gallon standard of 25 miles today to 35 miles in a 10-year period, this would unquestionably be a great accomplishment.

Attached to this legislation is also very important consumer protection legislation that provides the Federal Trade Commission the tools it needs to protect consumers against price gouging. With our current statutes, the FTC has the ability to investigate certain cases on the basis of antitrust laws, which are based on whether we think the companies are colluding to set prices. What we really have to question is whether the companies may be conducting activities that actually take supply offline and thereby decrease the supply, leading to shortages at the pump. Therefore we need to give the FTC the authority it needs through this legislation and make sure consumers are protected.

This legislation, as part of a package, was passed unanimously out of the Commerce, Science, and Transportation Committee yesterday. It was the result of a bipartisan effort, led by the work of the chairman, Senator INOUYE, and the ranking member, Senator STEVENS. Unfortunately certain provision did not make it into the final version of this bill, however I firmly believe that it is a historic and important piece of bipartisan legislation that will come to the Senate floor for all of us to discuss.

Just recently, the Energy and Natural Resources Committee passed another very positive landmark legislation which relates to setting a higher mandate on biofuels. In the last Energy bill we were able to pass, we stipulated that we should have a goal of producing 7 1/2 billion gallons of biofuel a year by 2012. Both the President and the Congress are trying to achieve a higher goal. In this legislation, that sets the goal that by 2022, we would actually have a mandate of having 36 billion gallons of alternative fuel produced in this country. I firmly believe that this is a realistic goal and an achievable mandate for us, and that it will aid in starting mass-production of alternative fuels in this country.

In addition, that legislation had money for what we call a biofuels infrastructure—how we do actually get this product out to the consumer and to the corridors of transportation so the public does not have to worry about whether they can fill up their cars. Thanks in part to this legislation we will have the infrastructure to do that.

In the Commerce Committee, we also produced legislation focusing on flex-fuel cars so that, by 2015, 80 percent of the cars being driven on our roads will be flex-fueled. These are vehicles that could either use gasoline or an alternative fuel.

We have also passed legislation now for studying plug-in hybrids and making sure the plug-in hybrid research continues to move ahead.

In the Energy bill, we also included language about carbon sequestration, making sure we move ahead so carbon sequestration becomes a reality. Again, this is an important issue and it is a very important bill to my colleagues in various parts of the country in which we have an ample supply of coal. I commend Senators Domenici and BINGAMAN for working so closely together. That legislation also was passed in a bipartisan effort. It is a great compliment to those two distinguished Senators who worked so closely on the last Energy bill to pass the Energy bill.

We are in a position to make a very positive impact on what I think is one of the biggest challenges we face, getting off our overdependence on foreign oil and providing sources of cleaner energy. We are well poised to take up that debate here on the Senate floor with this landmark bipartisan legislation out of two different committees.

We will have a lot of work to do across the aisle. We still have great opportunities to see legislation out of those other four committees I mentioned that will contribute to this energy package. But we should embrace the opportunity the President laid out in his State of the Union Address when he said that if we could ensure we had a higher fuel efficiency standard and that we also set a higher renewable fuel standard, and that is exactly what we are doing now.

I personally think we should also set a renewable standard for the amount of electricity we use from our electricity grid to further reduce our dependence on fossil fuel. These are topics that will be debated. I am sure later in the year we will have an important debate about climate change. But for now we are making great progress. I hope my colleagues will focus on the fact that this energy bill gives us another opportunity to work together here on the Senate floor and put real energy solutions before the American public.

Right now, with gas prices reaching $1, Americans want to know we are going to have an aggressive policy, not only giving them consumer protections but better planning for the future so our economy can benefit from alternative sources of fuel.

I yield the floor.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will now read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Brown (for Grassley) amendment No. 1039, to clarify the authority of the Office of Surveillrance and Epidemiology with respect to postmarket drug safety pursuant to recommendations by the Institute of Medicine.

Brown (for Grassley) amendment No. 996, to provide for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies.

Brown (for Durbin/Bingaman) amendment No. 987 to reduce conflict of interest in FDA Advisory Panels.

The PRESIDING OFFICER. Under the previous order, there will be 60 minutes for debate currently on the bill and remaining amendments, with an equal amount of time for the Senator from Iowa, Mr. GRASSLEY or his designee, 5 minutes under the control of the Senator from Illinois, Mr. DURBEN or his designee, and the remaining time equally divided between the chairman and ranking member or their designees.

The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I yield myself 6 minutes of our time.

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

Mr. KENNEDY. Madam President, we will see later this morning the successful conclusion of this legislation. We have many important matters to consider, which we will do in a very short period of time. But as we are coming into the closing time for this amendment, I think it is appropriate that we review very quickly what this legislation does and what it does not.

I am a strong believer in this legislation, which has strong bipartisan support. I am enormously grateful to Senator ENZI and Members on our side of the aisle as well as those on the other side for all of their help and assistance in getting us to the point where we are ready to take final action on something that makes a major difference to families in America. We ensure the safety of our prescription drug system and also are making very important progress in the safety of our food supply.

This is, in an important way, break-through legislation. I will review quickly what this does and then come back to the amendments that are before the Senate and how we think the Senate should dispose of them; why this legislation is urgent, why it is extremely important, and why the American people deserve the best.

Very quickly, again, there is strong emphasis on safer medicines for families in this country. We spelled out at the earlier part of our presentations the effective systems we have supported to make sure we are going to have the safest prescription drug program in the world, using different kinds of modern technologies and also modern surveillance systems for monitoring postmarketing safety. This will ensure in the future we are going to have the safest prescription drug program in the world. We will have safer medicines for families and pets. I think all Americans have been alarmed, as they should have.
been, by what has been reported in the news in the last few weeks. Many families have lost their pets because the agency lacked the authorities provided in this bill.

We will have earlier warnings on drugs that present the potential for unacceptable reactions or adverse effects. This approach represents an extremely important step forward. We are enormously impressed with the excellent work that has been done by Senator Dodd and appreciative of the excellent work that has never been done before.

We are going to have better medicines for children. We are enormously appreciative of the excellent work that has been done by Senator Dodd and Senator Clinton. This was done in a bipartisan way with Senator DeWine, who is not here. We all realize that children are not little people; children are children, and therefore their bodies react differently to various kinds of preservatives. This legislation provides mechanisms to get information on safe and effective use of medications in children as well as to promote studies of drugs in pediatric populations. In the past few years, we have made extraordinary progress and we believe this legislation will help to an even greater extent.

We are going to have more transparency and stronger science at the FDA because of the wonderful work done by Dr. Ben Helfand and others worked to assure that we have greater awareness by the public of what is happening at the agency.

There is greater focus and attention on making sure the agency is going to have the best in terms of the new sciences. We are in the life science century at the present time. This has been impressed on the country with the extraordinary convention on biosciences that took place in Boston in the last few days. There I listened and read about the potential the life sciences have, not only in terms of energy and agriculture but also in terms of medicines. The United States is absolutely poised to continue to be the world leader in these fields, with all of its implications of healthier families here and around the world.

We need to make sure we are going to have the best kind of science at the FDA. We do that in the way we have given priority over the last 10 years to the implementation of the science function at FDA. We also provided a rather unique foundation that will be able to use public and private funding. This foundation will seek out the best and the newest modalities to help speed the review of various prescription drugs. That is going to be enormously important because time means cost. If we are able to resolve these issues more quickly the costs will be more understandable and reasonable to consumers and we will get the faster and cheaper drugs.

Briefly to comment on some of the amendments, we have taken a position in our proposal that both the safety and efficacy of particular prescription drugs is a function that ought to be considered in tandem. I know there are those who think we ought to separate those functions. We can imagine a circumstance, for example, where the side reaction of a particular drug is that individuals simply become nauseated. Clearly I am describing the impact of methotrexate. That can happen to an individual on many anticancer drugs. You would not prescribe that for athlete’s foot because it is too dramatic, but you would approve that for another kind of regime to try to treat cancer.

We also have items on civil penalties for the first time. There is a question of what those civil penalties should be. I want them to be higher, but I am mindful as well that this is the first time we are going to have those civil penalties. We are going to be working on those matters with the House. I basically think they should be a little higher than anticipated so that there is some leverage on this issue and we are going to try to make sure we get something that is going to be fair and can do the job.

I am also mindful of the concern we have in terms of the potential of conflicts of interest. I am going to use my time to deal with this issue. This is a very important issue. We want to make sure, on the one hand, as we have these breakthroughs in science, that we are going to have the best experts participating in these review groups. We also have to be sensitive to the issues of conflicts of interests. I know the Senator from Illinois has a proposal on this.

I will reserve the rest of my time to be able to discuss that later.

Elements to Assure Safe Use

Ms. Murkowski. Madam President, I rise to engage in a colloquy with the Senator from Wyoming and ranking member of the Senate Health, Education, Labor, and Pensions Committee, Senator Enzi.

First, I would like to thank the chairman and the ranking member of theHELP Committee for their efforts to address the issue of access to health care in frontier areas. Much of Alaska is a frontier area and it is not an easy task to access health care in general, let alone find a specialist to obtain needed medications.

Toward that end, I am pleased that the bill the provider may recognize the problem of access and provides a willing provider in a frontier area with the ability to receive the training and certification necessary to prescribe a drug that has potential serious risks. For clarification purposes, I would like to ask the Senator from Wyoming if it is the intent of Congress that section 202 of S. 1082, the FDA Revitalization Act, allows all physician and nonphysician health care providers in frontier areas to be able to receive “training or certification necessary to prescribe or dispense a particular drug without the need for an additional degree or medical specialty?”

Mr. Enzi. Yes, this is the intent.

Ms. Murkowski. And under the provisions of section 202, would the willing health care provider be able to receive this training or certification through remote learning methods so that a provider would not need to travel to distant areas in order to get the requisite training?

Mr. Enzi. Yes. The language in the bill recognizes that travel in frontier areas, particularly in remote places where Alaska, can be time consuming and expensive, so it specifically notes that the training or certification should be available in a widely available training or certification method, such as an online course or through the mail. This is intended to reduce the amount of travel and expense a willing provider in a frontier area must undertake in order to be able to prescribe or dispense needed medicines to their patients.

Ms. Murkowski. I appreciate the Senator. And since the provider would not be required to obtain a professional degree or medical specialty, and the training or certification would hopefully be through an online course or through the mail, is there any indication of how long such training would take so that a provider is sufficiently trained to prescribe a specific drug?

Mr. Enzi. While I cannot give the Senator a guaranteed time frame, I would point out that the training and certification necessary to prescribe the drug the provider is seeking to prescribe or dispense—may be unavailable for a range of drugs. Thus, the time frame should not be a lengthy one, particularly if the training can be conducted online.

Ms. Murkowski. Now, I understand that many physicians around the country are invited to attend conferences or training seminars in order to be certified to prescribe certain drugs. Given the low volume of the high risk drugs—many anticancer drugs—you wouldn’t be required to attend a lengthy seminar. Is there any indication of how long such training would take in order to be able to prescribe or dispense needed medicines to their patients?

Mr. Enzi. Yes. This is the intent.
American has access to prescription drugs regardless of whether they live in a large urban city like New York, or a frontier community like Bethel, AK. I believe that with the modifications that have been made to this bill, we will take a step in the right direction. I believe that the changes that have been made to this bill, as proposed by Senator KENNEDY and ENZI, will make the bill more acceptable to the House. I appreciate the willingness of Senators KENNEDY and ENZI to listen to my concerns and take action to address them. Many of the changes I requested are included in the final product that we have just sent to the House.

Mr. COBURN. Madam President, I appreciate the attention to drug safety on the part of Senators KENNEDY and ENZI. The drug safety problems our nation experienced surrounding Vioxx and the SSRIs demanded that we take a serious look at the FDA. I appreciate the hundreds and hundreds of staff hours that have gone into working on this legislation both before and after the HELP Committee markup.

When the Health, Education, Labor, and Pensions Committee marked up this legislation, I strongly opposed it. I appreciated the willingness of Senators KENNEDY and ENZI to listen to my concerns and take action to address them. Many of the changes I requested are included in the final product that we vote on today.

This bill comes a very long way since its consideration in the HELP Committee. Instead of requiring a risk evaluation and mitigation strategy, REMS, for every drug, a REMS may
from Colorado, Senator ALLARD, for the floor debate we had on BPCA, I want to assure him and those that voted for his amendment that this bill is about increasing pediatric clinical trials and improving our knowledge on products being used in children where previously we have lacked information. BPCA is and has always been about striking an appropriate balance between the cost to consumers and benefits to children.

Ten years ago when Senator Mike DeWine and I undertook this effort, only 11 drugs on the market that were being used in children had actually been tested and studied for their use. Prior to the enactment of BPCA 10 years ago, pediatricians were essentially flying blind because they lacked information regarding the safety and effectiveness of drugs they were prescribing for children. But it was children who suffered the most from taking drugs where so little was known about their effects.

What we have learned over the past 10 years of experience is that children have been exposed to ineffective drugs, ineffective dosing, overdosage, or side effects from drugs that were previously thought to be safe and harmless. In 10 years, the number of studies involving more than 45,000 children in clinical trials have been completed. Useful new pediatric information is now part of product labeling for more than 119 drugs. In sum, there has been a twentyfold increase in the number of drugs studied in infants, children, and adolescents as a result of BPCA since its enactment.

Children with a wide range of diseases such as HIV/AIDS, cancer, allergies, asthma, neurological and psychiatric disorders, and obesity can now lead healthier, more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases where previously there was none.

This successful program for children will expire on September 30 unless we act to reauthorize it. The reauthorization of BPCA contained within S. 1082, makes several important improvements to this program which I have spent many months developing. It is my belief that these improvements will help ensure that this program continues to thrive well into the future. I strongly support the reauthorization of BPCA so that we can closely monitor how the program is working and make improvements as they are needed in the future.

S. 1082 will increase the amount and quality of pediatric information by streamlining BPCA and PREA at the Food and Drug Administration, FDA, and ensuring that labeling changes as a result of BPCA are communicated to physicians. S. 1082 will improve transparency and accountability by making market exclusivity determinations and requests for pediatric studies public within 30 days of exclusivity being awarded. It also will improve the accuracy and speed of labeling changes.
by requiring such changes to be made within the FDA’s timeline and ensuring that labeling reflects the results of the BPCA study that was conducted. S. 1062 will ensure that BPCA continues to yield more and better drug studies in children, while addressing the minority of cases where the cumulative 6 months additional market exclusivity has far exceeded the “carrot” it was intended to provide to drug sponsors. It improves market certainty by not requiring an additional 3 years of market exclusivity to be granted within nine months of the end of the drug’s patent and increases data about the use and applicability of BPCA through reports conducted by the Institute of Medicine, IOM, and the Government Accountability Office to review the program and assess the impact of the changes made within the legislation.

BPCA has shown us that it is unsafe to simply treat children as smaller versions of adults. Children face a similar impact with respect to medical devices. Far too few medical devices are specifically designed for children’s small and growing bodies. Experts say that the development of children’s medical devices lags 5 to 10 years behind that of adult versions. That is largely due to the limited size of the market for pediatric devices.

When a medical device suitable for a child is needed to save that child’s life but it does not exist, doctors are often forced to use an adult version of the device or, in some cases, perform a riskier surgery on the child. Ventilator masks, for instance, are far too large to fit over a baby’s mouth. Often, the only alternative is to run an invasive tube down the baby’s throat.

Because of what we witnessed over the past ten years with the market incentives provided under BPCA, I introduced an initiative called the Pediatric Medical Device Safety and Improvement Act to create similar incentives for device manufacturers. This legislation also streamlines the approval process for cutting-edge technology and establishes grants for matchmaking between inventors and manufacturers and the Federal Government.

Balancing incentives with safety, the legislation closely mirrors recommendations made by the IOM in its 2005 report on pediatric medical device safety to improve the serious flaws in the current safety framework for these devices. Specifically, the IOM called for and the legislation allows the FDA to require postmarket studies as a condition of clearance or approval for certain categories of devices and it gives the FDA the ability to require studies longer than 3 years once the device is on the market with respect to a device that is to have significant use in pediatric populations if such studies would be necessary to address longer term pediatric questions, such as the impact on growth and development.

Some in the medical device industry continue to offer proposals to chip away at the authorities in the legislation intended to ensure the FDA can request manufacturers to conduct postmarket safety surveillances and ensure devices used in children are safe. I am disheartened by anyone who would attempt to deprive children and physicians of information that pertains to devices that could either help or harm their patients to weaken the postmarket safety standards contained within the legislation as the bill heads to conference.

The fast lane can get new, safe pedi atric devices to market, the fewer parents have to stake their children’s lives on improvisation and guesswork.

I have previously mentioned the broad-ranging support for these important initiatives for children but it is worth restating that the level of support from pediatrics, patient advocacy organizations, drug and device companies, and many others indicates that this important legislation will greatly benefit children and their families.

I want to thank the tremendous work of the staff on this bill. They have devoted countless hours and many week ends to working on this legislation. Specifically, I want to thank David Dilworth, David Dumbrille, Mark Del Monte, Jesse Bowden, Senator Kennedy and Shana Chirustrop, Keith Flanagan and Amy Muhlb erg with Senator Enzi who worked so closely with my office on the pediatrics initiatives in title IV of this legislation. I also want to thank the FDA and Senator Enzi’s staff and Exper iment 1999 and Kevin Hulshak and Exper iment 1999 whose terrific leadership helped guide this legislation to passage.

I also want to acknowledge the leadership of the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation whose staff, Mark Del Monte, Jeanne Ireland and Elaine Vining, have provided tremendous technical assistance on the pediatrics initiatives in S. 1082.

Before I close I want to address the other provision in this legislation which reauthorizes vital user fee programs at the FDA for drugs and devices and addresses the important issue of drug safety at the FDA, an agency that regulates 25 percent of the products consumed by Americans. In recent years, we have witnessed a public crisis of confidence in the FDA’s ability to ensure that the drugs taken by millions of Americans are safe and effective.

Since the Vioxx scandal that would have given FDA’s office of postmarket drug surveillance the independence, stature and funding to take action when a safety problem arises. We reintroduced the bill this congress with several colleagues withing the HELP Committee, including Senators MIKULSKI and BINGMAN and I thank them for their support. While I do not agree with some of my colleagues who have argued that this authority would create a bigger bureaucracy at the FDA, the experience showed us that the support to move such a proposal simply wasn’t there.

However, I believe that my colleagues and I were able to make significant improvements to S. 1082 with respect to drug safety. I believe those improvements will strengthen science at the FDA, improve transparency of decisionmaking so that dissenting views can be heard, and improve safety oversight once they are on the market.

The drug safety and clinical trials components of S. 1082 are by no means perfect. In fact, I have serious concerns about what I view as inadequate enforcement authority in the bill and am particularly concerned about whether the bill will prevent companies from withholding information about clinical trials which were negative or were trials that companies abandoned because initial results were negative. As opposed to Vioxx, the FDA has made inappropriately injected themselves into FDA determinations or actions.

The same study also found that 378

FDA scientists disagreed or strongly disagreed that the FDA is acting effectively to protect public health. With Vioxx, antidepressants in children, and now Ketek, the FDA has repeatedly been accused of suppressing internal safety concerns and ignoring repeated warnings of serious concerns from the FDA’s own scientists.

We need to restore the public trust in this vital agency, rid it of undue influences that benefit a political, rather than public health agenda, and, above all, we need to adequately fund the FDA through the appropriations process so that the agency is less reliant on user fees collected from private industry. Congress must act swiftly to give the FDA more resources. That, I believe, is how we maintain the FDA as the world’s gold standard in drug and device safety.

Senator Grassley and I authored one of the first drug safety and clinical trials bills in the Senate in the wake of the Vioxx scandal that would have given FDA’s office of postmarket drug surveillance the independence, stature and funding to take action when a safety problem arises. We reintroduced the bill this congress with several colleagues withing the HELP Committee, including Senators MIKULSKI and BINGMAN and I thank them for their support. While I do not agree with some of my colleagues who have argued that this authority would create a bigger bureaucracy at the FDA, the experience showed us that the support to move such a proposal simply wasn’t there.

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amendment offered by Senators DURBIN and BINGAMAN would have made great improvements to the recruitment of qualified advisory committee members. The amendment would have required the FDA to conduct aggressive outreach to recruitment, and it was a great deal of time describing to the legislation to the President for his signature. It is my hope that we can send this legislation and look forward to this legislation is vital to our nation’s children. It is my hope that we can find a way to address these issues in the conference with the House.

Taken as a whole, the underlying legislation is vital to our nation’s children as well as consumers needing timely access to safe and effective drugs. Therefore, it is essential that the House act quickly so that we can send a conference report to the President in the coming months. I urge the House to pass all of the major provisions contained in S. 1862. I support this legislation and look forward to continuing to work with my colleagues on both sides of the aisle and in both Chambers so that we can send this legislation to the President for his signature.

Mr. KENNEDY. Madam President, I would like to take some time to talk about some issues that I haven’t spent a great deal of time describing to the Senate about S. 1862, the Food and Drug Administration Revitalization Act.

First, I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me and with many members of the committee on the important issue of direct-to-consumer, or DTC, advertising.

We have worked together to accomplish our common goal—a constitutionally sound, effective, workable way to see that DTC ads provide accurate information to patients about the drugs they are taking. Some have advocated a ban on such advertising altogether, but Senator ENZI and I rejected that approach since it failed to meet the constitutional test. Instead, we included a more measured provision in our legislation that allows FDA to impose a moratorium in extraordinary circumstances where needed to protect public health.

During our committee’s consideration of this legislation, Senator ROBERTS brought up his concerns that even this limited provision fell afoul of recent Supreme Court decisions on free speech. Senator HARKIN raised his strong interest in ensuring that these DTC ads include strong, effective safety information that is clearly and prominently presented to consumers in a way that does not gloss over important information. Senator Enzi and I committed to work with Senator Roberts to see that any provision on DTC met the constitutional threshold, and we agreed to work with Senator HARKIN to make certain that it provided strong safety information to consumers. The Roberts-Harkin amendment is an amendment that our two colleagues offered. It is a true bipartisan compromise, worked out by two Senators committed to making real progress on an important issue, and I am pleased to support the amendment.

Instead of the moratorium included in our original bill, the Roberts-Harkin amendment puts in place strong safety disclosures for DTC ads, coupled with effective enforcement. Under current law, safety disclosures can be an afterthought—a rushed disclaimer read by an announcer at the conclusion of a TV ad while distracting images help gloss over the important information provided. Our proposal requires safety announcements to be presented in a manner that is clear and conspicuous without distracting imagery.

We also give FDA the authority to require safety disclosures in DTC ads if the risk profile of the drug requires them. Senator Roberts had a concern that this authority not be used indiscriminately, so we have made clear that the required disclosure must pertain to a specific identified risk. We have made substantial improvements in FDA’s ability to enforce the requirement to provide clear and accurate information to consumers.

For advertisements, as in so many other areas, FDA’s enforcement tools are now limited. Although FDA does have the capacity under current law to remove a drug from the market for misleading ads, that authority is not often used and rightly so, since it punishes the innocents and the manufacturers. Since removing a drug from the market is an empty threat, FDA is often left with little option but to make polite requests to companies to change their ads. Under the Roberts-Harkin amendment, FDA will have the ability to levy fines of up to $150,000 for false or misleading ads. It is unacceptable for patients to be put at risk by inaccurate ads. The Roberts-Harkin amendment makes certain that FDA will have the ability to see that this does not occur, in a way that is clearly consistent with the Constitution.

The amendment is a victory for bipartisan common sense on a difficult issue. I would also like to address the affect of title II of this bill. Generally speaking, title II grants the FDA new authority over postapproval safety surveillance activity in order to improve drug safety.

In enacting title II, we do not intend to alter existing State law duties imposed on the holder of an approved drug application to obtain and disclose information regarding drug safety hazards either before or after the drug receives FDA approval or labeling. Nor are we expressing a belief that the regulatory scheme embodied in the bill is comprehensive enough to preempt the field or every aspect of State law. FDA’s approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to raise this minimum requirement into a maximum.

