol 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—

1 5-(1,1-dimethylheptyl)-2-(1H,3)3-hydroxycyclohexyl-phenol (CP–47,497) (cannabicyclol);

2 5-(1,1-dimethylheptyl)-2-(1H,3)3-hydroxycyclohexyl-phenol (cannabicyclohexanol); and

3 1-pentyl-3-(1-naphthyl)indenol (JWH–018 and AM678);
Mr. REID. Madam President, I move to reconsider the vote and move to state 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 feedback of the working groups throughout the past year. The Bipartisan Working Groups have contributed significantly to this process.

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;

Deidre Fruh—Casey; Andrew Hu—Klobuchar;

Hannah Katch, Whitney Brown—Franken; Jennifer DeAngelo—Whitehouse;

Sophie Kastmow—Sanders; Rohini Kosoglu, Sally Mayes—Bennett;

Susan Lexen—Merkley; Joshua Teitelbaum—Hagan;

Sandra Wilkins—Bingaman; Jennifer Boyer—Roberts;

Hayden Rhudy—Hatch; MarySumpter Lipinski—Alexander;

Christopher Bowlin—McCain;

Anna Abram, Margaret Coulter—Burr; Anna Owalt—Corker;

Amanda Makki—Murkowski. GENERATING ANTHOCYANIN INCENTIVES

NOW

Rohini Kosoglu—Bennett;

Joshua Teitelbaum—Hagan;

Sandra Wilkins—Bingaman; Matt Prowler, Deidre 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;

Deidre Fruh, Matt Prowler—Casey;

Hannah Katch, Whitney Brown—Franken;

Sophie Kastmow—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 DeAngelo, Justin Florence—Whitehouse;

Anna Abram—Burr;

Erika Smith—Grassley;

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.

Mr. HARKIN. 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.

Concealed weapons violations involving drugs meant to be accessed by patients with no prescription are a growing concern.