As the Institute of Medicine and others have found, the FDA’s past performance has been inadequate. While we do expect substantial improvement as a result of the enactment of this bill, we cannot and do not expect the FDA or this new process to identify every drug-specific safety concern before a drug manufacturer becomes aware or should have become aware of such concerns. Nor are the bill’s requirements that holders disclose certain safety information to the Government intended to substitute for the disclosure requirements that may be required under State law.

I would also like to focus on another aspect of our legislation, the Reagan-Udall Foundation.

During the discussions that led to consideration of this bill, we heard that and again that there was a major need for better research tools to aid FDA in evaluating the safety of drugs and help researchers move through the long process of developing drugs more effectively. Every day that a new medicine is needlessly delayed is another day that a patient does not receive a treatment that could well mean the difference between health and continued illness. If new research tools and better ways to evaluate the safety and effectiveness of drugs could be developed, patients will benefit from quicker drug development. If current procedures can be made more effective, then the cost of developing new drugs will drop.

One area where scientists can make real progress is developing new cell lines and new genetic techniques for testing drugs that reduce the need for costly forms of testing. The Reagan-Udall Foundation sets up a foundation to develop these new tools—not so they can help just one researcher or one company, but so they can help the entire research enterprise. New ways to test drugs for effectiveness and safety
will bring new advances to patients quicker and more smoothly. Through the Reagan-Udall Foundation, they will be available to the FDA and to the entire research enterprise. This new foundation is not many pages in a long bill, but it is an important component to help bring medicines to patients as quickly as safety will allow.

I also wish to mention another critical aspect of our legislation—it’s registry of clinical trials.

This provision serves two essential purposes. First, it allows patients who want to enroll in those trials an accessible and central Internet site to find out which trials are being conducted and whether they might be eligible.

This provision builds on an existing provision of law to create a clinical trials site, but report after report has shown that the requirement to list trials has not been complied with. Our legislation puts more force in the requirement to list trials so that patients will benefit.

Listing trials is important for patient access—but reporting results is critical for safety. Our legislation requires that the results of trials be reported. No longer will companies be able to manipulate the outcome of a trial that did not turn out the way they hoped.

Examples of this kind of abuse are shocking. The manufacturer of the antidepressant drug Paxil conducted five clinical trials of the drug in adolescence and children, yet published only one study whose mixed results it deemed positive. The company sat on two major studies for up to 4 years, although the results of one were divulged by a whistleblower and all of the studies were submitted to the FDA when the company sought approval for new uses of Paxil. At that time it became apparent that Paxil was no more effective than a placebo in treating adolescents with depression.

Under the bill these kinds of abuses will not be permitted, since clinical trials will have to be reported—no matter what the result.

Senator Enzi, Senator Dodd and many others in the committee worked hard to get this provision right. We require immediate listing of all publicly available data and require a negotiated rulemaking, backed by the full authority of statute to develop the precise requirements for other results information to be limited.

I would like to thank my colleagues for considering these comments as they relate to S. 1062, and I urge my colleagues to support the bill.

Mr. COBURN. Madam President, as we debate the important issue of drug safety, I want to address the safety of one drug in particular: RU-486 or mifepristone. This drug was approved in 2000 under a special pathway, subpart H drug approval that is reserved for drugs that treat very severe life-threatening illnesses. Subpart H approvals generally require a special “restricted distribution” approval process.

Unfortunately some drugs, RU-486 for example, approved under subpart H have caused serious adverse health events in women.

Every drug approved under Subpart H is listed on the Food and Drug Administration’s Web site. The vast majority of drugs on that list are to treat HIV or specific types of cancer. One governs the use of thalidomide in treating leprosy. These drugs are supposed to relate to the treatment of life-threatening illnesses.

One exception of a subpart H approval makes a mockery of the regulatory process by an expedited approval of two extremely risky drugs for abortions. Pregnancy is not an illness and certainly not one that is life-threatening in the first 7 weeks, unless it is a tubal or ectopic pregnancy in which case RU-486 abortions are absolutely contra-indicated.

RU-486 was inappropriately approved in 2000. RU-486 was approved using special “subpart H” regulations to address problems for new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses...and under restricted distribution conditions due to serious hazards present in the drug; for example, severe hemorrhage and ectopic pregnancies. This was an inappropriate approval of RU-486 as pregnancy is not normally a life-threatening condition. Today many health care providers do not follow the distribution requirements of RU-486’s approval.

RU-486 has put women’s lives at risk. To date there have been six North American deaths related to the use of the RU-486 abortion regimen: five Americans and one Canadian have died from septic shock stemming from infection by the anaerobic bacteria Clostridium sordellii. Five other international deaths have been related to RU-486.

RU-486 causes serious safety issues. More than 1,000 adverse event reports—232 hospitalizations, 116 blood transfusions, and 88 cases of infection—have been submitted regarding RU-486 and are significant because they confirm that large numbers of mifepristone patients require surgical intervention for infection, hemorrhage, complications from ectopic pregnancy, and incomplete abortions. While lives have been lost from the use of RU-486, not a single case has been documented where RU-486 has been used to save a woman’s life.

RU-486 is not always effective and when it is not the consequences are dire. I recently learned of a woman who was given RU-486 after she had a seizure. Her doctors assumed that the seizure was life-threatening to the baby she was carrying and gave her RU-486 for a therapeutic abortion.

RU-486 was not effective in her case and the woman carried the baby to term. When the baby was born at a low birth weight, it also suffered from failure to thrive. That baby has had three subsequent brain surgeries due to hydrocephalus. The baby also suffers from idiopathic lymphocytolysis—an inflammatory disease of the colon, which is extremely rare in children. It is clear that RU-486 not only is unsafe in women, but it is also not completely effective. And when it is not effective, the stakes are devastating.

I appreciate the desire to effect safer drugs through this bill. Senator Kennedy and Senator Enzi have done a great deal of work in designing the REMS scheme for certain drugs to ensure that they can be safely and effectively used.

Under the risk evaluation and mitigation system, REMS, provisions of the drug safety bill, a drug that has previously been approved under subpart H is deemed to have a REMS. Every REMS is subject to a periodic review. Therefore, RU-486 is deemed to have a REMS and is subject to periodic reviews.

I am pleased that the amendment offered by Senator DeMint was accepted by the full Senate. Senator DeMint’s amendment sets a “date certain” REMS assessment for RU-486 to properly evaluate its safety in women. Women in this country deserve to know the safety risks associated with RU-486.

The PRESIDENT: Who yields the floor to the Senator from Illinois?

Mr. DURBIN. Madam President, I have an amendment pending and scheduled for a vote this morning on the conflict of interest provision. I believe I have 5 minutes to speak to it.

The PRESIDENT: The Senator does have 5 minutes.

Mr. DURBIN. I ask the chair and ranking member if this a convenient time to raise the issue?

Thank you very much.

Yesterday I proposed this amendment with Senator Bingaman. The Food and Drug Administration Advisory Committees make important decisions about life-and-death drugs. They decide whether the drugs and medical devices which are going to be used in America are safe and effective. In other words, if a person in America has a prescription from a doctor and takes this drug, is it going to be good for their health, or bad?

This is a critical situation. If they make the wrong decision, if the advisory committee turns a dangerous drug loose on the market, it can have terrible consequences. The advisory committees literally have life-and-death decisions in their hands on approving drugs, on deciding what the warning labels say, deciding what you have to say in advertising. There might be a danger in these drugs. The advisory committee is the jury of scientific experts who have to make these calls. That is one of the most important decisions of our Government.

They are not just life-and-death decisions, they are decisions involving millions and millions of dollars. Drug companies spend a fortune over a long period of time trying to bring a drug to
market. They would hope this will be a drug very popular and profitable for them and their shareholders. That is a natural inclination of a business. So the advisory committee not only decides the safety and efficacy of the product, it makes that decision which has a direct impact worth millions of dollars to the drug companies involved.

Do you know what we found out? We found out over the last 10 years many people who serve on these advisory committees, those who are actually sitting on the so-called juries and deciding the fate of these drugs, have a conflict of interest. Some of them were already receiving, from the companies that make these drugs, tens of thousands of dollars in consulting fees and speaking fees. It turns out they are on the payroll, some of them, of the very companies on which they are being asked to stand in judgment. That is a conflict of interest which people cannot accept and I cannot accept.

The Food and Drug Administration argues that there are so few experts that we have to sometimes turn to those who have a conflict of interest; there is no place else to go. So occasionally we have to put a waiver in and allow someone to sit on an advisory committee panel who frankly has a financial interest in the company they are making a decision about.

That worries me. Because if you are going to have truly objective jurisdictions, that are right for the consumers of America, that approve drugs or disapprove them on the merits, not because of the conflict or conflict of interest in which you might bring to the table, you don’t need these conflicts of interest.

So basically what Senator Bingaman and I have said is: Let’s strengthen the conflicts-of-interest provisions on advisory committees. Let’s make certain that there is confidence in the process. We know what happened with Vioxx. There were 10 people sitting on the advisory committee who had a financial conflict of interest. Had they been removed from the deliberation, the panel would not have recommended they go back on the market, endangering the health of thousands of Americans.

How can you even justify that kind of conflict of interest? Our language tightens it. What we are trying to do is to make sure the Food and Drug Administration, with this amendment, limits the number of waivers to one per each advisory committee meeting; allows advisory committees to receive information from guest experts who have a financial conflict but prevents those experts from participating in the deliberations.

The amendment would: require the FDA to issue financial conflicts of interest waivers, which are not permitted, to the advisory committee; limit the number of waivers to one per advisory committee meeting; and establish a specific process to allow experts with a financial conflict to present information to an advisory committee while not permitting them to deliberate or vote with the committee; and enhance the FDA’s outreach activities for identifying non-conflicted experts to participate in advisory committees.

We have 125 medical schools in this country, 90 schools of pharmacy, 40 schools of public health. If the FDA is more aggressive in filling the slots on the advisory committees, we can remove this shadow of doubt which is over this process.

Now, some will argue: Well, the FDA has come forward with draft guidance to improve this. This is draft guidance. They are suggestions. This is law. This tells them they will have to follow the law to avoid these conflicts of interest. This is not an idea that Senator Bingaman and I bring to the table without support.

I ask unanimous consent, Madam President, to have printed in the RECORD with my remarks letters from the Consumers Union, the Union of Concerned Scientists, and a broader advisory committee responsible for assessing the drug’s safety are not inappropriately influenced by scientists or others with financial ties to the affected drug company.

A recent national survey by Consumer Reports National Research Center found that Americans are extremely concerned about conflicts of interest waivers to the scientific experts the FDA serves on its 30-plus advisory committees.

Conflicts of interest can have serious consequences for drug safety. For example, ten of the scientists on the February 2006 advisory committee that considered the safety of Cox-2 inhibitors, including Vioxx, had ties to the drug companies that made the products. The scientists voted to permit the companies to continue marketing the drugs, even though Vioxx had already been withdrawn from the market and had been implicated in tens of thousands of deaths.

The Durbin-Bingaman amendment would: limit the number of waivers to one per advisory committee meeting; establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while permitting them to deliberate or vote with the committee; and enhance the FDA’s outreach activities for identifying non-conflicted experts to participate in advisory committees.

The integrity of science is vital to ensuring that decisions by federal policymakers benefit the public, and not the agendas of any special interest. We at the Union of Concerned Scientists strongly urge you to support the Durbin-Bingaman amendment to the FDA Revitalization Act, S. 1082. This amendment would: protect the Food and Drug Administration’s assessment of the safety and efficacy of drugs is not inappropriately influenced by scientists with ties to the drug companies affected by an FDA approval decision.

This amendment would make it more difficult for the FDA to issue financial conflicts of interest waivers to the scientific experts we serve on its 30-plus advisory committees.

CONSUMERS UNION,

DEAR SENATOR, Consumers Union, the nonprofit, nonpartisan publisher of Consumer Reports, urges you to support the Durbin-Bingaman amendment to S. 1082, the Food and Drug Administration Revitalization Act. We urge you to support the amendment to establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while permitting them to deliberate or vote with the committee; and enhance the FDA’s outreach activities for identifying non-conflicted experts to participate in advisory committees.

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BILL VAUGHAN, Senior Policy Analyst.
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advisory committees; limit the number of waivers that can be granted to one per committee per year; and authorize the FDA to hire experts who have conflicts of interest to make key answer questions at an advisory committee meeting if the FDA believes their expertise is crucial. However, these experts will not be allowed to vote or otherwise participate in the discussions leading up to committee vote.

The FDA advisory committee process has been severely compromised in recent years. According to the agency’s most recent report, one in four experts advising the FDA received waivers because they have financial ties to the companies. Nearly a third of the advisors had ties to Cox-2 manufacturers and had their votes not been counted, the vote would have been reversed.

The legislation gives the FDA the tools needed to get drugs to the market quickly and efficiently and to respond to potential problems the same way, especially when lives are on the line and people need new drugs and therapies.

FDA currently has no mechanism from active, routine surveillance of potential safety problems. It cannot easily detect safety problems after a drug has been put on the market. This legislation fixes that challenge and ensures that FDA has the right tools to address drug safety after the drug is on the market.

The legislation allows for routine, active safe monitoring using large linked databases, what I call health IT for drug safety. I wish to thank Senator GREGG for being the champion of this provision and ensuring that we crafted this provision properly.

Title IV of the bill before us contains a number of critical provisions to improve children’s health. Up to 75 percent of drugs used by kids have not been tested in kids. Without information from pediatric studies, kids are often overdosed, underdosed or receive ineffective treatment. They may suffer needlessly or even die. The Best Pharmaceuticals for Children Act makes drugs safer for kids by creating incentives to perform pediatric drug studies. The incentives have produced astonishing results. In the 7 years before BPCA incentives, a total of 11 pediatric studies were performed; 7 years, 11 studies.

In the 10 years since incentives were authorized, at least 132 studies have been completed and many more are underway. As a grandfather, I am very happy that the law is in place. If my grandson Trey is sick, I want the drugs he needs to have been tested for kids. All of us want that for our children and grandchildren.

The bill also reauthorizes a companion study, the Pediatric Research Improvement Act, which enables FDA to require a pediatric study if it is not done under the incentive program or through the National Institutes of Health. These two laws work together as a carrot and a stick. I strongly support their reauthorization and continuing to keep them together.
Now, so far I have only talked about drugs for kids. The bill will also make medical devices safer for kids. Devices designed for adults might not fit in kids. A scaled-down device might fit at first, but a child can grow out of it, so doctors have to jury-rig adult devices or improvise or use more invasive treatments. In addition, the market for kids’ devices is small, and the development costs are very high, so few kids’ devices get made.

The bill before us creates new incentives to grow the market for kid’s medical devices. I am hopeful these new incentives will be as helpful as the kids’ drug incentive. I would like to thank Senator Alexander, Senator Allard, Senator Bond, Senator Dodd, Senator Clinton, and others for their leadership on behalf of kids.

A number of other FDA issues were also addressed during debate of this legislation. The legislation was improved when the Senate adopted a food safety provision by a vote of 94 to 0. This amendment adds additional food safety provisions to better protect our pet food supply and track when food is adulterated. My colleagues and I also reached consensus that the issue of follow-on biologics will be addressed in the Help Committee early this summer.

As my colleagues know, I have some concerns with the Dorgan amendment on drug importation that was adopted last week. I supported the Cochran safety amendment that was also adopted. I did not support the Dorgan approach to foreign drug importation because I do not believe it adequately ensures the safety of the prescription drug supply.

I was pleased to work with my colleague, Senator Dorgan, to add some very significant anticounterfeiting language to the bill in the managers’ amendment. But a lot of work still remains. I support the process moving forward and will continue to work with my colleagues and Senator Dorgan and Senator Snowe to improve this language during the conference process.

Finally, I would like to thank Senator Hatch for his work on the antiotics and other Hatch-Waxman issues and the follow-on biologics. Senator Hatch was responsible for the first FDA Revitalization Act in 1990, before I was even elected a Member of the Senate. I would like to thank him for helping me to bring that full circle and for the mentoring he has done as a former chairman of the committee.

I will have a lot more thank-yous to deliver after the votes, but right now we have a bit of business left to conduct. I yield the floor and retain the remainder of my time.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. Kennedy. Madam President, how much time remains?

The PRESIDING OFFICER. The managers have 14 minutes.

Mr. Kennedy. Madam President, I yield myself 4 minutes.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized for 4 minutes.

Mr. Kennedy. Madam President, I would like to thank my friend from Illinois and my colleague from New Mexico for their amendment on the conflicts of interest and for working with us to address these issues in appropriations bills during the past year.

Their amendment includes many thoughtful proposals I support: including the right to call for the FDA to improve its outreach to experts who have no conflicts of interest and their right to call for greater transparency in the process of waivers.

But where I disagree with my friend from Illinois and New Mexico is that there should be an inflexible cap on the number of waivers for conflicts of interest an advisory committee can grant, no matter what the expertise of the scientist involved.

The amendment would impose a one-size-fits-all, one waiver per conflict, per committee, relenting additional members with conflicts to a secondary guest status on the committee.

The bill before us creates new incentives to grow the market for kid’s medical devices. I am hopeful these new incentives will be as helpful as the kids’ drug incentive. I would like to thank Senators Alexander, Allard, Bond, Dodd, Clinton, and others for their leadership on behalf of kids.

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The PRESIDING OFFICER. The Senator from Iowa.

Mr. Grassley. Madam President, I yield myself 5 minutes out of the 10 allotted to me.

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

Mr. Grassley. I am going to speak about amendment No. 1039. I ask unanimous consent that Senators Mikulski, Brown, Snowe, and Bingaman be added as cosponsors.

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

Mr. Grassley. This amendment is important because S. 1082 does not sufficiently address the underlying problems that, as the Food and Drug Administration during my tenure as chairman of the Senate Finance Committee looking into the problems of the Food and Drug Administration, with the goal in mind that the Federal Government should only be paying for drugs that are safe. That problem is the lack of equality between the Office of New Drugs, which reviews drug applications and decides whether to approve a drug for marketing, and the Office of Surveillance and Epidemiology, which reviews drug applications and assesses the safety of drugs postmarketing.

Many times I quote the Institute of Medicine as justification for my amendment. They recognize this problem. The Institute of Medicine recognizes joint authority between these two offices for postapproval regulatory action related to safety. Even the Consumers Union supports this amendment.

Having equality between preapproval and postapproval offices at the FDA is fundamental to real reform. Concentrating on the entire life cycle of drugs...
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is critical. After all, the vast majority of a drug’s life cycle is spent post-approval. In essence, the bill before us promotes the status quo when it comes to the specific role played by the Office of Surveillance. That means the Office of Surveillance and Epidemiology will remain more consultative to the Office of New Drugs. This is not acceptable.

Amendment 1039 gives the Office of Surveillance sign-off authority. They are currently postmarketing safety. Even the Institute of Medicine recognized that through their recommendations. Let me be clear: This is not the amendment Senator Dodd and I originally proposed. I still believe an independent postmarketing safety center would be best to solve the problem. But under the process, that is not going to happen. Through this amendment, at least joint postmarketing decision-making between the Office of Surveillance and the Office of New Drugs will allow the office with the postmarketing safety expertise to have a say in what drug safety action will be taken by the FDA.

The bill is not only the FDA having enough tools—this bill gives additional tools—it is about FDA managers disregarding concerns raised by its own scientists in the Office of Surveillance and not taking prompt action. This amendment makes common sense when you weigh the evidence I presented over the last 3 years about these problems at the FDA.

Opponents of this amendment say it is unnecessary because the bill includes a dispute resolution process with strict deadlines. But that process is for disputes between the FDA and the drug company, not internal disagreements between FDA offices.

Getting down to brass tacks, when the office that looks at postmarketing surveillance is under the thumb of the Office of New Drugs, and the Office of New Drugs says: This drug is safe, they aren’t going to want to get on their faces by listening to the advice of the Office of Surveillance that can hurt Surveillance. If that had been the case, Dr. Graham, in the case of Vioxx, and Dr. Mosholder, in the case of antidepressant drugs, when kids were committing suicide, would have been listened to, but they weren’t until they came as whistleblowers to the Congress.

We have to have it so that we have enough independent decisionmaking within the FDA to make sure these drugs are safe.

This amendment provides an approach with checks and balances between the office that approves a drug for marketing and the office that watches a drug once it is on the market.

The PRESIDING OFFICER. The Senator has used 5 minutes. Who yields time?

The Senator from Iowa, Senator Grassley.

Mr. GRASSLEY. Madam President, I yield myself such time as I may need.

I rise in opposition to the amendment offered by my colleague from Iowa. Senator Grassley, No. 1039, regarding the joint signing authority under the Office of New Drugs and the Office of Surveillance and Epidemiology. This amendment would add an unnecessary layer of bureaucracy into an agency that we have designed to be streamlined and efficient in their process to deal with emerging drug safety issues.

Before the bill is passed, the option after market is to suggest changes or pull the drug off the market, kind of a nuclear option. The underlying bill has surveillance and techniques to notice problems quicker. That is why we will be able to get drugs on to the market faster. The underlying bill does have a dispute resolution process with firm and tight deadlines. There is both one with companies and with staff disputes. It requires by its very nature close collaboration between the two offices. This amendment only serves to separate what should be a together process and delay what should be a rapid process.

I urge my colleagues to oppose the amendment. The tools we have put in the toolbox will do what the Senator from Iowa wants to have done, which is quick response when there is a problem. I hope we don’t add this extra layer of bureaucracy. We looked at this problem through a number of hearings and a number of concerns by members on the committee from both sides and came up with ways being able to do it that had not been polarized and that had some agreement. I hope people will stick with what is in the bill.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Iowa.

AMENDMENT NO. 998

Mr. GRASSLEY, Madam President, I yield myself such time as I consume on amendment No. 998. I ask unanimous consent that Senator Dodd, Snowe, and Bingaman be added as cosponsors.

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

Mr. GRASSLEY. This amendment provides for the application of stronger civil monetary penalties for violations of approved risk evaluation and mitigation strategies. Currently, the bills before us contain penalties, but those penalties won’t mean much to large global corporations. In fact, the penalties might even be an incentive to the public interest.

We have seen this happen many times. For the Food and Drug Administration’s new authorities to be meaningful in this legislation, there must be stronger civil monetary penalties in the underlying bill; hence, my amendment. Fines are nothing more than the cost of doing business, and we can’t change behavior. More importantly, we can’t even deter bad behavior. If a company does what it is supposed to do, a drug company doesn’t need to fear any penalties. It is that simple.

I ask Members of the Senate to support this amendment because it adds real teeth to the FDA’s bite.

I thank Senators Kennedy and Enzi for the tremendous efforts they went to making this an effective Senate floor. Again, I want to make this bill even better. They have already included several ideas Senator Dodd and I have shared with them.

I reserve the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. ENZI, Madam President, I yield myself such time as I need.

I thank the Senator from Iowa, Mr. Grassley, for his participation in this bill. It has been tremendous. I mentioned the hearings he held, as we were holding hearings, as there were some crises with food and drugs. The valuable information he shared with us, as well as amendments, as he has correctly stated, are already a part of the bill.

With respect to amendment No. 998, I also have to oppose this amendment regarding the level of civil monetary penalties that can be assessed for violations of the drug safety plan.

I appreciate Senator Kennedy’s earlier comments. The level of civil penalties in the underlying bill was carefully crafted to reflect existing FDA policies for other regulated products. These first-tier civil penalties in this portion covering the area of food and drugs. It was no small feat to get a consensus position so that we could have civil penalties in the bill, and I think that is necessary.

There is a precedent for the levels that we have selected, the current levels. Medical devices have the same levels. I reiterate that has never before been available to the FDA as a tool on drug safety issues, but we are providing it as a tool. Furthermore, I believe the very threat of a civil penalty is sufficient to deter behavior. This is the name-and-shame principle. The fine may be affordable to the company, but the loss of reputation is not.
I urge my colleagues to oppose this amendment as well. This is not the end of the process. I suspect the House will have something to say on it, as I have reported to the Senator from Iowa before. There will be additional negotiations. I am certain, on civil penalties. I think we should agree with the civil penalties that have a basis in the medical devices as some basis from which to negotiate and would hope that the Senate position will be the one that is in the bill. I ask people to oppose that amendment.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, how much time do I have?

The PRESIDING OFFICER. The Senator has 10 minutes remaining.

Mr. KENNEDY. Mr. President, I yield myself 5 minutes. I support the comments Senator ENZI has made about the fines. We are going to have to look at this in conference, and it is clear the House is going to raise the fines, it seems to me, as Senator ENZI pointed out. So we will have a chance to look at it in conference. I think that is probably the best way to do it.

Let me point out two other items—something I think most Americans have been concerned about in recent times. It was reported today that China has detained managers from two companies linked to contaminated foods. As a first step, we need to determine the extent of the contamination and see how far into the food supply this internal adulteration has gone.

Yesterday’s report from the FDA that contaminated wheat flour from China was fed to fish raised for human consumption is another example of the need for a comprehensive examination of our food safety system. We also found out yesterday that what we thought was contaminated highly processed wheat gluten was actually unprocessed wheat flour spiked with melamine to make it appear to be higher quality.

A month ago, the FDA warned that certain types of pet food were suspected of being contaminated. Then, there were more kinds of pet food. Then it was hogs being fed the contaminated feed. It is clear that those had been caught before human consumption. Then we found out that tens of millions of chickens eaten by people had been fed the tainted food. Yesterday, we were informed that fish raised for human consumption had been fed contaminated food.

The incremental expansion of this crisis raises serious concerns about the FDA’s ability to rapidly identify the source of food-related problems and bring to bear the effective tools. We know the issue of food safety is divided into different kinds of committees, but it has to be of concern to American families.

We have included strong new protections to allow FDA to better ensure the safety of human and pet foods, but this is a first step. Senator ENZI and Senator DURBIN have joined with me and others and we are committed to taking a comprehensive look at the safety of our foods and committed to taking the actions, with our colleagues, needed to ensure that the foods our families and pets eat are as safe as possible.

As part of the managers’ package adopted last night, we included important new provisions to allow the FDA to oversee the safety of farm-raised fish. We owe this—this is a story in the paper today—to Senators LINCOLN and PYOR and SESSIONS on this important proposal.

This morning’s newspaper talks about doctors reaping millions for the use of anemia drugs. People are going to wonder what we are doing in this bill, if anything, on this issue. Well, this is the issue exactly. It is safety and efficacy. But there are different agencies in what they call health research and quality. AHRQ has responsibility for this. We will be in touch with them to examine this issue and benefit from the advice and recommendations to doctors and patients.

The FDA does not practice medicine. But this kind of action has to be of concern because it reflects itself in increased costs to the American consumer, and it does raise health issues as well.

So this is illustrative of the range of different areas of concerns the American families have. We believe we have made very important and substantial progress in trying to address those questions.

Mr. President, at this time I will yield the remainder of my time.

The PRESIDING OFFICER. The Senator from Wyoming.

AMENDMENT NO. 1034

Mr. ENZI. Mr. President, I have to make some comments in regard to the other amendment we will be voting on this morning, which I also hope people will oppose, and that is amendment No. 1034, offered by my colleague from Illinois, Senator DURBIN.

The FDA relies on 30 advisory committees to provide independent expert advice, which lends credibility to the decisions under review. It informs consumers of trends and product development. Given the complex issues that are considered by the FDA, outside help is needed and beneficial, and it is advisory. The decisions are not made by the committees. They advise. But any scientist who is expert enough to merit interest by the FDA has almost certainly merited interest by other entities, such as granting agencies and companies involved in the field.

The amendment would seriously limit the FDA’s ability to access the best experts in the field to assist the Agency with its decisionmaking process. It would restrict FDA to granting only one waiver per committee meeting.

How would the FDA decide who gets that one waiver? Who is more worthy, the toxicologist, the drug safety expert, the specialist in women’s health? This is not an easy question.

The FDA, in March, released a guidance document outlining strict new limits on evaluating advisory personnel committee members for service. The comment period on this guidance has not even closed. It is premature to void that guidance before we even know whether and how it will work.

Let’s take a step back and think about what might happen if we do not allow people who have worked with or for industry to be involved in an advisory committee meeting.

Louis Pasteur was a brilliant microbiologist who revolutionized human food and health safety. Every time you buy milk in the grocery store, you are benefiting from his contributions to science. But under this amendment, Pasteur would probably not have been able to serve on any advisory committee. You see, Pasteur’s research was funded by the wine industry.

Now, do you want to prevent the FDA from benefiting from the advice of the best and the brightest they have to offer? We do want to move so there are not conflicts of interest. I think the guidelines that are out there, if finalized, will do that. The amendment allows us into a position of not conflicts of interest but biases—much harder to determine. If we are going to do that, we will never be able to have anybody on any of the committees, particularly with the expertise we need.

So I ask we oppose that amendment as well.

I yield time to the Republican leader. The PRESIDING OFFICER. The Republican leader is recognized.

Mr. MCCONNELL. Mr. President, I thank my friend from Wyoming.

I wish to take a moment to congratulate Senator ENZI on this wonderful, bipartisan effort he has been engaged in with our friend from Massachusetts, Senator KENNEDY. They have worked tirelessly for the past 3 weeks, through markup and floor consideration.

I also wish to commend Senator GREGG, who worked very hard with Senator ENZI to reach a bipartisan compromise on this important measure.

I particularly wish to note Senator ROBERTS was instrumental in working out the problems with direct-to-consumer advertising provisions. I know he would have liked to have been here today to support this bill, but he is out in Kansas with the President touring hurricane damage in his State.

Also, I wish to commend Senator COHAN. We appreciate his efforts to bring drugs from other countries that are not easy and to ensure that any proposal to bring drugs in from other countries must be certified by the Secretary of Health and Human Services as safe for the American people.
So again, I thank the Senator from Wyoming for his extraordinary accomplishment in moving this important, bipartisan legislation forward.

With that, I yield the floor.

The PRESIDING OFFICER. Who yields the floor?

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I think we are about—I see my friend from Iowa on his feet so I will withhold. I will make a very brief comment at this point, so I will yield.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I yield myself such time as I might consume. I only have 2½ minutes.

On the very important amendment about making sure there is adequate cooperation and dialog between the Office of New Drugs and the Office of Postmarket Surveillance, I wish to make clear this amendment is not, as some people characterized it, about the respect for the American people on the safety of drugs. It is based on so many examples I found over the last 3 years, where I have not the respect for the Office of Postmarketing Surveillance there ought to be from the Office of New Drugs.

A lot of safety issues would not have gotten out if we had not had a lot of red-blooded patriotic whistleblowers who would come to Congress, such as Dr. Graham, for instance, in the case of Vioxx, such as Dr. Mosholder, in the case of depressants for children who were committing suicide. This ended up with black-box safety measures in the case of the antidepressants.

The Institute of Medicine has recognized the importance of these two groups within the FDA working very closely together on making a determination on postmarketing surveillance. That is what my amendment does. It makes sure this process works the way the Institute of Medicine indicated it should.

So as you consider voting on this amendment, I ask my colleagues—I myself or herself—one basic question before voting: Since the Institute of Medicine recommends equality between the preapproval process—in other words, before the drug is marketed—and the postapproval process at the FDA, why not vote for this amendment and improve postmarketing safety for the American people?

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, in a few minutes, we will be prepared to vote. I yield myself 3 or 4 minutes.

I yield the floor. At the conclusion of this debate, the names of the staff on our committee who have done superb work. It has been extraordinarily detailed and on both sides of the aisle. We are enormously appreciative and grateful.

I am also personally appreciative of the work of my friend and colleague, the Senator from Ohio, Mr. Brown, who was so kind as to fill in for me. I had the opportunity to travel to Ireland, where they signed and put in place, after 400 years of struggle, the democratic institutions over there, in a very moving ceremony, which President Bush had supported—a very special day for Ireland.

This legislation is a reflection of 2½ years of hearings under the leadership of Senator Enzi, when he was chair of the committee, and myself. It incorporates the Institute of Medicine’s recommendations, by and large, after they had months and months of hearings. The American people ought to understand the legislation, which reflects bipartisan support in the Senate, is a reflection of the best judgments we could have made, months and years of work on this issue and of the membership on it. We are enormously grateful.

This legislation is going to make the prescription drugs our families take are even safer. That is very important. It is going to ensure that the Agency has resources to do follow-on reviews to continue its important function to be the world leader, the gold standard, for safety for our people and the example for the rest of the world. So this is very important legislation.

We are reminded every day of the additional kinds of challenges we are facing in terms of safety for our families. We are very aware of it. Senator Enzi and I and the members of our committee are going to continue our study, our review, and continue our activity to ensure we are going to have the best in terms of a safe and secure food supply, placement of food supply, and take advantage of this life science century so every American is going to have the best and, hopefully, at the most reasonable price, so they can have healthier and stronger families.

Mr. President, I yield back my remaining time.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I have a number of people I need to thank for their efforts on this bill, and I will do that following the vote so that we don’t hold up the vote.

There has been tremendous cooperation, effort, knowledge, and capability that has been involved, not just of the Senators but also of the staffs. The staffs on both sides of the aisle have spent countless hours on this, even on weekends. In fact, I know of one day on one weekend they worked about 20 hours together to pull this thing together and get some of the final pieces. But that included the entire weekend for at least the last three weekends. They will look forward to a little time to rest, and we will probably give them a day. That is because we have so many things happening in the committee, and Senator Kennedy and I are determined to get a lot of that done to help the American people with their health and with their education and in the area of workplace safety and training and pensions.

But on this bill, I hope people will join us in supporting it. Of course I hope they will join us in maintaining a balance to take it to conference committee and to defeat the three amendments that have been before this morning.

I yield back the remainder of my time.

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate equally divided prior to a vote in relation to amendment No. 1039.

Who yields time?

Mr. GRASSLEY. Mr. President, I will speak in favor of 1039. I have 30 seconds, or whatever you say, off the clock.

The PRESIDING OFFICER. The Senator has 1 minute.

Mr. GRASSLEY. Mr. President, one of the issues that has been very much a shortcoming within the FDA besides the lack of a review for the safety of the drugs that are approved, is the cases of postmarketing surveillance. This legislation is going to make the prescription drugs our families take are even safer. That is very important. It is going to ensure that the Agency has resources to do follow-on reviews to continue its important function to be the world leader, the gold standard, for safety for our people and the example for the rest of the world. So this is very important legislation.

We are reminded every day of the additional kinds of challenges we are facing in terms of safety for our families. We are very aware of it. Senator Enzi and I and the members of our committee are going to continue our study, our review, and continue our activity to ensure we are going to have the best in terms of a safe and secure food supply, placement of food supply, and take advantage of this life science century so every American is going to have the best and, hopefully, at the most reasonable price, so they can have healthier and stronger families.

Mr. President, I yield back my remaining time.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I oppose the amendment. I appreciate the thought that went into it, and I know that before we did this bill and put into place some of the processes we have in the toolbox for postapproval—which, nevertheless, existed before for the FDA—this amendment was not necessarily. But in light of the toolbox we provide and the dispute resolution we have, it would add an unnecessary layer of bureaucracy.

We have designed the bill to be a nimble and responsive process to deal with emerging drug safety issues. We want drugs on the market faster, we want to know about anything that goes wrong faster, and we think that is built into it. We do have a dispute resolution in the bill with tight guidelines that we think will work. We don’t need the additional process.

The amendment separates what should be together and delays what
should be rapid. So I urge my colleagues to oppose the amendment.

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

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

Mr. KENNEDY. Mr. President, parliamentary inquiry: Could we ask unanimous consent that we have the yeas and nays on the other two amendments? I ask unanimous consent that it be in order now for the yeas and nays on the other two amendments and then on final passage.

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

Mr. KENNEDY. I thank the Chair.

The PRESIDING OFFICER. Is there a sufficient second on the remaining amendments? There appears to be a sufficient second. The yeas and nays are ordered on the remaining amendments as well.

The question is on agreeing to amendment No. 1039.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Indiana (Mr. BAYH) and the Senator from South Dakota (Mr. JOHNSON) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 46, nays 47, as follows:

[Rollcall Vote No. 154 Leg.]

YEAS—46

Baucus
Biden
Bingaman
Boxer
Brown
Byrd
Cantwell
Cardin
Enzi
Feingold
FEINSTEIN
Obama
Pryor
Reid
Rockefeller
Schumer
Snowe
Tester
Whitehouse
Wyden

NAYS—47

Akaka
Alexander
Allard
BenNETT
Bond
Bunning
Burton
Chambliss
Colburn
CoCrhan
Corker
Craig
DeMINT
Dole

NAYS—47

Baucus
Alexander
Allard
Bennett
Bond
Bunning
Burton
Chambliss
Colburn
CoCrhan
Corker
Craig
DeMINT
Dole

NOT VOTING—7
Bayh
Brownback
Crapo

NOT VOTING—6
Johnson
Brownback
Crapo

The amendment (No. 1039) was rejected.

Mr. ENZI. I move to reconsider the vote, and I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 998

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate equally divided prior to a vote in relation to amendment No. 998.

The Senator from Iowa. Mr. GRASSLEY. I have 1 minute.

The PRESIDING OFFICER. One minute.

Mr. GRASSLEY. Mr. President, the issue is the level of civil and monetary penalties. If the fines are nothing more than the cost of doing business, you can't change behavior and you can't deter bad behavior. My feeling is that levels in this underlying bill are not high enough to get the attention of the drug companies. After all, if a company does what it is supposed to do, a drug company doesn't need to fear any penalties. It is that simple.

I ask my colleagues to support my amendment so it has real teeth.

Mr. DURBIN. I announce that the amendment (No. 998) was agreed to.

Mr. GRASSLEY. Mr. President, I move to reconsider the vote and to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1034

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes of debate, equally divided, prior to a vote in relation to amendment No. 1034.

The Senator from Illinois is recognized.

Mr. DURBIN. Mr. President, 2 years ago, an advisory committee of the FDA sat down to judge painkiller drugs and whether they were safe to sell to America. They made the recommendation that selling Vioxx to America was safe. Ten of the members of that advisory committee had a financial conflict of interest when they made the decision. Had those 10 members with the conflict not been there, the panel would not have recommended keeping those drugs on the market.

This amendment Senator BINGAMAN and I offer will take the conflict of interest out of the advisory committees. We will allow one waiver for someone with a conflict of interest, and we will say that others who participate as guest experts have to leave the room before any deliberation or vote. We will hear from the other side that the Food and Drug Administration has an idea of how they are going to change this rule at some future time.
This is not an idea we are proposing. It is a law—a law to protect the integrity of the advisory committees and the drugs and medical devices which are sold across America.

I urge my colleagues to support this amendment.

Mr. KENNEDY. Mr. President, the FDA has a new policy, a new procedure out there.

Basically, what the Durbin amendment says is, one size fits all. That concept has been rejected by the Europeans, rejected by the Canadians, and basically rejected by the Institute of Medicine. In this life science century, researchers who are looking at cancer drugs may be examining 15 different components. We are going to say that if a conflict exists with one of those components that they meet the Durbin amendment standard. This would exclude some of the most knowledgeable people in this country from participating in the review of breakthrough drugs.

The FDA says they have adopted transparency. Everyone in the Senate is going to know who sits on the advisory committees. There is a financial limitation of $50,000 at the FDA now. Everyone is going to know the existence of any conflicts. It is a new day out there. We have now have transparency, but virtually everyone who understands that we are in the life science century says we have to have the best scientific minds at the table, and so the Institute of Medicine said: Don’t go with a one-size-fits-all, which the Durbin amendment does.

The PRESIDING OFFICER. All time has expired.

The question is on agreeing to amendment No. 1034. The yeas and nays have been ordered.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 47, nays 47.

The amendment (No. 1034) was rejected.

The PRESIDING OFFICER. Under the previous order, the committee substitute amendment, as modified and amended, is agreed to, to the motion to reconsider is considered made and laid upon the table, and the cloture motion on the bill is withdrawn.

Under the previous order, the clerk will read the third time.

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

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill, as modified and amended, pass?

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 93, nays 1, as follows:

[Rollcall Vote No. 157 Leg.]

YEAS—93

Akaka
Baucus
Biden
Bingaman
Boxer
Brown
Cantwell
Cardin
Carper
Clinton

Reed
Reid
Salazar
Sanders
Alexander
Allard
Bennett
Bunning
Burr
Chambliss
Cochran
Coleman
Corzine
Craig
DeMint
Dodd
Brownback
Crapo

Schumer
Snowe
Stabenow
Tester
Dole
Domenici
Ensign
Enzi
Graham
Hatch
Isakson
Kennedy
Kerry
Kyl
Lugar
Martinez
McCaskill
McConnell
Menendez

Whitehouse
Wyden
Martinez
McConnell
Murkowski
Nelson (NE)
Rockefeller
Sessions
Smith
Specter
Sensenbrenner
Saxby
Sessions
Shelby

Wyden

NOT VOTING—6

Brownback
McCrery
Vitter

The amendment (No. 1034) was rejected.

The PRESIDING OFFICER. Under the previous order, the committee substitute amendment, as modified and amended, is agreed to, to the motion to reconsider is considered made and laid upon the table, and the cloture motion on the bill is withdrawn.

Under the previous order, the clerk will read the third time.

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

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill, as modified and amended, pass?

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 93, nays 1, as follows:

[Rollcall Vote No. 157 Leg.]

YEAS—93

Akaka
Baucus
Biden
Bingaman
Boxer
Brown
Cantwell
Cardin
Carper
Clinton

Reed
Reid
Salazar
Sanders
Alexander
Allard
Bennett
Bunning
Burr
Chambliss
Cochran
Coleman
Corzine
Craig
DeMint
Dodd
Brownback
Crapo

Schumer
Snowe
Stabenow
Tester
Dole
Domenici
Ensign
Enzi
Graham
Hatch
Isakson
Kennedy
Kerry
Lugar
Martinez
McCaskill
McConnell
Menendez

Whitehouse
Wyden
Martinez
McConnell
Murkowski
Nelson (NE)
Rockefeller
Sessions
Smith
Specter
Sensenbrenner
Saxby
Sessions
Shelby

Wyden

NOT VOTING—6

Brownback
McCrery
Vitter

The amendment (No. 1034) was rejected.

The PRESIDING OFFICER. Under the previous order, the committee substitute amendment, as modified and amended, is agreed to, to the motion to reconsider is considered made and laid upon the table, and the cloture motion on the bill is withdrawn.

Under the previous order, the clerk will read the third time.

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

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill, as modified and amended, pass?

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 93, nays 1, as follows:

[Rollcall Vote No. 157 Leg.]
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, by 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 during such fiscal year for which the report is made.

"(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

"(c) AUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, 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, the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

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

"(F) the regulated industry.

"(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary—

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

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

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

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

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

"(d) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(d) DEFINITIONS.—For purposes of this part:

"(2) in subsection (d),

"(A) in paragraph (1),

"(i) in subparagraph (A), by striking "§505(b)(1)" and inserting "§505(b), or";

"(ii) in paragraph (2),

"(A) in subparagraph (C), by—

"(i) inserting before the period at the end the following: ""(such as

"(such a list)""; and

"(ii) as subparagraphs (F) and (G), respectively; and

"(B) in subparagraph (D),

"(i) in the matter following subparagraph (D), by—

"(A) in subparagraph (A), by striking ""OR WITHDRAWN BEFORE FILING"" after ""RESEND OF FEE IF APPLICATION REFUSED FOR FILING""; and

"(ii) by inserting before the period at the end the following: ""(II) at least 95 percent of the total number of doses of each compounded positron emission tomography drugs; and

"(F) as subparagraphs (F) and (G), respectively; and

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

"(1) IN GENERAL.—Except as provided in clause (2) of such paragraph, any person who is named as the applicant in an approved human drug application for a compounded positron emission tomography drug shall be subject to such subparagraph (A) unless an exception under subparagraph (C) (or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D); and

"(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

"(A) in the matter preceding subparagraph (A), by striking ""fiscal year 2003"" and inserting ""fiscal year 2008"";

"(B) in subparagraph (A), by striking ""or"" at the end;

"(C) in subparagraph (B), by striking the period at the end and inserting `, or';

"(D) by inserting after subparagraph (B) the following:

"(E) by amending subparagraph [(C) as added by this paragraph], by striking ""fiscal year 2000"" and inserting ""fiscal year 2008"";

"(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

"(A) by striking ""; commercial investigational new drug applications"" and inserting ""; adjusted for changes in review activities""; and

"(B) by inserting before the period at the end the following: ""; the change in the number of commercial investigational new drug applications with a submission during the previous fiscal year (adjusted for changes in review activities); and

"(d) by amending paragraph (1) to read as follows:

"(1) IN GENERAL.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012:

"(f) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(f) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012:

"(f) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012:

"(f) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012:

"(f) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012:
(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—
(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and
(B) by inserting after paragraph (2) the following:
"(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Beginning with fiscal year 2010, the Secretary shall, before making the adjustments under paragraphs (1) and (2), reduce the 50 percent established in subsection (b), if actual costs paid for rent and rent-related expenses are less than $11,721,000. The reduction for this paragraph, if any, shall not exceed the amounts by which costs fell below $11,721,000, and shall not exceed $11,721,000 in any fiscal year.
"(4) FINAL YEAR ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—
(A) in paragraph (4), as redesignated by this subsection—
(i) by striking "2007" each place it appears and inserting "2012"; and
(ii) by striking "2008" and inserting "2013"; and
(B) in paragraph (5), as redesignated by this subsection, by striking "2007".
(d) FEE WaIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379d) is amended—
(1) in paragraph (1), in the matter preceding subparagraph (A), by—
(A) striking "the person who is named as the applicant" after "The Secretary shall grant";
(B) inserting "or that person" after "a waiver from or a reduction of one or more fees assessed"; and
(C) striking "finds" and inserting "determines";
(2) in redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;
(3) by inserting after paragraph (1) the following:
"(2) EVALUATION.—For the purpose of determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant and any affiliate of the applicant.; and
(4) in paragraph (4), as redesignated by this subsection, in subparagraph (A), by inserting before "the amendment was enacted at the end", and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into intrastate commerce.
(e) CREDIBILITY AND AVAILABILITY OF FEES.—
(1) AUTHORIZATION OF APPROPRIATIONS.—
Section 760(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:
"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section such sums as are authorized to be assessed and collected under this section in each of fiscal years 2008 through 2012.
"(2) OFFSET.—Section 760(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:
"(2) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in aggregate appropriation Acts for such fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount otherwise authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.
"(3) CONFORMING AMENDMENTS.—
(A) Section 736(a) (21 U.S.C. 379h(a), as amended by this section, is amended—
(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in aggregate appropriation Acts for such fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount otherwise authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.
"(3) CONFORMING AMENDMENTS.—
(A) Section 736(a) (21 U.S.C. 379h(a), as amended by this section, is amended—
(5) AMOUNTS.—Fees under subsection (a)(1) shall be adjusted to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsection (c).
(6) ADJUSTMENTS.—
(A) IN GENERAL.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice published in the Federal Register for a fiscal year to reflect the greater of—
"(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;
"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in section 5302 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia;
"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.
"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in section 5302 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia;
"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.
The adjustment made each fiscal year by this paragraph shall be added on a cumulative basis to the adjustments made each fiscal year after fiscal year 2008 under this subsection.
(2) **Workload Adjustment.**

(A) In General.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year, and in addition to the fee adjustment pursuant to paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of direct-to-consumer television advertisements for advisory review prior to initial broadcast.

(B) Determination of Workload Adjustment.

(1) In General.—The workload adjustment under this paragraph for a fiscal year shall be determined by the Secretary.

(2) Subsequent Fiscal Years.—Beginning with fiscal year 2009, and in addition to the fee adjustment pursuant to paragraph (1), the fee revenues shall be adjusted further for each fiscal year to reflect changes in the workload of the Secretary with respect to the submission of direct-to-consumer television advertisements for advisory review prior to initial broadcast.

(3) Annual Fee Setting.

(A) Number of Advertisements.—The Secretary shall, 60 days before the start of each fiscal year, publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of direct-to-consumer television advertisements identified pursuant to paragraph (A) of subsection (a) for that fiscal year, excluding allowable previously paid carry over submissions.

(B) Annual Fee.—The Secretary shall, 60 days after the start of each fiscal year, establish, for the next fiscal year, the direct-to-consumer television advertisement advisory review fee established pursuant to paragraph (A) of subsection (a), excluding allowable previously paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue amount established pursuant to paragraph (A), excluding allowable previously paid carry over submissions, by the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue amount established pursuant to paragraph (A), excluding allowable previously paid carry over submissions, by the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions.

(C) Fiscal Year 2008 Fee Limit.—Notwithstanding subsection (b), the fee established under subparagraph (B) for a fiscal year after fiscal year 2008 may not be more than 50 percent of the fee established for the prior fiscal year.

(D) Annual Fee Limit.—Notwithstanding subsection (b), the fee established under subparagraph (B) for a fiscal year after fiscal year 2008 may not be more than 50 percent of the fee established for the prior fiscal year.

(E) Limit.—The total amount of fees obligated for a fiscal year may not exceed the total fee revenues from that fiscal year. Notwithstanding the provisions of this subsection, if in any fiscal year the total fee revenues from prior fiscal years, plus the total fee revenues from that fiscal year, is less than 5 percent of the total fee revenues from that fiscal year, the Secretary may use funds from the reserves established pursuant to subsection (c)(3) to make up the difference between the fee revenue amount established for that fiscal year and the total fee revenues.

(F) Fee Setting.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee, based on the number of direct-to-consumer television advertisements identified by that person pursuant to subsection (c)(3)(A) of the advisory review fee established pursuant to paragraph (B) for that fiscal year. In no case shall the operating reserve fee assessed be less than the amount of fees collected and the Secretary may use funds from the reserves established pursuant to subsection (c)(3) to make up the difference between the fee revenue amount established for that fiscal year and the total fee revenues.

(G) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding any other law or regulation, fees authorized by this section for fiscal year 2008 may not be more than 50 percent of the fee established for the prior fiscal year.

(H) Use of Operating Reserve.—The Secretary may use funds from the reserves established pursuant to paragraph (B) for a fiscal year after fiscal year 2008 to pay the operating reserve fees collected for that fiscal year pursuant to subsection (a)(2) or to pay costs of ending the Program if it is terminated pursuant to subsection (i) or if it is not reauthorized after fiscal year 2012.

(I) Refund of Operating Reserves.—Within 120 days of the end of fiscal year 2012, or if the Program is terminated pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the Program, shall refund all amounts remaining in the operating reserve fund for a fiscal year to a person that paid an operating reserve fee assessment. In no event shall the refund be to any person except for the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

(J) Effect of Failure to Pay Fees.—Notwithstanding any other law or regulation, the fees authorized by this section for a fiscal year after fiscal year 2008 may not be more than 50 percent of the fee established for the prior fiscal year.

(K) Effect of Inadequate Funding of Program.—Beginning in fiscal year 2009, if on November 1 of a fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, operating reserve fees from prior fiscal years, and all fees collected in any prior fiscal years is less than $9,000,000, adjusted for inflation (in accordance with sub-section (c)(1)), the Program shall be terminated, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserve fees reserved to terminate, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the Program, the Secretary shall refund all fees collected in any prior fiscal years, plus the total fee revenues from prior fiscal years, plus the total fee revenues from that fiscal year, plus the total fee revenues from prior fiscal years, and the operating reserves, and then unused advisory review fees from the relevant fiscal years.

(L) Creditability of Adverse Decisions.—The Secretary may use funds from the reserves established pursuant to paragraph (B) for a fiscal year after fiscal year 2008 to pay the operating reserve fees collected for that fiscal year pursuant to subsection (f).

(2) Collections and Appropriation of Fees.

(A) In General.—Fees authorized by this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

(B) Authorization of Appropriations.—There are authorized to be appropriated for fees under this section not less than $6,250,000 for each of fiscal years 2008, 2009, 2010, 2011, and 2012, as adjusted to reflect adjustments in the total fee revenues made under this section, plus amounts collected for the reserve fund under paragraph (B).

(C) Offset.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for a subsequent fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(D) Definitions.—For purposes of this section:

(1) the term ‘advisory review’ means review, and providing information, comments regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

(2) the term ‘carry over submission’ means a submission for an advisory review for which a fee was paid in a fiscal year that is submitted for review in the following fiscal year.

(3) the term ‘direct-to-consumer television advertisement’ means an advertisement for a prescription drug product as defined in section 735(3) intended to be disseminated to the public, without regard to the form of the advertisement, and any affiliate thereof or successor association, and any affiliate thereof or successor in interest.
The term ‘process for the advisory review of prescription drug advertising’ means the activities necessary to review and provide advisory comments on proposed direct-to-consumer television advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the Program that are not necessary for other advisory review activities such as direct-to-consumer television advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.


(7) The term ‘resources allocated for the process for the advisory review of prescription drug advertising’ means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

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

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

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

(D) collection of fees required by such part for a fiscal year with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 106. TECHNICAL AMENDMENT.

(1) The term ‘fiscal year’ means the fiscal year beginning after the date of the enactment of this Act.

(2) The term ‘Program’ means the Program defined in section 739 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11) and includes the Program funded under section 739 of the Food and Drug Administration Amendments Act of 2007, act in collaboration with academic institutions and private entities to—

(i) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

(ii) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012.

(3) The term ‘resubmission’ means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary’s comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

(4) The term ‘submission for advisory review’ means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

SEC. 107. EFFECTIVE DATES.

(a) In general—Except as provided in subsection (b), the amendments made by this title shall take effect October 1, 2007.

(b) Exception.—The amendment made by section 104 of this title shall take effect on the date of enactment of this title.

TITLE II—DRUG SAFETY

SEC. 200. SHORT TITLE.

This title may be cited as the ‘Enhancing Drug Safety and Innovation Act of 2007’.

Subtitle A—Risk Evaluation and Mitigation Strategies

SEC. 201. ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) In general—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is amended by adding at the end the following:

‘‘(B) DATA COLLECTION ACTIVITIES.—

(I) An advisory committee shall—

(aa) provide for adverse event surveillance by collecting and reporting on Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmacy claims data and health insurance claims data);

(cc) provide for adverse event surveillance by monitoring standardized electronic health records and other data;

(dd) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(ee) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

(ff) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012.

(b) DATA COLLECTION ACTIVITIES.—

(I) An advisory committee shall—

(aa) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(bb) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmacy claims data and health insurance claims data);

(cc) provide for adverse event surveillance by monitoring standardized electronic health records and other data;

(dd) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(ee) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting;

(ff) TIMELINESS OF REPORTING.—The procedures developed under clause (i) shall ensure that such data are collected, monitored, and reported to the Secretary in a timely, systematic, and transparent manner, taking into consideration the need for data completeness, coding, cleansing, and transmission.

(gg) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(hh) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(i) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

The Secretary shall, not later than 2 years after the date of enactment of this Act, establish and maintain an active surveillance infrastructure to—

(A) collect and report data for pharmaceutical postmarket risk identification and analysis, in compliance with the regulations promulgated under section 912 of the Public Health Service Act, to provide the risk identification and analysis of the data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary, in order to—

(I) improve the quality and efficiency of postmarket drug safety risk-benefit analysis; and

(II) provide the Secretary with routine access to expertise to study advanced drug safety data; and

(III) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active surveillance infrastructure established under clause (i) is not sufficient to gather data and information relevant to priority drug safety questions, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included within the data used to support the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Safety Datalink or the Vaccine Safety Datalink System and the Vaccine Safety Datalink or successor databases.

(iv) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(v) RISK IDENTIFICATION AND ANALYSIS.—

(I) PURPOSE.—To carry out this paragraph, the Secretary shall establish collaborations with other Government, academic, and private entities, including the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for the risk identification and analysis of the data collected under paragraph (B) and data that is publicly available or is provided by the Secretary, in order to—

(II) mechanism for answering such questions, including through—

(aa) routine active surveillance under subparagraph (B); and

(bb) when such surveillance is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C).

(vi) PROGRAM FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(I) priority drug safety questions; and

(II) mechanisms for answering such questions, including through—

(aa) routine active surveillance under subparagraph (B); and

(bb) when such surveillance is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C).

(vii) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(I) IN GENERAL.—Not later than 180 days after the date of the establishment of the active surveillance infrastructure under subparagraph (B), the Secretary shall establish the procedures under which the Secretary may routinely collaborate with a qualified entity to—
Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(iii) an adverse event occurring from abuse of the drug;
(iv) an adverse event occurring from withdrawal of the drug; and
(v) any failure of expected pharmacological action of the drug;"
“(I) shall be no less frequently than 18 months and 3 years after the drug is initially approved and at a frequency specified in the strategy for subsequent years; and

“(II) determined after the first 3 years if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately mitigated.

“(II) for a drug other than a drug described under clause (I), shall occur at a frequency determined by the Secretary; and

“(III) be increased or reduced in frequency as necessary as provided for in paragraph (7)(B)(v)(VI).”

“4. ADDITIONAL POTENTIAL EVALUATION ELEMENTS FOR RISK EVALUATION AND MITIGATION STRATEGY.—

“(A) RISK EVALUATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional evaluation elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

“(B) POSTAPPROVAL STUDIES.—If the Secretary determines that the reports under subsection (k)(5) of the additional evaluation element as available under subsection (k)(3)(I) (including available complementary approaches under subsection (k)(3)(B)(iv)) will not be sufficient to—

“(i) assess a signal of a serious risk with use of a drug; or

“(ii) identify, based on a review of a demonstratable pattern of use of the drug, unexpected serious risks in a domestic population, including older people, people with comorbidities, pregnant women, or children, the risk evaluation and mitigation strategy for the drug may require that the applicant conduct an appropriate postapproval study, such as a prospective or retrospective observational study, of the drug (which shall include a timeframe specified by the Secretary for completing the study and reporting the results to the Secretary).

“(C) POSTAPPROVAL CLINICAL TRIALS.—If the Secretary determines that the reports under subsection (k)(1), routine active surveillance as available under subsection (k)(3)(I) (including available complementary approaches under subsection (k)(3)(B)(iv)), and a study or studies under subparagraph (B) will likely be inadequate to assess a signal of a serious risk with use of the drug, the drug may require that the applicant conduct an appropriate postapproval clinical trial of the drug (which shall include a timeframe specified by the Secretary for completing the clinical trial and reporting the results to the Secretary) to be included in the clinical trial registry data bank provided for under subsection (k)(3)(B) and section 402 of the Public Health Service Act.

“5. ADDITIONAL POTENTIAL COMMUNICATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

“(A) RISK COMMUNICATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional communication elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

“(B) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop and disseminate a package insert as patient counseling information included in the labeling of the drug that states that the drug is dispensed either or both of the following:

“(I) A Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

“(II) a patient package insert, if the Secretary determines such insert may help mitigate a serious risk listed in the labeling of the drug.

“(C) COMMUNICATION PLAN.—If the Secretary determines a communication plan to health care providers may support implementation of an element of the risk evaluation and mitigation strategy for a drug, such strategy may require that the applicant’s conduct such a plan, which may include—

“(i) sending letters to health care providers;

“(ii) disseminating information about the elements of the strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests); or

“(iii) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

“(D) PRIORITY.—

“(i) IN GENERAL.—If the Secretary determines that preapproval of advertisements is necessary for the inclusion of a true statement describing components of information in brief summary relating to a serious risk listed in the labeling of a drug, or relating to a protocol to ensure the safe use described in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary advertisements of the drug for preapproval not later than 45 days before dissemination of the advertisement.

“(ii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to be submitted under clause (I).

“(E) SPECIFIC DISCLOSURES.—

“(I) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisement elements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug, for preapproval, a risk evaluation and mitigation strategy for a drug requires the specific disclosure to assure the drug is dispensed only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a serious specific risk listed in the labeling of the drug; and

“(ii) for a drug initially approved without elements to assure safe use, other elements under paragraphs (3), (4), and (5) are not sufficient to mitigate such serious risk.

“(F) COMMUNICATION PLAN.—If the Secretary determines that postapproval of advertisements is necessary for the inclusion of a true statement describing components of information in brief summary relating to a serious risk listed in the labeling of a drug, or relating to a protocol to ensure the safe use described in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary advertisements of the drug for preapproval not later than 45 days before dissemination of the advertisement.

“(G) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to be submitted under clause (I).

“(H) SPECIFIC DISCLOSURES.—

“(I) DISCLOSURE OF DATE OF APPROVAL.—If the Secretary determines that advertisements containing the date a drug was approved and at a frequency specified in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug, for preapproval, a risk evaluation and mitigation strategy for the drug requires the specific disclosure to assure the drug is dispensed only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a serious specific risk listed in the labeling of the drug; and

“(ii) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a serious specific risk listed in the labeling of the drug.

“(B) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under subparagraph (A) shall be commensurate with the specific serious risk listed in the labeling of the drug;

“(i) within 30 days of the date on which any element under subparagraph (A) is imposed, post publication of the Secretary with an explanation of how such elements will mitigate the observed safety risk;

“(ii) the elements are not unduly burdensome on patient access to the drug, considering in particular—

“(A) patients with serious or life-threatening diseases or conditions;

“(B) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

“(C) the extent practicable, so as to minimize the burden on the health care delivery system;

“(II) conform with elements to assure safe use for other drugs with similar, serious risks; and

“(II) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs under paragraph (5).

“(C) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under subparagraph (A) shall include 1 or more goals to mitigate a serious specific risk listed in the labeling of the drug and, to mitigate such risk, may require that—

“(I) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a serious specific risk listed in the labeling of the drug; and

“(B) the drug be dispensed to patients only in certain health care settings, such as hospitals;

“(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;
(A) that are described in clauses (i), (iii), or (iv) of subparagraph (C) may include a system through which the applicant is able to take reasonable steps to—

(i) seek input from patients, physicians, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

(ii) work to improve implementation of such elements by such persons.

(E) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration—

(i) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this paragraph may be standardized so as not to be—

(I) unduly burdensome on patient access to the drug; and

(II) to the extent practicable, minimize the burden on the health care delivery system;

(ii) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

(I) assure safe use of the drug;

(II) are not unduly burdensome on patient access to the drug; and

(III) to the extent practicable, minimize the burden on the health care delivery system;

(iii) considering such input and evaluations—

(I) issue or modify agency guidance about how to implement the requirements of this paragraph; and

(II) modify elements under this paragraph for 1 or more drugs, as appropriate.

(F) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this paragraph. The Secretary shall promulgate regulations for how a physician may request the drug under the mechanisms of section 561.

(G) WAIVER IN PUBLIC HEALTH EMERGENCY.—The Secretary may waive any requirement of this paragraph during the period described in section 319(a) of the Public Health Service Act with respect to a qualified clinical trial described under section 319F-1(a)(2) of such Act, to which a requirement under this paragraph has been applied, if the Secretary has—

(i) declared a public health emergency under such section 319; and

(ii) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

(7) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—

(I) VOLUNTARY PROPOSAL.—If there is a signal of a serious risk with a drug, an applicant may include a proposed risk evaluation and mitigation strategy for the drug in an application, including in a supplemental application, for the drug under subsection (b) or section 351 of the Public Health Service Act.

(ii) REQUIRED PROPOSAL.—(I) DETERMINATION NECESSARY TO REQUIRE A PROPOSAL.—(aa) IN GENERAL.—The Secretary may require that the applicant for a drug submit a proposed risk evaluation and mitigation strategy for a drug if the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) determines that, based on a signal of a serious risk with the drug, a risk evaluation and mitigation strategy is necessary to assess such signal or mitigate such serious risk.

(II) NON-DELEGATION.—A determination under item (aa) for a drug shall be made by individuals at or above the level of individual cabinet officials empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(II) CIRCUMSTANCES IN WHICH A PROPOSAL MAY BE REQUIRED.—The applicant shall submit a proposed risk evaluation and mitigation strategy for a drug—

(aa) in response to a letter from the Secretary (acting through such offices) under item (ii)(aa) for a drug; and

(bb) during a public health emergency declared under section 319 of the Public Health Service Act.

(III) APPLICATION.—The applicant shall submit a proposed risk evaluation and mitigation strategy for a drug—

(aa) if the Secretary determines that there may be a cause for action by the Secretary under subsection (e); and

(bb) within 90 days after the Secretary (acting through such offices) under item (ii)(aa) for a drug.

(IV) CONTENT OF ORDER.—An order under subparagraph (A)(ii)(aa) shall describe—

(I) the data or information in the application indicating that an element under paragraph (4), (5), or (6) should be included in a strategy for the drug;

(II) within a timeframe specified by the Secretary, not to be less than 45 days, when the Secretary determines that new safety information indicates that—

(aa) the labeling of the drug should be changed; or

(bb) an element under paragraph (4) or (5) should be included in a strategy for the drug;

(cc) within 90 days after the Secretary determines that new safety information indicates that an element under paragraph (6) should be included in a strategy for the drug;

(d) any action, if any, with respect to the drug;

(II) whether and how such strategy should be included in a strategy for the drug;

(III) whether and how the labeling of the drug should be changed and what elements under paragraphs (4), (5), or (6) should be included in a strategy for the drug;

(IV) CONTENT OF ORDER.—An order under subparagraph (A)(ii)(bb) of clause (I) of paragraph (3) or the Office of the Secretary (acting through the office responsible for postapproval safety with respect to the drug) shall describe—

(I) the data or information in the application indicating that a proposed risk evaluation and mitigation strategy for the drug was required under paragraph (4), (5), or (6) should be included in a strategy for the drug;

(II) whether and how to implement the requirements of this paragraph; and

(III) whether and how to implement the requirements of this paragraph for 1 or more drugs, as appropriate.

(F) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this paragraph. The Secretary shall promulgate regulations for how a physician may request the drug under the mechanisms of section 561.

(G) WAIVER IN PUBLIC HEALTH EMERGENCY.—The Secretary may waive any requirement of this paragraph during the period described in section 319(a) of the Public Health Service Act with respect to a qualified clinical trial described under section 319F-1(a)(2) of such Act, to which a requirement under this paragraph has been applied, if the Secretary has—

(i) declared a public health emergency under such section 319; and

(ii) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

(7) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—

(I) VOLUNTARY PROPOSAL.—If there is a signal of a serious risk with a drug, an applicant may include a proposed risk evaluation and mitigation strategy for the drug in an application, including in a supplemental application, for the drug under subsection (b) or section 351 of the Public Health Service Act.

(ii) REQUIRED PROPOSAL.—(I) DETERMINATION NECESSARY TO REQUIRE A PROPOSAL.—(aa) IN GENERAL.—The Secretary may require that the applicant for a drug submit a
(V) adding, modifying, or removing an element to assure safe use under paragraph (6); or

(VI) modifying the timetable for assessments of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B).

(D) DISCUSSION.—The Secretary (acting through the offices described in subparagraph (A)(ii)) shall initiate discussions of the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B), with the applicant to determine a strategy—

(i) if the proposed strategy or assessment is submitted as part of an application (including a supplemental application) under subparagraph (F) or (G), the Secretary shall issue an action letter or order, which shall be made public, that describes the strategy and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(ii) EFFECTS.—Upon request of the Secretary (acting under subparagraph (A)(ii)(I)) and the applicant, a postmarketing study of the drug may be required, including to meet an action deadline on an application (including a supplemental application); (A)(ii)(II)(aa) or to an assessment of the approved risk evaluation and mitigation strategy for such drugs until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(iii) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B) and if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B).

(i) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B).

(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

(1)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(bbb) may convene a special meeting of the Drug Safety Oversight Board to review the strategy or, more promptly, including to meet an action deadline on an application (including a supplemental application); (A)(ii)(II)(aa) or to an assessment of the approved risk evaluation and mitigation strategy for such drugs until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(iii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

(1)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(bbb) may convene a special meeting of the Drug Safety Oversight Board to review the strategy or, more promptly, including to meet an action deadline on an application (including a supplemental application); (A)(ii)(II)(aa) or an assessment of the risk evaluation and mitigation strategy for such drugs until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(iv) EFFECT ON ACTION DEADLINE.—With respect to the application or supplemental application in which a proposed risk evaluation and mitigation strategy or assessments was submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or in which an assessment of the strategy is submitted under subparagraph (B)(ii), the Secretary shall be considered to have met the action deadline for the action letter on such application if the applicant requests the dispute resolution process as described in this subparagraph and if the Secretary—

(i) has initiated the discussions described under subparagraph (D) by the target date referred to in subparagraph (D)(i); and

(ii) has complied with the requirement of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under clauses (ii), (iii), and (iv), respectively.

(9) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women’s Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under clause (iv) of the Drug Safety Oversight Board.

(10) USE OF ADVISORY COMMITTEES.—The Secretary (acting through the offices described in subparagraph (A)(ii)) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

(i) review a dispute under subparagraph (D)(ii); or

(ii) review a dispute under subparagraph (D)(ii).

(11) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who participated in an administrative appeal under clause (iii)(I) with respect to such drug may serve on the Drug Safety Oversight Board to review a drug or drug group under clause (ii) to review a dispute about the risk evaluation and mitigation strategy for such drug.

(12) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women’s Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under clause (iv) of the Drug Safety Oversight Board.

(13) USE OF ADVISORY COMMITTEES.—The Secretary (acting through the offices described in subparagraph (A)(ii)) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

(i) review a dispute under subparagraph (D)(ii); or

(ii) review a dispute under subparagraph (D)(ii).

(14) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

(i) IN GENERAL.—When a concern about a serious risk of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under subparagraph (II), (III), (IV), or (V) of subparagraph (B)(ii).

(ii) REVIEW OF THE BOARD.—The Secretary (acting under subparagraph (A)(ii)) shall provide a written recommendation on resolution of the dispute to the Secretary.

(15) ACTION BY THE SECRETARY.—

(1) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B) and if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B).

(iii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (i) the Secretary (acting under subparagraph (A)(ii)) shall approve and include the risk evaluation and mitigation strategy for a drug submitted under subparagraph (B)(i) or (A)(ii)(II)(aa) or an assessment of the strategy submitted under subparagraph (B)(i) or (A)(ii)(II)(aa) or to an assessment of the approved risk evaluation and mitigation strategy for such drugs until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight Board under subparagraph (A)(ii), the Board shall resolve disputes under paragraph (1) hereof.

(v) ORDER OF THE BOARD.—Not later than 5 days after such meeting of the Drug Safety Oversight Board, the Board shall provide a written recommendation on resolution of the dispute to the Secretary.

(vi) ACTION BY THE SECRETARY.—

(1) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B) and if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B).

(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

(1)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(bbb) may convene a special meeting of the Drug Safety Oversight Board to review the strategy or, more promptly, including to meet an action deadline on an application (including a supplemental application); (A)(ii)(II)(aa) or to an assessment of the approved risk evaluation and mitigation strategy for such drugs until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

(iii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

(1)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(bbb) may convene a special meeting of the Drug Safety Oversight Board to review the strategy or, more promptly, including to meet an action deadline on an application (including a supplemental application); (A)(ii)(II)(aa) or an assessment of the risk evaluation and mitigation strategy under subparagraph (B)(ii) or under subparagraph (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described under subparagraph (B).

(iv) EFFECT ON ACTION DEADLINE.—With respect to the application or supplemental application in which a proposed risk evaluation and mitigation strategy or assessment was submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or in which an assessment of the strategy is submitted under subparagraph (B)(ii), the Secretary shall be considered to have met the action deadline for the action letter on such application if the applicant requests the dispute resolution process as described in this subparagraph and if the Secretary—

(i) has initiated the discussions described under subparagraph (D) by the target date referred to in subparagraph (D)(i); and

(ii) has complied with the requirement of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under clauses (ii), (iii), and (iv), respectively.

(v) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who participated in an administrative appeal under clause (iii)(I) with respect to such drug may serve on the Drug Safety Oversight Board to review a drug or drug group under clause (ii) to review a dispute about the risk evaluation and mitigation strategy for such drug.
(I) 1 or more meetings of the applicants for such drugs;
(II) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under subparagraph (H); or
(III) 1 or more workshops of scientific experts and other stakeholders.

(4) After considering the discussions from any meetings under clause (I), the Secretary may—
(I) announce in the Federal Register a planning document, a cost-benefit analysis, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class that as a trade secret is entitled to protection; and
(II) seek public comment about such action; and
(III) after seeking such comment, issue an order under subsection (D) that shall—
(J) INTERNATIONAL COORDINATION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may coordinate the timetable for submission of assessments under paragraph (3)(B), a study to an application for a drug.

(K) EFFECT.—Use of the processes described in paragraphs (I) and (J) shall not delay action on a supplemental application or a supplement to an application for a drug.

(L) NO EFFECT ON LABELING CHANGES THAT DO NOT REQUIRE PREAPPROVAL.—In the case of a labeling change to which section 314.70 of title 21, Code of Federal Regulations (or any successor regulation), applies for which the submission of a supplemental application is not required or for which distribution of the drug involved may commence upon the receipt by the Secretary of a supplemental application for the change, the submission of an assessment of the approved risk evaluation and mitigation strategy for the drug under this subsection is not required.

(8) DRUG SAFETY OVERSIGHT BOARD.—
(I) ANNOUNCE IN THE FEDERAL REGISTER A PLANNING DOCUMENT.—The Secretary shall—
(a)组成由科学家和健康护理实践人员组成的公共卫生系统;"和"系统);"和"系统);"
(b) conduct, or contract for, any postapproval study required under subsection (o)(4)(B) for the applicable listed drug.

(III) shall conduct, or contract for, any postapproval study required under subsection (o)(3)(A) for the applicable listed drug.

(IV) in order to minimize the burden on the health care delivery system of different elements to assure safe use for the drug approved under this subsection and the applicable listed drug, may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such drug may use an element of the aspects to assure safe use, if required under subsection (o)(6) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.
Section 355(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)) is amended—
(1) in subsection (a)(2), by adding at the end the following:
(II) make a labeling change required by such strategy after the Secretary has approved a risk evaluation and mitigation strategy if required under subsection (o)(3)(A) for the applicable listed drug.

(2) ADDITIONAL FEE REVENUE FOR DRUG SAFETY.—

(1) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 505 of such Act, after approval, may be subject to only the following elements of the approved risk evaluation and mitigation strategy if required under subsection (o) for the applicable listed drug:

(1) Labeling, as required under subsection (o)(3)(A) for the applicable listed drug.

(II) A Medication Guide or patient package insert, if required under subsection (o)(5)(A) for the applicable listed drug.

(III) Prereview of advertising, if required under subsection (o)(5)(D) for the applicable listed drug.

(IV) Specific disclosures in advertising, if required under subsection (o)(5)(E) for the applicable listed drug.

(V) Elements to assure safe use, if required under subsection (o)(6) for the applicable listed drug, except that such drug may be a different, comparable aspect of such elements as are necessary to assure safe use of such drug if—
(aa) the corresponding aspect of the element to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection; and
(bb) the applicant certifies that it has obtained a license for use of such aspect of the elements to assure safe use for the applicable listed drug.

(II) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under this subsection, the Secretary—
(I) shall undertake any communication plan to health care providers required under section (o)(5)(C) for the applicable listed drug.

(II) shall conduct, or contract for, any postapproval study required under subsection (o)(4)(B) for the applicable listed drug.

(III) shall inform the applicant for a drug approved under this subsection if the approved risk evaluation and mitigation strategy for the applicable listed drug is modified; and

(IV) in order to minimize the burden on the health care delivery system of different elements to assure safe use for the drug approved under this subsection and the applicable listed drug, may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such drug may use an element of the aspects to assure safe use, if required under subsection (o)(6) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.

SEC. 207. RESOURCES.
(a) USE OF FEE.—Subparagraph (F) of section 735(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d(6)), as amended by section 103, is amended—
(I) in clause (ii), by striking "systems;" and
(ii) inserting "systems;"

(II) in clause (iii), by striking "bases;" and
(iii) inserting "bases;" and;

(III) by adding at the end the following:
(iv) reviewing, implementing, and enforcing compliance with risk evaluation and mitigation strategies.

(b) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—Section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), as amended by section 103, is amended by—
(I) striking the subsection designation and all that follows through "—Except" and inserting the following:

(II) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Except;

(2) adding at the end the following:
(III) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

(A) IN GENERAL.—Subject to subparagraph (C), in each of fiscal years 2008 through 2012, the amount described in paragraph (1) shall be reduced by subtracting the amount determined under subparagraph (A) for $392,783,000.
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“(B) AMOUNT DETERMINED.—For any fiscal year 2008 through 2012, the amount determined under this subparagraph is the sum of—

(1) $302,783,000; plus

(2) the amount equal to—

(i) $82,783,000; for fiscal year 2008, $25,000,000; and

(ii) for fiscal year 2009, $35,000,000; and

(iii) for fiscal year 2011, $35,000,000; and

(3) $35,000,000; plus

(ii) the amount equal to one-fifth of the excess (if any) of item (bb), provided that—

(a) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of fees appropriated for such fiscal year, adjusted as provided under subsection (c)(1)); and

(b) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1)); and

(II) for any fiscal year 2008 through 2012, subclause (II) shall be applied by substituting

(i) request in writing that the holder submit a supplement to an application under section 505 of this Act or to a license under section 351 of the Public Health Service Act (referred to in this section as a ‘holder’) shall promptly notify the Secretary if the holder believes that new safety information the holder believes should be included in the labeling of the drug. The Secretary shall promptly notify the holder if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug.

(2) DISCUSSION REGARDING LABELING CHANGES.—Following notification pursuant to paragraph (1), the Secretary and holder shall initiate discussions of the new safety information in order to reach agreement on whether the labeling of the drug should be modified to reflect the new safety information and, if so, on the contents of such labeling changes.

(3) SUPPLEMENT.—If the Secretary determines that there is reasonable scientific evidence that an adverse event is associated with use of the drug, the Secretary may request the holder to submit a supplement to an application under section 505 of this Act or to a license under section 351 of the Public Health Service Act (referred to in this section as a ‘holder labeling change’). If the Secretary determines that new safety labeling change is necessary or appropriate based upon the new safety information, the Secretary shall notify the holder of this determination in writing.

(4) LABEL TO BE INCLUDED.—

(1) IN GENERAL.—The holder shall submit a supplement whenever the holder seeks, either at the holder’s own initiative or at the request of the Secretary, to make a safety labeling change.

(2) NONACCELERATED PROCESS.—Unless the accelerated labeling review process described in subsection (b) is initiated, any supplement proposing a safety labeling change shall be reviewed and acted upon by the Secretary not later than 30 days after the date the Secretary receives the supplement. Until the Secretary acts on such a supplement proposing a safety labeling change, the existing approved labeling shall remain in effect and be displayed without change.

(3) NEW SAFETY INFORMATION.—Nothing in this section shall prohibit the Secretary from informing health care professionals or the public about new safety information prior to approval of a supplement proposing a safety labeling change.

(4) ACCELERATED LABELING REVIEW PROCESS.—An accelerated labeling review process shall be available to resolve disagreements in a timely manner between the Secretary and a holder about the need for, or content of, a safety labeling change.

(A) REQUEST TO INITIATE ACCELERATED PROCESS.—The accelerated labeling review process shall be initiated upon the written request of the holder.

(B) REQUEST TO INITIATE ACCELERATED PROCESS.—The accelerated labeling review process shall be initiated upon the written request of the holder.

(C) LIMITATION.—This paragraph shall not apply for any fiscal year if the amount determined under subparagraph (B)(ii) is less than $25,000,000.

(C) STRATEGIC PLAN FOR INFORMATION TECHNOLOGY.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology infrastructure, including systems for data collection, access to data in external health information systems, data mining capabilities, personnel, and personnel training programs, needed by the Food and Drug Administration to—

(A) comply with the requirements of this subtitle (and the amendments made by this subtitle); and

(B) achieve interoperability within and among the centers of the Food and Drug Administration and between the Food and Drug Administration and product application sponsors;

(C) standardize electronic health records;

(D) implement routine active surveillance under section 505(k)(3) (including complementary approaches under subsection (c) of such section) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act; and

(E) communicate drug safety information to physicians and other health care providers;

(2) an assessment of the extent to which the current information technology assets of the Federal Government are insufficient to meet the needs assessments under paragraph (1); and

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessments under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.
Safety Oversight Board, the written recommendation of the Drug Safety Oversight Board shall be considered the order of the Secretary under this paragraph.

"(C) The Secretary’s authority under this paragraph shall not be delegated to an individual below the level of the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, of the Food and Drug Administration.

"(D) MISHANDLING.—If the holder, not later than 10 days after receiving an order under subparagraph (A) or (B) of paragraph (5), does not agree to make a safety labeling change ordered by the Secretary, the Secretary may deem the drug that is the subject of the request to be misbranded.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.

"(B) CONFORMING AMENDMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 205, is further amended by adding at the end the following:

"(7) If a drug is the subject of an order under subparagraph (A) or (B) of paragraph (5), the Secretary may deem the drug that is the subject of the order to be misbranded.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.

"(B) CONFORMING AMENDMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 205, is further amended by adding at the end the following:

"(7) If a drug is the subject of an order under subparagraph (A) or (B) of paragraph (5), the Secretary may deem the drug that is the subject of the order to be misbranded.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.

"SEC. 209. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 251, is amended by adding at the end the following:

"(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet website by outside entities to help facilitate the dissemination of the information available to facilitate the efficient flow of information to patients and providers.

"(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet website by outside entities to help facilitate the dissemination of the information available to facilitate the efficient flow of information to patients and providers.

"(5) PROVISION OF DATA TO PHARMACEUTICAL MANUFACTURERS.—(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval received under section 520 of title 5, United States Code, for any other drug or biological product.

"(2) DUTIES OF COMMITTEE.—The Committee shall advise the Secretary to:

"(1) evaluate the food and drug authority’s proposals for the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved by the Secretary under this section or licensed under such section 351;

"(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet website;

"(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

"(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet website.

"(B) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Risk Communication, to include an expert in the field of risk communication, experts on the risks associated with the use of drugs, experts on the risks of drug misuse, experts on the role of the media in risk communication, experts on the role of the food and drug administration, and representatives of patient, consumer, and health professional organizations.

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(4) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

(1) IN GENERAL.—The Secretary shall partner with professional medical societies, scientific societies, universities, medical schools, academia, medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers and the public and to coordinate efforts among emerging postmarket drug risks.

(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

(A) foster diversity among physicians in terms of practice, affinity for technology, and focus; and

(B) include the use of existing communication systems, including electronic communications, in place at the Food and Drug Administration.”

SEC. 212. REFERRAL TO ADVISORY COMMITTEE. Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 202, is further amended by adding at the end the following:

“(p) REFERRAL TO ADVISORY COMMITTEE.—

(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any active ingredient) which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described under such paragraph may occur within 1 year after approval of such a drug if—

(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

(B) the Secretary determines that it would be beneficial to the public health.”

SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE. (a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary shall prepare a report responding to the 2006 report of the Institute of Medicine entitled “The Future of Drug Safety—Promoting and Protecting the Health of the Public.”

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described in such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under paragraph (7) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for post-approval safety with respect to the drug act together to assess, implement, and ensure compliance with the requirements of such section 505(o).

SEC. 214. EFFECTIVE DATE AND APPLICABILITY. (a) EFFECTIVE DATE.—

(1) GENERAL.—Except as provided in paragraph (2), this subtitle shall take effect 180 days after the date of enactment of this title.

(2) USER FEES.—The amendments made by subsections (a) through (c) of section 207 shall take effect on October 1, 2007.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have an approved risk evaluation and mitigation strategy under section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) if there are no postmarket restrictions of the type specified in this subtitle on distribution or use—

(A) required under section 314.520 or section 801.62 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) RISK EVALUATION AND MITIGATION STRATEGY.—The approved risk evaluation and mitigation strategy deemed in effect for a drug under paragraph (1) shall consist of the elements described in subparagraphs (A) and (B) of paragraph (5) of such section 505(o) and any other additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(3) NOTIFICATION.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1)—

(A) that such drug has risks that the applicant has agreed to have an approved risk evaluation and mitigation strategy pursuant to such paragraph; and

(B) of the date, which, unless a safety issue with the drug arises to earlier than 6 months after the applicant is so notified, by which the applicant shall submit to the Secretary an assessment of such approved strategy under paragraph (7)(B) of such section 505(o), except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant so notifies the Secretary.

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement under paragraph (2) until—

(A) the Secretary has completed review of, and acted on, the first assessment of strategic such strategy under such section 505(o).

(c) NO EFFECT ON VETERINARY MEDICINE.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall not apply to the Committee established under section 512(a)(5) of such Act.

(2) USER FEES.—The amendments made by this subtitle, and the amendments made by title restrictions on distribution or use—

(a) IN GENERAL.—Chapter VII of the Federal Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

“Subtitle A—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION. (a) IN GENERAL.—Chapter VII of the Federal Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

“Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 222. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 223. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 224. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 225. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 226. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 227. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

SEC. 228. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

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SEC. 270. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

(1) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this chapter as the ‘Foundation’), shall be an agency or instrumentality of the United States Government.

(2) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to advance the public health by providing objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency’s public health mission.

(3) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(1) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this chapter as the ‘Board’), which shall be composed of ex officio and appointed members in accordance with this subsection.

All
appointed members of the Board shall be voting members.  

“(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:  

“(i) The Commissioner.  

“(ii) The Director of the National Institutes of Health.  

“(iii) The Director of the Centers for Disease Control and Prevention.  

“(iv) The Director of the Agency for Healthcare Research and Quality.  

“(C) REQUIRED REPRESENTATIVES.—  

“(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote of the Board, select from a list of candidates to be provided by the National Academy of Sciences.  

“Of such appointed members—  

“(I) 3 shall be representatives of Government agencies, including the Food and Drug Administration and the National Institutes of Health;  

“(II) 2 shall be representatives of Government agencies, including the Food and Drug Administration;  

“(III) 3 shall be representatives of Government agencies, including the Food and Drug Administration and the National Institutes of Health;  

“(IV) 2 shall be representatives of patient or consumer advocacy organizations; and  

“(V) 1 shall be a representative of health care providers.  

“(ii) REQUIREMENT.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.  

“(D) INITIAL MEETING.—  

“(i) IN GENERAL.—Not later than 30 days after the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—  

“(I) incorporate the Foundation; and  

“(II) appoint the members of the Board in accordance with subparagraph (C).  

“(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.  

“(iii) REAL OR PERSONAL PROPERTY OF THE BOARD.—The Board shall—  

“(A) establish bylaws for the Foundation that—  

“(1) are published in the Federal Register and available for public comment;  

“(2) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;  

“(3) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of gifts, grants, and legacies made to the Foundation;  

“(4) establish policies for the selection of officers, employees, agents, and contractors of the Foundation;  

“(5) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;  

“(6) establish licensing, distribution, and publication policies that support the widest and least restrictive use of the public information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (b) and (d) of this section; and  

“(7) include charging cost-based fees for published material produced by the Foundation;  

“(v) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;  

“(vi) specify a cap on administrative expenses, including travel, subsistence, and contract, or cooperative agreement from the Foundation;  

“(vii) establish policies for the execution of memoranda of understanding and cooperation agreements between the Foundation and other entities, including the Food and Drug Administration;  

“(viii) establish policies for funding training fellowships, with the foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;  

“(ix) specify a process for annual Board review of the operations of the Foundation; and  

“(x) appoint the members of the Board as are necessary to carry out its powers, duties, and functions.  

“(F) TERMS AND VACANCIES.—  

“(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices of the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.  

“(B) VACANCY.—Any vacancy in the membership of the Board—  

“(i) shall not affect the power of the remaining members to execute the duties of the Board; and  

“(ii) shall be filled by appointment of the appointed members described in paragraph (1)(C) by majority vote.  

“(C) PARTIAL TERM.—If a member of the Board does not serve the term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual so appointed.  

“(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.  

“(E) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.  

“(F) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.  

“(G) EXECUTIVE DIRECTOR.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.  

“(H) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on the Board and carry out the functions of the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.  

“(I) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—  

“(I) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Such each employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the Federal Government. If such employee is detailed and those of the Foundation.
(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees of the Federal agencies with or without reimbursement to those agencies.

(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner shall retain the uncommitted services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

(C) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmeti- c act (21 U.S.C. 379(b)) is amended by adding at the end the following: “Any such follow-
sed persons under this section or under section 776(d)(2)(A)(ix) may include provision by such scientists and phy-

리는 does determine

appropriate. Such scientists and phys-

icians shall subject to all legal and eth-

trical requirements applicable to o

of the Department of Health and Human Services.”.

SEC. 222. OFFICE OF THE CHIEF SCIENTIST.

Chapter WX. Food, Drug, and Cosmeti- c act (21 U.S.C. 391 et. seq.) is amended by adding at the end the following:

SECTION 910. OFFICE OF THE CHIEF SCIENTIST.

(a) Establishment.—The Secretary shall establish an office to be known as the Office of the Chief Scientist. The Sec-

(b) Duties of the Office.—The Office of the Chief Scientist shall:

(1) oversee, coordinate, and ensure qual-

ity and regulatory focus of the intramural research programs of the Food and Drug Ad-

(2) track and, to the extent necessary, co-

ordinate intramural research awards made by each center of the Administration or scientific center of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

(3) develop and advocate for a budget to support intramural research;

(4) develop a peer review process by which intramural research can be evaluated; and

(5) identify and solicit intramural re-

search proposals from across the Food and Drug Administration and an executive board composed of employees of the Admin-

istration that shall include—

(A) representatives of each of the centers and the science-based offices within the Of-

ce of the Commissioner; and

(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health.

Subtitle C—Clinical Trials

SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by—

(1) redesignating subsections (i) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the fol-

lowing:

(1) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(1) DEFINITIONS.—REQUIREMENT.—

(A) DEFINITIONS.—In this subsection:

(I) APPLICABLE DEVICE CLINICAL TRIAL.—

The term ‘applicable device clinical trial’ means—

(1) a prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an applica-

ion under section 515 or 520(m), or a re-

port under section 510(k), of the Federal Food, Drug, and Cosmeti- c act (other than a limited device regulation) that includes essential information used to refine the device or design a piv-

otal trial and that is not intended to deter-

mine safety and effectiveness of a device; and

(II) if no sponsor exists, the grantee, con-

tractor, or awardee for a trial funded by a Federal agency or the principal investigator of such clinical trial if so designated by such spon-

or;

(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—

(1) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a platform to track subsequent progress of clinical trials, the Secretary, acting through the Di-

ector of NIH, shall expand, in accordance with this subsection, the registry of the data bank described under sub-

section (i)(3)(A) (referred to in this sub-

section as the ‘registry data bank’). The Di-

ector of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(II) CONTENT.—Not later than 18 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry of the data bank to include information on the registry data bank of clinical trial information for applicable drug clinical trials and applicable device clinical trials that—

(i) conforms to the Federal Clinical Trials Registry Platform trial registration data set of the World Health Organization;
(II) during the period in which such clinical trial was conducted.

(III) after the drug involved is approved or cleared.

(IV) after a clinical trial that is not an expanded access trial in a premarket application, premarket approval application, or license application, respectively, if any.

(V) not later than 30 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the needs of different populations of users of the registry data bank.

(VI) the clinical trials results information data elements prescribed under subsection (c)(2).

(VII) the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Department of Veterans Affairs, and the Office of the Assistant Secretary for Preparedness and Response, in consultation with the Food and Drug Administration, the National Institutes of Health, the Department of Veterans Affairs, the Department of Defense, and other Federal agencies.

(VIII) such clinical trials results information data elements prescribed under section 506 of the Food and Drug Administration Act.
the possible impacts on publication of manuscripts based on the clinical trial;

“(IV) a standard procedure for the verification of clinical trial results information, including that true text data elements are non-promotional; and

“(V) an implementation plan for the prompt inclusion of clinical trials results information in the registry data bank.

“(D) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements and clinical trial results of the World Health Organization when promulgating the regulations under subparagraph (C).

“(E) TRUTHFUL CLINICAL TRIAL INFORMATION.—

“(i) In General.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

“(ii) Effect.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

“(F) WAIVERS REGARDING CERTAIN CLINICAL TRIAL INFORMATION.—The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

“(G) GRANTS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

“(i) In General.—No Federal agency may release funds under a research grant to an awardee who has not complied with paragraph (2) for any applicable drug clinical trial or applicable device clinical trial for which the responsible party has made submission required under subparagraph (A).

“(ii) Grants from Certain Federal AGENCIES.—If an applicable drug clinical trial or applicable device clinical trial is funded in whole or in part by Federal Agency for Drug and Administration, National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veteran Affairs, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

“(H) COORDINATION AND COMPLIANCE.—

“(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

“(1) IN GENERAL.—No Federal agency may release funds under a research grant to an awardee that consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable drug clinical trial or an applicable device clinical trial under paragraph (1); and

“(2) EFFECT.—If the Secretary determines that such research is an applicable drug clinical trial or an applicable device clinical trial, such research under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subparagraph have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

“(B) CERTIFICATION TO ACCOMPANY DRUG, HUMANICRODUCT, AND DEVICE SUBMISSIONS.—A certification that an applica-

tion under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this paragraph have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

“(C) VERIFICATION OF SUBMISSION PRIOR TO POSTING.—In the case of clinical trial information that is submitted under paragraph (2), but is not made publicly available pending regulatory review or clearance, as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed scientific journals to confirm that such clinical trial information has been submitted but has not yet been posted.

“(D) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

“(1) IN GENERAL.—Nothing in this subsection or section 552 of title 5, United States Code shall require the Secretary to publicly disclose, from any record or source other than the registry data bank, information described in this subparagraph that has been submitted but has not yet been posted.

“(2) INFORMATION DESCRIBED.—Information described in this subparagraph is—

“'(i) information submitted to the Director of NIH under this subsection, or information that is submitted under paragraph (2), by a certification that all applicable requirements of this subsection have been met.

“(ii) not otherwise publicly available, including because it is protected from disclosure under section 502 of title 5, United States Code.

“(E) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

“(F) COMFORMING AMENDMENTS.—

“(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“'(j)(1) The failure to submit the certification required under section 402(j)(4)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

“(2) The submission of clinical trial information under subsection (i) or (j) of section 402 of the Public Health Service Act that is promotional or false in misleading in any particular under paragraph (2) or (3) of such subsection.

“(G) CIVIL MONEY PENALTIES.—Section 353(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), as amended by section 285, is further amended by—

“(1) redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively;

“(2) inserting after paragraph (3) the following:

“(4) Any person who violates section 301(j)(4) shall be subject to a civil monetary penalty of not more than $10,000 for the first violation, and not more than $20,000 for each subsequent violation.

“(H) IN GENERAL.—

“(1) Rule of Construction.—The fact of submission of clinical trial information, if submitted in compliance with subsection (i) or (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not
included in the official labeling of the approved drug or device shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use or a new intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information under such subsections (i) and (j), if submitted in compliance with such subsections, shall not be considered as labeling, adulteration, or misbranding of a drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(D) ANNOUNCEMENT OF EFFECTIVE DATE OF FUNDING RESTRICTIONS.—

(1) TRANSITION RULE FOR CLINICAL TRIALS INITIATED PRIOR TO EXPANSION OF REGISTRY DATA BANK.—The responsible party (as defined in paragraph (1) of section 402(j)(3) of the Public Health Service Act (as added by this section)) for an applicable drug clinical trial or applicable device clinical trial (as defined under such paragraph (1) that is initiated after the date of enactment of this subtitle and before the effective date of the regulations promulgated under paragraph (2) of such section 402(j)(3)) shall submit required clinical trial information under such section not later than 120 days after such effective date.

(2) FUNDING RESTRICTIONS.—Subparagraph (A) of paragraph (4) of such section 402(j)(3) shall not take effect 210 days after the effective date of the regulations promulgated under paragraph (2) of such section 402(j)(3).

(E) EFFECTIVE DATE.—

(1) IN GENERAL.—Beginning 90 days after the date of enactment of this title, the Secretary shall notify the Food and Drug Administration of the date on which the regulations apply.

(2) RULEMAKING.—

(A) IN GENERAL.—Except as provided in subparagraph (B), subsection (c)(1) shall become effective on the date on which the regulations promulgated under paragraph (2) of such section 402(j)(3) that is initiated after the date of enactment of this title and before the effective date of such regulations issued under subparagraph (A) of paragraph (2) of such subsection, shall submit clinical trial information under such paragraph (2).

(B) EXCEPTION.—Subsection (c)(1) shall apply with respect to any clinical trial for which the registry data bank includes links to results information, as provided for under section 402(j)(3)(A) of such Act, as added by this section.

Subtitle D—Conflicts of Interest

SEC. 241. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

"SEC. 711. CONFLICTS OF INTEREST.

"(a) DEFINITIONS.—For purposes of this section:

"(1) ADVISORY COMMITTEE.—The term ‘advisory committee’ means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding the activities of the Food and Drug Administration.

"(2) FINANCIAL INTEREST.—The term ‘financial interest’ means a financial interest under section 208(a) of title 18, United States Code.

"(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

"(1) RECRUITMENT.—

"(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary shall carry out informational and recruitment activities for purposes of recruiting individuals to serve as advisory committee members. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies.

"(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

"(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

"(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

"(iii) developing a method through which an entity receiving National Institutes of Health funding can identify a person who the Food and Drug Administration can contact regarding the availability of individuals to serve on advisory committees.

"(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to section 18 U.S.C. 208(a)(1)(A) of title 18, United States Code, for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in subsection (c)(5) of this section for each meeting of each advisory committee.

"(3) WAIVER.—The Secretary may grant a waiver under paragraph (3) if the Secretary finds that the disclosure of the financial interest that becomes known to the Secretary after the date of enactment of this title will serve an important public interest, including alleviating a conflict of interest, would not prove practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

"(4) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 52 U.S.C. (also known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration—

"(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver relates,

"(ii) the reasons of the Secretary for such determination, certification, or waiver,

"(iii) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2) of such subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 52 U.S.C. (also known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration—

"(1) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver relates,

"(2) the reasons of the Secretary for such determination, certification, or waiver,

"(3) with respect to such year, the number of vacancies of the advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

"(4) with respect to such year, the aggregate number of disclosures required under subsection (c)(5) for each meeting of each advisory committee and the percentage of individuals who received such disclosure and who did not apply who served on such committee for each such meeting.

"(5) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

"(6) PERIODIC REVIEW OF GUIDANCE.—Not less frequently than every calendar year, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest
waiver determinations with respect to advisory committees and update such guidance as necessary.

(b) CONFORMING AMENDMENT.—Section 502(n)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by—

(1) striking paragraph (4); and

(2) inserting paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.


SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

“(q) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

“(1) IN GENERAL.—(A) PUBLICATION.—The Commissioner shall—

“(i) not later than 9 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs, including the name of the brand company manufacturer, and the date the authorized generic drug entered the market; and

“(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

“(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Indian Health Service, any time the Commissioner updates the information described in subparagraph (A).

“(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 2009.

“(3) AUTHORIZED GENERIC DRUG.—In this section, the term ‘authorized generic drug’ means a listed drug (as that term is used in subsection (c)(1)(B)) and a product identified by the Commissioner as a qualified generic drug.

“(a) ASSUMPTIONS.—(1) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (ii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

“(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED IN THIS CLASS.—(1) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in this clause.

“(i) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

“(ii) REQUIREMENTS.—(A) has been approved under subsection (a) of section 505 of this Act (as in effect before November 21, 1997).

“(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an application described in subparagraph (B)(i) to the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

“(B) LIMITATIONS.—(1) IN GENERAL.—Paragraphs (1)(A) and (2)(A) shall not apply to any condition of use for which the drug referred to in subparagraph (B)(i) is approved.

“(2) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A) shall not apply to any condition of use for which the drug referred to in subparagraph (B)(i) is approved.

“(3) USE IN INSTITUTIONS.—(1) IN GENERAL.—Paragraphs (1)(A) and (2)(A) shall not be construed to include a listed drug used in institutions, product code, labeler code, trade name, or trade mark than the listed drug.

“(B) INCLUSION.—The Commissioner shall—

“(i) not later than 9 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs, including the name of the brand company manufacturer, and the date the authorized generic drug entered the market; and

“(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

“(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Indian Health Service, any time the Commissioner updates the information described in subparagraph (A).

“(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 2009.

“(3) AUTHORIZED GENERIC DRUG.—In this section, the term ‘authorized generic drug’ means a listed drug (as that term is used in subsection (c)(1)(B)) and a product identified by the Commissioner as a qualified generic drug.

“(a) ASSUMPTIONS.—(1) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (ii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

“(ii) REQUIREMENTS.—(A) has been approved under subsection (a) of section 505 of this Act (as in effect before November 21, 1997).

“(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an application described in subparagraph (B)(i) to the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

“(B) LIMITATIONS.—(1) IN GENERAL.—Paragraphs (1)(A) and (2)(A) shall not apply to any condition of use for which the drug referred to in subparagraph (B)(i) is approved.

“(2) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A) shall not apply to any condition of use for which the drug referred to in subparagraph (B)(i) is approved.

“(3) USE IN INSTITUTIONS.—(1) IN GENERAL.—Paragraphs (1)(A) and (2)(A) shall not be construed to include a listed drug used in institutions, product code, labeler code, trade name, or trade mark than the listed drug.

“SEC. 252. MEDICAL MARIJUANA.

The Secretary shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements and penalties of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

Subtitle F—Antibiotic Access and Innovation

SEC. 261. INCENTIVES FOR THE DEVELOPMENT OF AN ANTIBIOTIC DRUG SUBMITTED BEFORE NOVEMBER 21, 1997.—

“(a) PUBLIC MEETING.—(1) IN GENERAL.—The Commissioner of Food and Drugs shall convene a public meeting, if appropriate, regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360aa(c)) or other incentives for development.

“(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360aa(c)) is amended to read as follows:

“(c) For grants and contracts under subsection (a) there are authorized to be appropriated—

“(1) such sums as have been appropriated for fiscal year 2007; and

“(2) $35,000,000 for each of fiscal years 2008 through 2012.

“SEC. 262. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIBIOMICS.

“(a) DEFINITION.—In this section, the term ‘clinically susceptible concentrations’ means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

“(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the ‘Secretary’), through the Commissioner of Food and Drugs, shall identify and periodically update clinically susceptible concentrations.

“(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available within 30 days of the date of identification and any update under this section.

“SEC. 263. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANIONIERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

“(1) CERTAIN DRUGS CONTAINING SINGLE ENANIONIERS.—

“(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

“(A) the single enantiomer has not been previously approved except in the approved racemic drug; and
(ii) the application submitted under subsection (b) for such non-racemic drug—

(1) includes full reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant; and

(2) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved non-racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve any such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(A) IN GENERAL.—For purposes of this subsection, the term ‘therapeutic category’ means a therapeutic category identified in the United States Pharmacopoeia pursuant to section 1860D–4(b)(3)(B)(ii) of the Social Security Act and as in effect on the date of enactment of this subsection.

(2) FISCAL REPORT.—For fiscal years 2008 through 2012—

(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that performs manufacturing changes to medical devices that are class II or class III devices, that may be reprocessed to achieve the same level of performance and safety as when the device was originally manufactured, shall—

(a) in paragraph (1) be striking ‘‘April of’’ and inserting ‘‘October of’’; and

(b) by striking ‘‘April 2002’’ and inserting ‘‘October 2002’’.

(5) in paragraph (9), as redesignated by paragraph (2), following:

(13) The term ‘‘establishment’’ means an establishment that performs manufacturing operations on a single-use device.

(6) by inserting after paragraph (9), as redesignated by paragraph (2), the following:

(10) The term ‘‘person’’ includes an affiliate of such person.

(7) by adding at the end the following:

(12) The term ‘‘establishment’’ subject to a registration fee means an establishment required to register under section 510(a) of title 21, Code of Federal Regulations, usually referred to as ‘‘annual reports’’:

(8) in paragraph (9), as redesignated by paragraph (2), following:

(11) The term ‘‘establishment’’ subject to a registration fee means an establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.

(9) in paragraph (9), as redesignated by paragraph (2), following:

(10) The term ‘‘registration fee’’ means a fee assessed by the Secretary to the Chairman of the Committee on Ways and Means of the House of Representatives, of the fees collected during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in the report and for any other purposes that the Administrator deems appropriate.

(11) in paragraph (9), as redesignated by paragraph (2), following:

(11) The term ‘‘registration fee’’ means a fee assessed by the Secretary to the Chairman of the Committee on Ways and Means of the House of Representatives, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in the report and for any other purposes that the Administrator deems appropriate.

(12) The term ‘‘registration fee’’ means a fee assessed by the Secretary to the Chairman of the Committee on Ways and Means of the House of Representatives, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in the report and for any other purposes that the Administrator deems appropriate.

(13) The term ‘‘registration fee’’ means a fee assessed by the Secretary to the Chairman of the Committee on Ways and Means of the House of Representatives, of the fees collected during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration, of the fees collected during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in the report and for any other purposes that the Administrator deems appropriate.

This title may be cited as the ‘‘Medical Device User Fee Amendments of 2007’’.
SEC. 305. AUTHORITY TO ASSESS AND USE DEVICE FEES.

Section 738 (21 U.S.C. 373b) is amended—

(1) in subsection (a)—

(A) in paragraph (2) (i) in the header, by inserting "and, and annual fee for periodic reporting concerning a class III device," after "FEF";

(B) in paragraph (3) (I) in subparagraph (C)—

(i) in the header, by inserting "75 percent of" after "a fee equal to";

(ii) in clause (iv), by striking "21.5" and inserting "15";

(iii) by striking clause (v), by striking "2.2" and inserting "7.2";

(iv) by redesignating clauses (vi) and (vii) as clauses (viii) and (ix), respectively;

(V) by inserting after clause (v) the following:

"(v) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i)."

(VI) in clause (viii), as redesignated by subparagraph (I)—

(aa) by striking "1.42" and inserting "1.84"; and

(bb) by striking "subject to any adjustment under subsection (e)(2)(C)(ii))"; and

(VII) by adding at the ending the following:

"(xi) For a request for classification information, a fee equal to 1.5 percent of the fee that applies under clause (i)."

(2) by striking subparagraph (i) of paragraph (4), and inserting the following:

"(i) by striking "For fiscal years 2006 and 2007, the" and inserting "The"; and

(ii) by striking "of fiscal year 2006" and inserting "of the next fiscal year";

(3) in subsection (c)—

(A) in the heading, by striking "Annual Fee Setting." and inserting "Annual Fee Setting."; and

(B) in paragraph (1), by striking the second sentence;

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

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

"(2) Adjustment of annual establishment registration fee.—

"(A) In general.—When setting the fees for fiscal years 2010, the Secretary may increase the establishment registration fee specified in subsection (b) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,250. The percent increase shall be the percent by which the estimate of establishments submitting fees in fiscal year 2009 is less than 12,250, but in no case shall the percent increase be more than 8.5 percent over the amount for such fee specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the establishment registration fee for fiscal year 2010, then the establishment registration fee for fiscal years 2011 and 2012 under subsection (b) shall be adjusted as follows: the fee for fiscal year 2011 shall be equal to the adjusted fee for fiscal year 2010, increased by 8.5 percent, and the fee for fiscal year 2012 shall be equal to the adjusted fee for fiscal year 2011, increased by 8.5 percent.

"(B) Publication in the Federal Register.—The Secretary shall publish any determination with respect to any establishment registration fee adjustment made under this paragraph (A), and the rationale for such determination, in the Federal Register.

(4) (A) as so redesignated—

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**Establishment Registration Fee**

(3) in paragraph (2)—

(A) in paragraph (1), by striking "An applicant shall" and inserting "The applicant shall";

(B) in paragraph (2)—

(i) by striking "partners, or parent firms, and it shall bear the official seal of which these receipts and sales were collected, and it shall bear the official seal of the local currency and in United States dollars, the exchange rate used in making this conversion to dollars, and the dates during which these receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

(II) by adding at the end the following:

"(x) Firms not submitting tax returns to the United States internal revenue service.—The applicant shall support:"

(III) by striking "partners, or parent firms" both places the term appears;

(IV) by striking "partners, or parent firms, the" and inserting the "the";

(V) by striking "partners, or parent firms, respectively;" and

(VI) by adding at the end the following:

"(ii) Firms not submitting tax returns to the United States internal revenue service.—The applicant shall support:"

(I) by striking "reduced rate of" and inserting "reduced rate of—";

(II) by striking "38 percent, and all that follows through the period and inserting the following:

"(I) by striking "the" and inserting "50 percent of the fee established under this subsection for a 30-day notice or a request for classification information."; and

(III) in subparagraph (C)—

(A) in paragraph (1), by striking "2004 and inserting "2006"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "partners, or parent firms";

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

"(B) Evidence of qualification.—

"(i) In general.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) Application for periodic reporting concerning a class III device, the annual fee shall be equal to 3.5 percent of the fee that applies under clause (i)."

(III) in subparagraph (C)—

(1) in the first sentence—and

(bb) by striking "or"; and

(b) by adding at the end the following:

"(C) Annual establishment registration fee.—

"(A) In general.—Except as provided in subparagraph (B), each establishment shall be subject to a fee for each initial or annual registration application submitted by a device manufacturer by the establishment is to be distributed commercially.

"(B) Fee Amounts.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the fee amounts:

"(B) in paragraph (2)—

(i) by striking "partners, or parent firms" both places the term appears;

(II) by striking "partners, or parent firms" both places the term appears;
affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for an affiliate, the applicant shall certify that the applicant has no affiliates.

"(iii) Firms not submitting tax returns to the United States internal revenue service shall support the claim that it meets the definition under subparagraph (A) by submission of the following:

(1) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

(II) A certification, in English, that states that the organization provides premarket notification submissions, and the dates during which such receipts and sales were collected, and shall be submitted to the internal revenue service.

"(III) Identical certifications shall be provided for each of the applicant’s affiliates.

"(IV) The statement signed by the President of the applicant's board of directors an officer of the corporation that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.

(III) by striking subparagraph (C) and inserting the following:

"(C) REDUCED FEES.—For fiscal year 2008 and any subsequent fiscal year, fees under this section may be paid at 50 percent of the fee that would otherwise be due to the Secretary for a premarket notification submission, except that fees may not be assessed under this section pursuant to appropriation Acts for fiscal year 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011 (which estimate shall be based upon the amount of fees received in fiscal years 2008, 2009, and 2010, as in effect on the day before the date of enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notifications, and premarket inspections (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration as provided in section 8(b) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

(4) by amending paragraph (6) to read as follows:

"(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection under subpart H of part 4 of this chapter, if it meets the definition under paragraph (2) of the following conditions are met:

(ii) The Secretary classified the results of the most recent inspection of the establishment as indicated or 'voluntary action indicated'.

(II) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

(1) provides the date of the last inspection of the establishment that the Secretary approved or the classification of that inspection;

(II) states the intention of the owner or person to use an accredited person to conduct inspections of the establishment;

(III) identifies the particular accredited person or persons that the owner or operator intends to select to conduct such inspections; and

(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.

(III) fees were not assessed under subparagraph (A) for the previous fiscal year.

(IV) Includes a certification that, with respect to the quality controls of the establishment, the data indicated or 'voluntary action indicated'.

(III) Identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

(IV) Includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.

(IV) Identifies the particular accredited person or persons that the owner or operator intends to select to conduct such inspections; and

(V) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.

(III) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

(II) identifies the particular accredited person that the owner or operator intends to select to conduct such inspections; and

(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.

(IV) Identifies the particular accredited person or persons that the owner or operator intends to select to conduct such inspections; and

(V) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.

(IV) Identifies the particular accredited person that the owner or operator intends to select to conduct such inspections; and

(V) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(a) at least 1 of the devices is marketed in the United States; and

(b) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries.
compliance by promptly correcting any compliance problems identified in such inspections.

"(1) A request to an accredited person under clause (ii) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

"(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(i) or (ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii) of paragraph (d), responds that the establishment has failed to fully respond to the request, or if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

"(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

"(iv) The Secretary may reject the selection of an accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

"(iv) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person under this paragraph (A) as they do to the selection of an accredited person under subparagraph (A)(ii)."
changes are appropriate, such changes are made within the timeframe requested by the Secretary; and

(K) by adding at the end the following:

"(2) The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) if the determina-

tion made under subsection (d)(3) is made less than 6 months prior to the expiration of such period;"

(3) in subsection (c)—

(A) in paragraph (1)(A)(i), by striking "(D)" both places it appears and inserting "(E)";

(B) in paragraph (1)(A)(ii), by striking "(D)" and inserting "(E)";

(C) by striking "(1)(A)(i)" and inserting "(1)(C)";

(D) by striking "(ii) the" and inserting "(II) the";

(E) by striking "(B) if the drug is desig-

nated" and inserting "(II) if the drug is desig-

nated";

(F) by striking "(2A)(i)" and inserting "(2A)(ii)";

(G) by striking "(i) a listed patent" and inserting "(i) a listed patent";

(H) by striking "(ii) a listed patent" and inserting "(II) a listed patent";

(i) if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that popu-

lation and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the re-

quest and the inquiry is completed using ap-

propriate formulations for each age group for which the study is requested within any such time-

frame, and the reports thereof are sub-

mitted and accepted in accordance with sub-

section (d)(3), and if the Secretary deter-

mines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary; and

(K) by adding at the end the following:

"(2) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) if the determina-

tion made under subsection (d)(3) is made less than 9 months prior to the expiration of such period;"

(4) by striking subsection (d)(3) and inserting the following:

"(d) CONDUCT OF PEDIATRIC STUDIES.—

(1) REQUEST FOR STUDIES.—

(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an applic-

ation for an investigational new drug under section 505(b)(1), the sponsor of an applic-

ation for a new drug under section 505(b)(2), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a time-

frame for such studies and a request to the sponsor or holder to propose pediatric labeling re-

quirements. An application for such drug shall be reviewed and approved under each of paragraph (B) and paragraph (C) of this subsection;"
did not follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under subsection (d)(4)."

"(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(r)(1)."

"(6) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "(c)(1)(A)(i)(II)" and inserting "(c)(1)(B)";

(ii) by striking "(c)(2)(ii)" and inserting "(c)(1)(B)";

(B) in paragraph (2), by striking "(c)(1)(B)" and inserting "(c)(1)(B)";

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking "LIMITATIONS.—A drug and its inactive ingredients,.

"(7) in subsection (c)—

(A) in paragraph (1)—

(i) by striking "(c)(1)(A)(i)" and inserting "(c)(1)(B)";

(ii) by striking "(c)(2)(ii)" and inserting "(c)(1)(B)";

(B) in paragraph (2), by striking "(c)(1)(B)" and inserting "(c)(1)(B)";

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking "LIMITATIONS.—A drug and its inactive ingredients,.

"(8) in subsection (e)—

(A) in paragraph (1)—

(i) by striking "(c)(1)(A)(i)(II)" and inserting "(c)(1)(B)";

(ii) by striking "(c)(2)(ii)" and inserting "(c)(1)(B)";

(B) in paragraph (2), by striking "(c)(1)(B)" and inserting "(c)(1)(B)";

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking "LIMITATIONS.—A drug and its inactive ingredients,.

"(9) in subsection (h)—

(A) in paragraph (1)—

(i) by striking "(c)(1)(A)(i)" and inserting "(c)(1)(B)";

(ii) by striking "(c)(2)(ii)" and inserting "(c)(1)(B)";

(B) in paragraph (2), by striking "(c)(1)(B)" and inserting "(c)(1)(B)";

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking "LIMITATIONS.—A drug and its inactive ingredients,.

"(10) in subsection (i)—

(A) in paragraph (1)—

(i) by striking "(c)(1)(A)(i)" and inserting "(c)(1)(B)";

(ii) by striking "(c)(2)(ii)" and inserting "(c)(1)(B)";

(B) in paragraph (2), by striking "(c)(1)(B)" and inserting "(c)(1)(B)";

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking "LIMITATIONS.—A drug and its inactive ingredients,.

"(11) in subsection (k), as redesignated by paragraph (9)—

(A) in paragraph (1)—

(i) by striking "a summary of the medical and statistical information;"

(ii) by striking "for the supplement" and all that follows through the period and inserting "under subsection (b) or (c)";

(B) by redesigning paragraph (2) as paragraph (3); and

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

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) distribute, as appropriate (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers."

"(12) by inserting after subsection (k), as redesignated by paragraph (9), the following:

"(1) ADVERSE EVENT REPORTING.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, during the 1-year period beginning on the date of enactment, and the second 1-year period described in subsection (i), the Secretary shall ensure that adverse event reports that have been received for such drug (regardless of when submitted) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107-109). In consideration of such report, the Director of such Office shall be required to submit to the appropriate congressional committees, a report describing the Office's efforts to encourage reporting of adverse events that occur in pediatric populations.

"(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer the Office of Pediatric Therapeutics to such reports by the Director of such Office and such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should require an assessment under section 505B of the Drug Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) distribute, as appropriate (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers."

"(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

"(13) by inserting after subsection (m), as redesignated by paragraph (9), the following:

"(v) REFERRAL TO PEDIATRIC STUDIES NOT COMPLETED.—

"(1) in general.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under subsection (f), determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the committee shall carry out the following:

"(A) For a drug for which the patient population has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B. Prior to making such determination, the Secretary may take not more than 60 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate 1 or more of the pediatric studies of such drug referred to in the sentence preceding this paragraph around 1 or more of such studies in their entirety. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer such pediatric study or studies for the National Institutes of Health for the conduct of such study or studies.

"(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 4001 of the Public Health Service Act for the conduct of such study or studies.

"(2) PUBLIC NOTICE.—The Secretary shall give the public notice of—

"(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision; and

"(B) any referral under paragraph (1)(B) of a drug for inclusion on the list established under section 4001 of the Public Health Service Act.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301 of this Act or section 301 of title 18, United States Code:"

"(4) in subsection (p), as redesignated by paragraph (9)—

(A) striking "6-month period" and inserting "3-month or 6-month period";

(B) by striking "(a)(1)" and inserting "(a)(2)"; and

(C) by striking "2007" and inserting "2012";

"effective date.—Except as otherwise provided in the amendments made by this Act or section 301 of title 18, United States Code:"

"SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 4001 of the Public Health Service Act (42 U.S.C. 285m) is amended—

"by striking subsections (a) and (b) and inserting the following:

"(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

"(1) in general.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall provide for the review of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) for the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) made after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the appropriate committees of the House of Representatives and the Senate, shall develop and publish a priority
list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every 3 years.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, and metabolism of drugs and biologics in children, and pediatric clinical trials;

(B) particular pediatric diseases, disorders, or conditions where more complete knowledge and testing of therapeutics, including biologics, may be beneficial in pediatric populations; and

(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

(b) PEDIATRIC STUDIES AND RESEARCH.—

(1) In subsection (a), in the heading, by striking “CONTRACTS” and inserting “PROPOSED PEDIATRIC STUDY REQUESTS”;

(2) in subsection (c)—

(A) by redesignating paragraphs (1), (2), and (3), as redesignated by subsection (a), (b), and (c), as paragraphs (2), (3), and (4); and

(B) by inserting before paragraph (2), (as redesignated by subsection (a)), the following:

“(A) in the heading, by striking “CONTRACTS” and inserting “PROPOSED PEDIATRIC STUDY REQUESTS”;

(B) by striking paragraphs (4) and (12); and

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

(D) by inserting before paragraph (2), (as redesignated by subsection (a)), the following:

“(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c) of such section 565A; and

(2) the number and importance of drugs for which test proposals have been submitted to the Secretary since 1997 under subsections (b) and (c) of such section 565A; and

(3) the number of drugs for which contract proposals have been submitted to the Secretary since 1997 under subsections (b) and (c) of such section 565A; and

(4) the effectiveness of 565A in ensuring that medicines used by children are tested and properly labeled, including—

(I) the number and importance of drugs for children that are being tested as a result of the amendments made by this section, and the number and importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(II) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this section and the amendments made by this section, and the number and importance for children, health care providers, parents, and others of labeling changes made as a result of amendments made by this subsection;

(III) the number and importance of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this title, together with a description of the pediatric health service act.

SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW’S PEDIATRIC RESEARCHERS.—Section 320(b)(2) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by inserting “including pediatric pharmacological research” after “pediatric pharmacological research”.

(b) PEDIATRIC PHARMACOTHERAPY.—Section 355a in ensuring that medicines used by children are tested and properly labeled, including—

(C) training of pediatric pharmacotherapists to conduct clinical trials of new drugs for children and to provide expert consultation and advice to the Secretary, the Public Health Service, and the Institute of Medicine in conducting such trials and to develop cost-effective mechanisms to expand such activities; and

(D) providing grants to such institutions to encourage such training.

SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTE OF HEALTH.

(a) INVESTMENT IN TOMORROW’S PEDIATRIC RESEARCHERS.—Section 320(b)(2) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by adding before the period at the end thereof the following: “, including pediatric pharmacological research.”

(c) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 447(f)(a)(1) of the Public Health Service Act (42 U.S.C. 288–6a(1)) is amended by inserting “including pediatric pharmacological research,” after “pediatric research.”
App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.

**SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.**

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking “and” after the semicolon;

(ii) in subparagraph (B), by striking “and” after the semicolon;

(B) in subsection (c), by striking the period at the end and inserting “; and”;

(C) by striking paragraph (3) and inserting the following:

“(3) DEFERRAL.—(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until 1 year from the effective date of approval of the drug or license for a biological product if—

(i) the Secretary finds that—

(I) such deferral is necessary to provide adequate pediatric labeling for the drug or biological product if such labeling could be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration; and

(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

(B) there is reason to believe that the drug or biological product would represent a partial or full therapeutic advance; or

(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients;”;

(2) in paragraph (2)(C), by adding at the end the following: “An applicant seeking either a partial or full waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration;”;

and

(D) by striking paragraph (3) and inserting the following:

“(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amendments subsection 303(l) of this Act or section 522 of title 5 or section 1905 of title 18, United States Code.”.

**SEC. 414. SUNSET, REVIEW OF PEDIATRIC ASSESSMENTS, ADVERSE EVENT REPORTING, LONGITUDINAL STUDIES, AND PEDIATRIC ASSESSMENTS.**

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) by redesigning subsection (h) as subsection (j);

(2) in subsection (i), as so redesignated, by striking “355A(n)” and inserting “355A(p)”;

(3) by redesigning subsection (f) as subsection (k);

(4) by redesigning subsection (g) as subsection (l); and

(5) by inserting after subsection (e) the following:

“(e) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS, PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVER.—

(1) REVIEW.—The Secretary shall establish an internal committee to review all pediatric assessment requests issued under this section, all pediatric assessments conducted under this section, all deferral and waiver requests made pursuant to this section. Such internal committee shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

(A) Pediatrics.

(B) Biopharmaceutics.

(C) Statistics.

(D) Drugs and drug formulations.

(E) Pediatric ethics.

(F) Legal issues.

(G) Appropriate expertise, such as expertise in child and adolescent psychiatry, pertinent to the pediatric product under review.

(2) 1 or more experts from the Office of Pediatric Therapeutics.

(3) Other individuals as designated by the Secretary.

(2) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function. A review of requests for pediatric assessments, deferrals, and waivers.—All written requests for a pediatric assessment
issued pursuant to this section and all requests for deferrals and waivers from the requirement to conduct a pediatric assessment under this section shall be reviewed and approved by the committee established under paragraph (1).

"(5) REVIEW OF ASSESSMENTS.—The committee established under paragraph (1) shall review all assessments conducted under this section to determine whether such assessments meet the requirements of this section.

"(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The committee established under paragraph (1) is responsible for tracking and making public in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

"(A) the number of assessments conducted under this section;

"(B) the specific drugs and drug uses assessed under this section;

"(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

"(D) the total number of deferrals requested and granted under this section, and, if granted, the reasons for such deferrals, the timeline for completion, and the number of waivers requested and granted under this section, including trial design, the types of assessments conducted under this section, the number of waivers requested and granted, and, if granted, the reasons for the waivers;

"(E) the number of waivers requested and granted under this section, and, if granted, the reasons for such deferrals, the timeline for completion, and the number of waivers requested and granted under this section, including trial design, the types of assessments conducted under this section, the number of waivers requested and granted, and, if granted, the reasons for the waivers;

"(F) the number of pediatric formulations developed and the number of pediatric formulations that were developed and the reasons any such formulations were not developed;

"(G) the labeling changes made as a result of assessments conducted under this section;

"(H) a summary of the labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (a)(2); and

"(I) an annual summary of the information submitted pursuant to subsection (a)(3)(B).

"(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(a)(1).

"(g) AWARD OF AWARDS.—

"(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENT.—Any supplement to an application under section 505 and section 351 of the Public Health Service Act proposing a labeling change that results from any pediatric assessment conducted pursuant to this section—

"(A) shall be considered a priority supplement; and

"(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

"(2) DISPUTE RESOLUTION.—

"(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on approvability of the labeling change on the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement, the Commissioner shall request that the sponsor make a labeling change that the Commissioner determines to be appropriate.

"(B) if the sponsor does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a request pursuant to subparagraph (1), the Pediatric Advisory Committee shall—

"(i) review the pediatric study reports; and

"(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

"(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, the sponsor shall—

"(i) request approval of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate; or

"(D) DISMISSAL.—If, within 30 days after receiving a request under subparagraph (C), the Commissioner—

"(i) does not make any labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded;

"(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

"(8) OTHER LABELING CHANGES.—If the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug is safe and effective, including whether such assessment results in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the assessment and a statement of the Secretary's determination.

"(b) DISSEMINATION OF PEDIATRIC INFORMATION.—

"(1) IN GENERAL.—Not later than 180 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments and shall post such assessments on the website of the Food and Drug Administration.

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall require that any pediatric assessment conducted under this section that results in labeling changes that are reflected in the annual summary developed pursuant to subsection (a)(6)(H) distribute such information to physicians and other health care providers.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(a) of this Act or section 562 of title 5, United States Code, or section 1905 of title 18, United States Code.

"(1) ADVISORY COMMITTEE REPORT.—

"(1) REPORTING IN YEAR 1.—During the 1-year period beginning on the date a labeling change is made pursuant to subsection (g), the Commissioner shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such report.

"(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics, pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) any adverse event report for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such committee regarding whether the Secretary should take action in response to such report.

"(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.''

SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.


"(A) by striking "estimates" and inserting "determines"; and

"(B) by striking "would" and inserting "could".

SEC. 416. REPORTS.

(a) INSTITUTE OF MEDICINE STUDY.—

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of this subtitle, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997.

"(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

"(A) the number and importance of drugs for which testing is required pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997 and labeling changes made as a result of such testing;

"(B) the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

"(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) from each review division within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in order to make the required assessment.

(b) GAO REPORT.—Not later than September 1, 2010, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

"(1) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

"(2) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

"(3) the number and importance of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established under section 505B; and

"(4) a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee.

SEC. 417. TECHNICAL CORRECTIONS.

Section 505B(a)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by striking "one" and inserting "1".
Subtitle C—Pediatric Medical Devices

SEC. 421. SHORT TITLE.

This subtitle may be cited as the “Pediatric Medical Device Safety and Improvement Act of 2017.”

SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

“SEC. 515A. PEDIATRIC USES OF DEVICES.

“(1) In general.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) under section 515 under a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

“(2) Required Information.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

“(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

“(B) the number of affected pediatric patients.

“(3) Annual Report.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

“(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

“(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

“(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

“(D) the review time for each device described in subparagraphs (A), (B), and (C).

“(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DISEASE ON ADULTS.—

“(1) In general.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

“(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one pediatric subpopulation can be extrapolated to another subpopulation.

“(c) PEDIATRIC SUBPOPULATION.—In this section, the term ‘pediatric subpopulation’ has the meaning given the term in section 520(m)(6)(E)(ii).”

SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) In general.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

“(1) in paragraph (3), by striking “No” and inserting “Except as provided in paragraph (6), no”;

“(2) in paragraph (5)—

“(A) by inserting “, if the Secretary has reason to believe that the requirements of paragraphs (6) and (8) are no longer met,” after “public health”; and

“(B) by adding at the end the following: ‘‘If the person granted an exemption under paragraph (1) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effective date of this subsection or the date of the report under section 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing;’’;

“(3) by striking paragraph (6) and inserting the following:

“(6)(A) As provided in subparagraph (D), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under paragraph (2) of the Pediatric Medical Device Safety and Improvement Act of 2007.

“(B) the review time for each device described in subparagraph (A) prior to the date of enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

“(C) the number of pediatric devices approved, labeled for use in pediatric patients or in a pediatric subpopulation in which the device or condition occurs.

“(D) the review time for each device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the device or condition occurs.

“(E) the device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subparagraph (D) prior to the date of enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

“(F) the number of pediatric devices approved, labeled for use in pediatric patients, including any increase in the number of children, including any increase or decrease in the number of—

“(1) the number of devices approved under such section 520(m)(2) for pediatric devices; and

“(2) the applications approved under section 515 of such Act (21 U.S.C. 360j(e)) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population.

“(G) the extent to which the costs of such devices are covered by health insurance.

“(H) the impact, if any, of allowing profit on access to such devices.

“(I) the profits made by manufacturers for each device that receives an exemption;

“(J) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

“(K) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and any regulatory actions taken.

“(b) In general.—Section 515(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)) is amended—

“(1) by striking “and” and inserting “, and” after “the Secretary may not grant an exemption unless the application submitted on or before October 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to each device to profit from paragraph (6) is subject to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

“(I) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

“(1) the number of devices approved under such section 520(m)(2) for pediatric devices; and

“(2) the applications approved under section 515 of such Act (21 U.S.C. 360j(e)) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

“(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated patient population for each condition or disease;

“(3) the costs of the pediatric devices, based on a survey of children with the estimated patient population for such condition or disease;

“(4) the extent to which the costs of such devices are covered by health insurance;

“(5) the impact, if any, of allowing profit on access to such devices;

“(6) the profits made by manufacturers for each device that receives an exemption;

“(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

“(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and any regulatory actions taken; and

“(9) an evaluation of the demonstration grants described in section 425, which shall include an evaluation of the number of pediatric medical devices—

“(A) that have been or are being studied in children; and

“(B) that have been submitted to the Food and Drug Administration for approval, clearance or labeling (as defined by this Act) and any regulatory actions taken.”
(c) GUIDANCE.—Not later than 180 days after the date of enactment of this subtitle, the Commissioner of Food and Drugs shall issue guidance for institutional review committees to determine the need for proposals for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking “and” after the semicolon at the end;

(2) by striking the period at the end of paragraph (22) and inserting “;”; and

(3) by inserting after paragraph (22) the following:

“(22) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.”.

SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of enactment of this subtitle, the Secretary of Health and Human Services shall issue a request for proposals under this section. The Secretary may require.

(b) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under this section, the Secretary shall make a determination on the grants or contracts under this section.

(c) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit to the Secretary an application containing such information as the Secretary requires.

(d) USE OF FUNDS.—A nonprofit consortium that is awarded a grant under this section shall use the grant funds to—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device development projects; and

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for each of fiscal years 2008 through 2012 $5,000,000 for each of fiscal years 2008 through 2012.

SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) IN GENERAL.—

(1) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 522 of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by adding at the end the following:

“(A) coordinate with the National Institutes of Health, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, the Foundation, the Department of Energy, the Department of Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a plan for the demonstration of developmental and pediatric medical devices.

(b) CONTENTS.—The plan under paragraph (1) shall include—

(i) the collaborative efforts of federally funded pediatric medical device research;

(ii) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(iii) a research agenda for improving pediatric medical device development and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by striking “(including drugs and biological products) and pediatric devices” and inserting “(including drugs and biological products and medical devices)” after “therapeutics”;

(2) in subsection (b), by striking “(A) in paragraph (1), by inserting “(including drugs and biological products and medical devices)” after “therapeutics”; and

(3) in subsection (c), by inserting “(B) identification of research priorities” after “(B) by striking the following:”.

SEC. 427. POSTMARKET SURVEILLANCE.

(a) POSTMARKET SURVEILLANCE.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended—

(1) in subsection (a), by striking paragraph (7) and inserting the following:

“(6) A life-sustaining or life-supporting device used outside a device user facility.

(b) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A) if—

(i) implanted in the human body for more than 1 year; or

(ii) a life-sustaining or life-supporting device.

(c) RULE OF CONSTRUCTION.—The proviso of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.”.

SEC. 428. AMENDMENTS TO OFFICE OF HUMAN AND ANIMAL HARMFUL EFFECTS.

(a) IN GENERAL.—

(1) HUMAN AND ANIMAL HARMFUL EFFECTS.—Section 527 of the Best Pharmaceuticals for Children Act (42 U.S.C. 396q(q)) is amended by adding after paragraph (22) the following:

“(23) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on—

(A) the effectiveness of activities conducted under subsection (c); (B) the impact of activities conducted under subsection (c) on pediatric device development; and

(C) the status of pediatric device development that has been facilitated by the consortium.

(2) POLICIES.—The Secretary shall—

(a) establish and make publicly available clear written policies to implement this section.
and govern the timely submission, review, clearance, and disclaimer requirements for articles.

(c) Timing of Submission for Review.—If an officer or employee of the Food and Drug Administration, including a contractor who performs staff work, or the Food and Drug Administration is required by the policies established under subsection (a) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for review and clearance not less than 30 days after such officer or employee submitted such article for review.

(e) Non-Timely Review.—If 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee shall not have such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policy established under subsection (b)."

SEC. 502. TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C-2(3)(B), by striking "section 319C-1(h)" and inserting "section 319C-1(i)";

(2) in section 422(b)(4), by inserting "minority and other" after "reducing";

(3) in section 422(c)(3), by striking "(I)" and inserting "and (II)";

(4) in section 516(c), by inserting "post doctoral training funded through investigator-initiated research grant awards" before the semicolon; and

(5) in section 603(c)—

(A) in the matter preceding paragraph (1), by inserting "graduate students supported by NIH for" after "with respect to";

(B) in paragraph (1), by inserting "such" after "percentage of"; and

(C) in paragraph (2), by inserting "(not including any leaves of absence)" after "average time".

SEC. 503. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

SEC. 504. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BILOGICS.

(a) Findings.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance consumer, business, and government needs are paramount in the system.

(b) Transferability.—It is the sense of the Senate that legislation should be enacted to—

(1) provide the Food and Drug Administration with flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(2) ensure that patient safety remains paramount in the system;

(3) establish a regulatory pathway that is efficient, effective, and scientifically justified; and

(4) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

SEC. 505. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

(a) Definitions.—In this section:

(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

(2) AIDS drug.—The term 'AIDS drug' means a drug indicated for treating HIV.

(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

(4) Neglected or tropical disease.—The term 'neglected or tropical disease' means—

(A) HIV, malaria, tuberculosis, and related diseases;

(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Programme, UNICEF, the World Bank, and the World Health Organization.

(5) Priority Review.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

(6) Priority Review Voucher.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application under section 505(b)(1) after the date of approval of the tropical disease product.

(7) Tropical Disease Product.—The term 'tropical disease product' means a product that—

(A) is a new drug, antibiotic drug, biologic product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

(b) Priority Review Voucher.—

(1) In General.—The Secretary shall award a priority review voucher to the sponsor of a new drug application for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

(2) Limitation.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

(c) Priority Review User Fee.—

(1) In General.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary that amount, determined under paragraph (2), that fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

(2) Amount.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

(3) Annual per Setting.—The Secretary shall establish, before the beginning of each fiscal year, a fee on September 30, 2007, for that fiscal year, the amount of the priority review user fee.

(4) Payment.—

(A) In General.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

(B) Complete Application.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee described in this subsection is not included in such application.

(5) Offsetting Collections.—Fees collected pursuant to this subsection for any fiscal year in which (A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

SEC. 506. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

"(A) In General.—

(1) No Delay of Consideration or Approval.—

(2) Delay of Consideration or Approval.—Except as provided in clause (i), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

(3) No Delay of Approval Without Determination.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is pending unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health."

"(B) Determination of Delay.—With respect to a determination by the Secretary under subparagraph (A)(ii), the Secretary shall—

(1) notify the petitioner that the petition has been denied and that the petition has been denied and that the application is in progress; and

(2) provide the applicant with the opportunity to submit additional information to the Secretary in support of the petition."
need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to make the determination.

“(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

“(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

“(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of the petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

“(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under paragraph (A) that a delay is necessary to protect the public health the following shall apply:

“(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons the Secretary determines that a delay is necessary to protect the public health. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petition. The detailed statement should also resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

“(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

“(3) Variances.—

“(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless the petition contains the following verification: ‘I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which I have based the action requested herein first became known to me on or about ______. I received or expect to receive payments, including cash or other forms of consideration, from the following persons or organizations to file this petition: ______. I verify under penalty of perjury that the foregoing is true and correct,’ with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank spaces, respectively.

“(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the Secretary, in its discretion, determines that the supplemental information or comments does so in written form and that the subject document is signed and contains the following verification: ‘I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about ______. I received or expect to receive payments, including cash or other forms of consideration, from the following persons or organizations to submit this information or its contents: ______. I verify under penalty of perjury that the foregoing is true and correct,’ with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank spaces, respectively.

“(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

“(A) the number of applications under subsection (b)(2) or (j) that were approved during the preceding 1-year period;

“(B) the number of petitions that were submitted during such period;

“(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

“(D) the number of petitions that were filed under this subsection that were deemed by the Commissioner to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

“(E) EXCEPTION. This paragraph does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

“(6) REPORT BY INSPECTOR GENERAL.—

“The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

“(7) DEFINITION.—For purposes of this subsection, the term ‘petition’ includes any request for an action in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.

“SEC. 507. PUBLICATION OF ANNUAL REPORTS.

“(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration a report concerning the results of the Administration’s pesticide residue monitoring program, that includes:

“(1) information and analysis similar to that contained in the report entitled “Food and Drug Administration Pesticide Program Residue Monitoring 2003” as released in June of 2005;

“(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including—

“(A) the number of applications that were submitted during the preceding year in which the report is published.

“(B) requires incision or is otherwise invasive, or involves exposure of private body parts.

“(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit agencies from using established methods, for handling cases of suspected or known child abuse and neglect, and that are in compliance with applicable Federal, State, or tribal law.”.

“SEC. 509. SAFETY OF FOOD ADDITIVES.

“Not later than 90 days after the date of enactment of this Act, the Secretary of Agriculture shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant research conducted by the Secretary, the Committee on Genetic Testing and other groups and shall be completed not later than 1 year...
after the date on which the Secretary entered into such contract.

SEC. 511. ORPHAN DISEASE TREATMENT IN CHILDREN.
(a) FINDINGS.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

SEC. 512. COLOR CERTIFICATION REPORTS.
Section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) is amended by adding at the end the following:

"(g) COLOR CERTIFICATION REPORTS.—Not later than—
(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a report for such fiscal year on the number of batches of color additives used in raw agricultural commodities, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.

SEC. 513. PROHIBITION ON IMPORTATION FROM A FOREIGN FOOD FACILITY THAT DENIES ACCESS TO FOOD INSPECTORS.
Notwithstanding any other provision of law, no food product may be imported into the United States if the product is from a foreign facility registered under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341) unless the Secretary of Health and Human Services permits United States inspectors, upon request, to inspect such facility or that unduly denies access to United States inspectors.

SEC. 514. COUNTERFEIT-RESISTANT TECHNOLOGIES.
Notwithstanding any other provision of this Act, the requirement that the Secretary of Health and Human Services certify that the implementation of the title of this Act relating to the Importation of Prescription Drugs will pose no additional risk to the public health and will result in a significant reduction in the cost of covered products to the American consumer shall not apply to the requirement that the Secretary require that the packaging of any prescription drug incorporates—
(1) not later than 18 months after the date of enactment of this Act, a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) unique to each package of such drug, and a point-of-manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing and repackaging) of any prescription drug incorporates—
(2) not later than 24 months after the date of enactment of this Act for the 50 prescription drugs with the highest dollar volume of sales in the United States, based on the calendar year that ends December 31, 2007, and, not later than 30 months after the date of enactment of this Act for all other prescription drugs—
(A) overt optically variable counterfeit-resistant technologies that—
(i) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;
(ii) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;
(iii) are manufactured and distributed in a highly secure, tightly controlled environment; and
(iv) incorporate additional layers of non-convertible security features up to and including forensic capability; or
(B) technologies that have a function of security comparable to that described in subparagraph (A), as determined by the Secretary.

SEC. 515. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.
(a) FINDINGS.—Congress finds the following:
(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are approved for use in food in the United States.
(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.
(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HIGHLIGHTED INSpections.—The Secretary of Health and Human Services (hereafter referred to in this section as the "Secretary") is authorized to, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that—
(1) describes the specifics of the aquaculture and seafood inspection program;
(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and
(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 516. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.
(a) FINDINGS.—The Senate makes the following findings:
(1) Inaction in developing life-saving prescription drugs saves millions of lives around the world each year.
(2) The responsible protection of intellectual property, including through development and ensuring patient access to vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(b) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(c) Strong and fair intellectual property protection, including patent, copyright, trademark, and data protection plays an important role in economic growth and development and ensuring patient access to the most effective medicines around the world.

(d) There are concerns that certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. Americans bear the major share of research and development costs for the world, which could undermine the value of existing United States pharmaceutical patents and could impede access to important therapies.

(e) There is a growing threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy tools to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(f) SENSE OF THE SENATE.—It is the sense of the Senate that—
(1) the United States Trade Representative should use all the tools at the disposal of the United States to safeguard United States intellectual property rights, and other concerns with intellectual property, including through—
(A) bilateral engagement with United States trading partners;
(B) transparency and balance of the annual "Special 301" review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;
(C) negotiation of responsible and fair intellectual property provisions as part of bilateral and regional trade agreements; and
(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and pursue a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SEC. 517. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.
The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

SEC. 518. REPORT ON THE MARKETING OF CERTAIN CRUSTACEANS.
Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall submit to the Health, Education, Labor, and Pension Committee, the Committee on Commerce, Science, and Transportation of the Senate, a report on the differences between taxonomy of species of lobster in the subfamily Nephropinae, including langostino, specifically from the infraorder Caridea or Anomura. This report shall also
describe the differences in consumer perception, including such factors as taste, quality, and value of the species.

SEC. 519. CIVIL PENALTIES—DIRECT-TO-CONSUMER ADVERTISEMENT.

(a) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

"(g)(1) Any applicant (as such term is used in section 505(o)) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and a violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first such violation in any 3-year period, and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized for a violation of paragraph (1) of this section in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

"(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be assessed and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the applicant requests a hearing, a hearing shall be held and an order shall be issued to the applicant to be assessed a civil penalty, the Secretary, in determining the amount of such penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

"(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 738A.

"(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

"(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the Secretary determined that the advertisement before the end of the 45-day comment period.

"(D) Whether the applicant failed to incorpate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to dissemination.

"(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraphs (1) or (2) of this section.

"(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

"(G) Whether the violations were material.

"(H) Whether the applicant who created the advertisement acted in good faith.

"(I) Whether the applicant who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

"(J) Scope and extent of any voluntary, subsequent remedial action by the applicant.

"(K) Such other matters, as justice may require.

"(4)(A) Subsequent remedial action by the applicant.

"(B) The Secretary may retrace or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary by an applicant, in exceptional circumstances, so long as the Secretary provides written notice to the applicant of such retrace or modification of the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under section 554 of title 5, United States Code. If such notice is not provided, when finally determined, or the amount charged upon in compromise, may be deducted from any amount paid by the United States to the applicant charged.

"(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), in any case, when finally determined, or the amount charged upon in compromise, may be deducted from any amount paid by the United States to the applicant charged.

"(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within 60 days of receipt of such final order. The order making such assessments was issued.

"(7) If any applicant fails to pay an assessment of a civil penalty—

"(A) after the order making the assessment becomes final, and if such applicant does not request a special review of the order in accordance with paragraph (6); or

"(B) after a court in an action brought under paragraph (1) of this section, and after a final judgment in favor of the Secretary, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States for a civil penalty in an action brought in any appropriate district court of the United States.

"(B) whether modifying the warning label required on tanning beds to read, "Ultra violet radiation can cause skin cancer" and any other additional warning, would communicate the risks of indoor tanning more effectively;

"(C) whether there is no warning that would be capable of adequately communicating such risks.

(b) Consumer Testing.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing, using the best available methods for determining consumer understanding of label warnings.

(c) PUBLIC HEARINGS; PUBLIC COMMENT.—The Secretary shall hold public hearings and solicit comments from the public in making the determinations under subsection (a).

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE VI—FOOD SAFETY

SEC. 601. FINDINGS.

(a) Findings.—The Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation’s economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures from emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(4) the United States is increasing the amount of food that it imports such that—

(A) from 2003 to the present, the value of imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of meat and 78.6 percent of fish and shellfish; and

(c) a shortage of adequate resources for monitoring and inspection;

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. 602. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall by regulation establish standards for the processing of pet food, including the following:

(1) an increasing volume of imported food from a wide variety of countries; and

(2) a food safety program for pet food that includes the following:

(A) a food safety program for pet food that includes the following:

(b) imported food accounts for 13 percent of the average Americans diet including 31 percent of meat and 78.6 percent of fish and shellfish; and

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(A) a food safety program for pet food that includes the following:

(b) imported food accounts for 13 percent of the average Americans diet including 31 percent of meat and 78.6 percent of fish and shellfish; and

(c) a shortage of adequate resources for monitoring and inspection;

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.
associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to an animal food (and any animal food waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

SEC. 601. EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illnesses associated with pet food.

(a) The Secretary shall—

(1) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(2) consult with relevant professional associations and private sector veterinary hospitals; and

(3) work with the Health Alert Network and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

(b) The Secretary shall, during an ongoing recall of human or pet food—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. 603. ENDURANCE, PRECIPITENCE AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

(a) The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce and that establish a mandatory reporting system of serious adverse events for non-prescription drugs and dietary supplements sold and consumed in the United States.

(b) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act will serve as the early warning system for any potential public health issues associated with the use of these foods.

(c) The Secretary shall, under the Food and Drug Administration, provide to a State, for planning, developing, and implementing such a food safety program—

(1) laboratory assistance (including necessary materials and equipment); and

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(d) SERVICE AGREEMENTS.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(e) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(f) SERVICE AGREEMENTS.—The Secretary may make available to a State food safety programs involving, or otherwise handled is a reportable adulterated food, the responsible party shall provide the notifications described under paragraph (1) or (2).

(3) REPORTABLE ADULTERATED FOOD.—The term ‘reportable adulterated food’ for purposes of this section means a food that is adulterated or—

(1) presents a situation in which there is a reasonable probability that the use of, or exposure to, such food will cause serious adverse health consequences or death as defined in section 7.3(m)(1) of title, Code of Federal Regulations (or any successor regulations).

(2) meets the threshold established in section 309(h).

(b) ESTABLISHMENT.

(1) In the event not later than 180 days after the date of enactment of this section, the Secretary shall establish such a Federal, State, and local health public officials;

(2) an importer;

(3) a responsible party; or

(4) a consumer or other individual.

(c) REVIEW BY SECRETARY.—The Secretary shall review and determine the validity of the information submitted under paragraph (1) for the purposes of identifying adulterated food, submitting entries to the Adulterated Food Registry, acting under subsection (c), and determining whether such food is unsafe for human consumption under the Act to protect the public health.

(d) ISSUANCE OF AN ALERT BY THE SECRETARY.—In general.

(1) GENERAL.—The Secretary shall issue an alert with respect to an adulterated food if the Adulterated Food Registry shows that the food—

(A) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or

(B) is a reportable adulterated food.

(2) SCOPE OF ALERT.—An alert under paragraph (1) may apply to a particular food or food product, food manufacturer, shipper, growing area, or country, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the food, food product, food manufacturer, shipper, growing area, or country.

(e) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a report to the Food and Drug Administration using the electronic portal data elements described in subsection (e).

(1) report to the Food and Drug Administration electronic portal, from—

(2) submit an alert with respect to an adulterated food, the responsible party shall provide the notifications described under paragraph (1) or (2).

(f) NOTIFICATION OF ADULTERATION.—

(A) IN GENERAL.—Not later than 5 days after a responsible party or importer receives a notification, the responsible party or importer, as applicable, shall review whether the food referenced in the report described in paragraph (1) is a reportable adulterated food.

(B) NOTIFICATION.—If a determination is made by such responsible party or importer that the food is a reportable adulterated food, the responsible party or importer shall, no later than 2 days after such determination is made, notify other responsible parties directly linked in the supply chain to which and from which the article of reportable adulterated food was transferred.

(g) SUBMISSION OF REPORTS TO THE FOOD AND DRUG ADMINISTRATION BY A RESPONSIBLE PARTY OR IMPORTER.—The responsible party or importer, as applicable, shall submit a report to the Food and Drug Administration through the electronic portal using the data elements described in subsection (f).

(h) The date on which an article of food was determined to be adulterated or suspected of being adulterated.

(i) The nature of the adulteration.

(j) The quantity or amount.

(k) The dispositions of the article.

(l) Product information typically found on packaging including product codes, use by dates, and names of manufacturers or distributors.

(m) The information about the place of purchase or process by which the consumer or
other individual acquired the article of adulterated food.

""(8) In the case of a responsible party or an importer, the elements required for the registration of food facilities under section 415(a)."

""(9) The contact information for parties directly linked in the supply chain and notified under subsection (b)(2).

""(10) In the case of an importer, the elements required for the prior notice of imported food shipments under section 801(m).

""(g) REGISTRATION AND INSPECTION OF RECORDS.—The responsible person or importer shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section and permit inspection of such records as provided for in section 414. Such records shall also be made available during an inspection under section 704.

""(h) REQUEST FOR INFORMATION.—Section 522 of title 5, United States Code, shall apply to any request for information regarding a record in the Adulterated Food Registry.

""(i) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (e), the Secretary suspects such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make available the data for the Adulterated Imported Food Registry available to the Secretary of Homeland Security.

""(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ""section 201(g)"" and inserting ""sections 201(g) and 417"".

""(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end the following:

""(kk) The failure to provide a report as required under section 417(e)(3).

""(1) The falsification as required by section 417(e)(3).

""(e) SUSPECTED FOOD ADULTERATION REGULATIONS.—The Secretary shall, within 180 days of enactment of this Act, promulgate regulations that establish standards and thresholds by which importers and responsible parties shall be required and consumers may be notified, under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section)—

(1) report instances of suspected reportable adulteration of food to the Food and Drug Administration, or possible inclusion in the Adulterated Food Registry after evaluation of such report; and

(2) notify, in keeping with subsection (e)(2) of such section 417, other responsible parties directly linked in the supply chain, including establishments as defined in section 415(b) of such Act.

""(f) EFFECTIVE DATE.—The requirements of section 417(e) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 180 days after the date of enactment of this Act.

SEC. 606. SENSE OF THE SENATE. It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration’s ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) the Senate should work to develop a comprehensive response to the issue of food safety.

SEC. 607. ANNUAL REPORT TO CONGRESS. The Secretary shall, on an annual basis, submit a comprehensive report on Food and Nutrition Security to the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Agriculture, Nutrition, and Forestry that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food; and

(2) the number and amount of food products regulated by the Food and Drug Administration inspectors of imported food products referred to in subparagraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. 608. RULE OF CONSTRUCTION. Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act; or

(2) adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

SEC. 609. AUTHORIZATION OF APPROPRIATIONS. There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

TITLE VII—DOMESTIC PET TURTLE MARKET ACCESS

SEC. 701. SHORT TITLE. This title may be cited as the “Domestic Pet Turtle Market Access Act of 2007”.

SEC. 702. FINDINGS. Congress makes the following findings:

(1) Pet turtle diameters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat these turtles for salmonella exist that can nearly eradicate salmonella in turtles, and individuals are more aware of the causes of salmonella, how to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regimen that allows the turtle to be maintained safely.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat these turtles for salmonella.

SEC. 703. SALE OF BABY TURTLES. Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, wholesaler, or commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the State or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a State license to breed, hatch, propagate, raise, grow, receive, ship, transport, export, or sell pet turtles or pet turtle eggs;

(2) such State or territory requires certification of sanitization that is signed by a veterinarian who is licensed in the State or territory, and approved by the State or territory agency; and

(3) the certification of sanitization requires each turtle to be sanitized or treated for diseases, including salmonella, and is dependant upon using the Siebeling method, or other such proven non-antibiotic method, to make the turtle salmonellosa-free; and

(4) the turtle farmer or commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the possibility that salmonella can recolonize in turtles; and

(ii) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if the turtle is not properly handled and safely maintained.

(3) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iv) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(5) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and who the buyer can contact if he or she wants more guidance.

(6) the turtle farm or commercial retail seller includes the tools, treatments, or any other required item to continually treat the turtle; and

(7) a statement that buyers of pet turtles should not abandon their pets in the wild, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

SEC. 704. FDA REVIEW OF STATE PROTECTIONS. The Commissioner of Food and Drugs may, after providing an opportunity for comment, determine that the state or territory is meeting the Federal requirements of this Act.

SEC. 801. SHORT TITLE. This title may be cited as the “Pharmaceutical Market Access and Drug Safety Act of 2007.”
SEC. 803. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is hereby repealed.

SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

(a) Importation of Prescription Drugs.—

"(1) In General.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers:

"(i) the drug is not safe or effective for an individual who cannot afford it;

"(ii) allowing and facilitating the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

"(iv) American spend more than $200,000,000,000 on prescription drugs every year;

"(b) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States;

"(c) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. 803. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.


SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

(a) Importation of Prescription Drugs.—

"(1) In General.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers:

"(A) the limitation on importation that is established in section 801(d)(1) is waived; and

"(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

"(2) Importers.—A qualifying drug may not be imported under paragraph (1) unless:

"(A) the drug is imported by a pharmacy, group of pharmacies, or wholesaler that is a registered importer; or

"(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

"(3) Rule of Construction.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

"(A) by a registered importer; or

"(B) from a registered exporter to an individual.

"(4) Definitions.—

"(A) Registered Exporter; Registered Importer.—For purposes of this section:

"(i) the term ‘registered exporter’ means an exporter for which a registration under subsection (b) has been approved and is in effect;

"(ii) the term ‘registered importer’ means a pharmacy, group of pharmacies, or wholesaler for which a registration under subsection (b) has been approved and is in effect;

"(iii) the term ‘registration condition’ means a condition that must exist for a registration under subsection (b) to be approved;

"(B) Qualifying Drug.—For purposes of this section, the term ‘qualifying drug’ means a drug for which there is a corresponding U.S. label drug.

"(C) U.S. Label Drug.—For purposes of this section, the term ‘U.S. label drug’ means a prescription drug that:

"(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

"(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

"(iii) is approved under section 505(c); and

"(iv) is not—

"(A) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802).

"(B) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

"(aa) a therapeutic DNA plasmid product;

"(bb) a therapeutic synthetic peptide product;

"(cc) a monoclonal antibody product for in vivo use; and

"(dd) a therapeutic recombinant DNA-derived product.

"(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

"(II) of clause (vii) will not be met by the date on which such transactional measure for the registration of human pharmaceutical products expires;

"(v) Japan;

"(vii) a country in which the Secretary determines the following requirements are met:

"(I) The country has statutory or regulatory requirements—

"(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

"(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

"(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

"(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

"(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

"(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (iv).

"(III) The importation of drugs to the United States from the country will not adversely affect public health.

"(IV) The Secretary determines that the registrant is in compliance with—

"(A) the training of pharmacists, the employment of pharmacists, and the protection of the privacy of personal medical information; and

"(B) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

"(V) The term ‘importer’ means a pharmacist, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

"(VI) The term ‘pharmacy’ means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(VII) The term ‘pharmacist’ means a person—

"(I) employed by a State to engage in the business of selling prescription drugs at retail; and

"(II) possesses a license to practice pharmacy.

"(VIII) The term ‘wholesaler’—

"(A) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

"(B) does not include a person authorized to import drugs under section 801(d)(1).

"(E) Permitted country.—The term ‘permitted country’ means—

"(i) Australia;

"(ii) Canada; and

"(iii) the member country of the European Union, but does not include a member country with respect to which—

"(i) the country’s Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the registration of human pharmaceutical products that has not expired; or

"(ii) the Secretary determines that the requirements described in clauses (I) and (II) of clause (vii) will not be met by the date on which such transactional measure for the registration of human pharmaceutical products expires;
sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples.

(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a), being licensed, registered, or exempt from license or registration conditions for individual importation; and maintenance of records and samples).

(A) the Secretary by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

(ii) Subject to clause (i), the Secretary may suspend the registration of the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(B) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter—

(1) failed to permit the Secretary to conduct an inspection described under subsection (d);

(2) has exported a drug to the United States that is not a qualifying drug or that is not in compliance with the following—

(1) of a registrant if the Secretary determines, after notice and opportunity for a hearing, that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the registration permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(3) The establishment was manufactured in an establishment—

(A) required to register under subsection (h) or (i) of section 510;

(B)(i) inspected by the Secretary; or

(ii) for which the Secretary has elected to rely on a satisfactory manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(5) SOURCES OF QUALIFYING DRUGS.—A registration condition that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

(1) The exporter or importer obtained the drug—

(A) directly from the establishment; or

(B) directly from an entity that, by contract with the exporter or importer—

(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(ii) agrees to permit the Secretary to inspect such statements and related records to determine whether violations of registration conditions will not occur.

(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(3) The establishment was manufactured in an establishment—

(A) required to register under subsection (h) or (i) of section 510; and

(B)(i) inspected by the Secretary; or

(ii) for which the Secretary has elected to rely on a satisfactory manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(6) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet and Drug A’s administration and a toll-free telephone number, the Secretary shall make readily available to the exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the registrant also shall provide to the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(7) The exporter or importer obtained the drug—

(A) directly from the establishment; or

(B) directly from an entity that, by contract with the exporter or importer—

(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(ii) agrees to permit the Secretary to inspect such statements and related records to determine whether violations of registration conditions will not occur.

(8) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(9) The establishment was manufactured in an establishment—

(A) required to register under subsection (h) or (i) of section 510; and

(B)(i) inspected by the Secretary; or

(ii) for which the Secretary has elected to rely on a satisfactory manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(10) The exporter or importer obtained the drug—

(A) directly from the establishment; or

(B) directly from an entity that, by contract with the exporter or importer—

(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(ii) agrees to permit the Secretary to inspect such statements and related records to determine whether violations of registration conditions will not occur.

(11) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

(12) The establishment was manufactured in an establishment—

(A) required to register under subsection (h) or (i) of section 510; and

(B)(i) inspected by the Secretary; or

(ii) for which the Secretary has elected to rely on a satisfactory manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent to United States regulations). The Secretary may make the registration permanent, or for a fixed period of not less than 1 year or for a fixed period of not more than 3 years. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the import or export enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.
inspect warehouses and other facilities, including records, of the entity for purposes of ascertaining the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

(A) the exporter agrees to permit the Secretary—

(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

(ii) to have access, including on a day-to-day basis, to—

(I) records of the exporter that relate to the export of such drugs, including financial records; and

(II) samples of such drugs;

(iii) to carry out the duties described in paragraph (b); and

(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary but not less than once annually, on the premises of places of business referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuing basis.

(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container any qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

(B) include antitamper features or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

(3) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

(A) during or immediately after each importation, but not less than 12 times annually, theplaces of business of the importer at which qualifying drugs are stored and from which qualifying drugs are shipped.

(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs imported into the United States; and

(C) Reviewing notices under paragraph (4).

(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time that a shipment of qualifying drugs is to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

(A) the name and complete contact information of the person submitting the notice;

(B) the name and complete contact information of the importer involved;

(C) the name and complete contact information, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

(E) the country from which the drug is shipped;

(F) the name and complete contact information for the shipper of the drug;

(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time; and

(H) any other information determined by the Secretary in determining whether the drug was manufactured to the exporter, including the port of arrival of the drug, and the lot number assigned by the manufacturer;

(I) the name and complete contact information of the shipper of the drug;

(J) such other information as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions.

(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution in any of the States, to affix to each container of such qualifying drug that bears comparable, track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the importer at which a qualifying drug is initially received after importation into the United States under subsection (a), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

(C) Reviewing notices under paragraph (4).

(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

(E) Determining whether the importer is in compliance with all other registration conditions.

(7) Certification.—The Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than the amount provided for in paragraph (3), to pay the costs of administering this section with respect to registered importers, including the costs associated with—

(i) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

(ii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

(8) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

(9) TOTAL PRICE OF DRUGS.—

(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than the amount provided for in paragraph (3), to pay the costs of administering this section with respect to registered importers, including the costs associated with—

(i) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

(ii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

(10) REVIEW.—

(A) ESTIMATE.—For purposes of complying with the limitation described in subparagraph (B), when computing the aggregate total of fees to be collected under paragraph (2) for a fiscal
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year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

‘‘(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which a registration is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary under subsection (b)(1)(J).

‘‘(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (i) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall increase the aggregate amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the volume of qualifying drugs imported by importers under subsection (a).

‘‘(iv) USE OF FEES.—

(A) IN GENERAL.—Subject to appropriation Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, for the sole purpose of paying the cost associated with—

(i) inspecting the facilities of registered importers for the purpose of determining if such a shipment should be refused admission under subsection (g)(5).

(ii) inspecting the facilities of registered importers under subsection (b)(1)(J).

(iii) developing, implementing, and operating a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

(iv) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

‘‘(B) LIMITATION.—Subject to subparagraph (B), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported into the United States by registered importers during that fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I).

‘‘(i) TOTAL PRICE OF DRUGS.—(I) The purposes of complying with the limitation described in subparagraph (B) when establishing under paragraph (A) the aggregate total of fees to be collected for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I).

(ii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during that fiscal year as calculated under clause (i) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter under subsection (b)(1)(I).

‘‘(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the volume of qualifying drugs exported by exporters under subsection (a).

‘‘(3) USE OF FEES.—(A) IN GENERAL.—Subject to appropriation Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

‘‘(B) USE FOR PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, for the sole purpose of paying the cost associated with—

(i) inspecting the facilities of registered importers for the purpose of determining if such a shipment should be refused admission under subsection (g)(5).

(ii) developing, implementing, and operating a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

‘‘(C) COMPLIANCE WITH SECTION 801(a).—

(1) IN GENERAL.—(A) The information that the person submitting a notice under clause (i)(I) shall include shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, the information that the Secretary of Commerce may require (if such approval is sought, include the following:—

(i) The name of the country that approved the drug for commercial distribution in the permitted country.

(ii) Information demonstrating that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(iii) The information that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(iv) Information demonstrating that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(i) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

‘‘(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the volume of qualifying drugs exported by exporters under subsection (a).

‘‘(E) INSPECTION FEE.—(I) The date on which the qualifying drug that is imported or offered for import under subsection (a) shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(II) The information that the person submitting a notice under clause (i)(I) shall include shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, the information that the Secretary of Commerce may require (if such approval is sought, include the following:—

(i) The name of the country that approved the drug for commercial distribution in the permitted country.

(ii) Information demonstrating that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(iii) The information that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(iv) Information demonstrating that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(v) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

(i) The name of the country that approved the drug for commercial distribution in the permitted country.

(ii) Information demonstrating that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

(iii) The information that the person submitting the notice has notified the government of the permitted country in writing that the person is submitting the notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.
of the drug in the country which, if in a lan-
guage other than English, shall be accom-
panied by an English translation verified to be 
complete and accurate, with the name, address
and statement of the qualifications of the person 
that made the trans-
lation.

(iii) CERTIFICATIONS.—The chief executive
officer of the Federal Trade Commission, the
manufacturer involved shall each certify in the
notice under clause (i) that—

(1) the information provided in the notice is 
complete and accurate; and

(ii) a copy of the notice has been provided 
to the Federal Trade Commission and to the
State attorneys general.

(iv) If the notice submitted under clause (i) includes a difference that would,
under section 506A, require the submission of a supplemental application if made as a
to change the U.S. label drug, the person 
that submits the notice shall pay to the Sec-
retary a fee in the same amount as would apply if the person were paying a fee pursuant
to section 790a(1)(A)(ii). Subject to ap-
propiations Acts, fees collected by the Sec-
retary under the preceding sentence are available only to the Secretary and are for
the sole purpose of paying the costs of re-
viewing notices submitted under clause (i).

(v) TIMING OF SUBMISSION OF NOTICES.—

(I) PRIOR APPROVAL NOTICES.—A notice
under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary
not later than 120 days before the qualifying
drug with the difference is introduced for
commercial distribution in a permitted
country, unless the country requires that
distribution of the qualifying drug with the
difference begin less than 120 days after the
country receives the notice.

(II) OTHER APPROVAL NOTICES.—A notice
under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary
not later than 12 days before the labeling
with the difference is introduced for
commercial distribution in a permitted
country.

(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first intro-
duced for distribution in a permitted country and annually thereafter.

(vi) REVIEW BY SECRETARY.—

(I) IN GENERAL.—In this paragraph, the difference
is a difference in which the U.S. label drug is
submitted in a notice under clause (i) from the
U.S. label drug if the Secretary determines that the
qualifying drug is not bioequivalent to the U.S. label
drug, the Secretary shall—

(a) provide the labeling provided under
paragraph (3) a prominent advisory
that the qualifying drug is not bioequivalent
in a supplemental application requiring the
U.S. label drug; and

(b) if the Secretary determines that such
a supplemental application requiring the
U.S. label drug would pose a threat to the
public health.

(IV) REVIEW BY THE SECRETARY.—The Sec-
retary shall review and approve or dis-
sapprove the difference in a notice submitted
under clause (i), if required under section
506A, not later than 120 days after the date
on which the notice is submitted.

(V) CERTIFICATION.—If review of
such difference would require an inspec-
tion of the establishment in which the quali-
ifying drug is manufactured—

(aa) such inspection by the Secretary
shall be authorized; and

(bb) the Secretary may rely on a satisfac-
tory report of a routine premarketing
inspection of the establishment from a per-
mitted country whose regulatory system the
Secretary recognizes as equivalent under a
mutual recognition agreement, as provided
under section 516(i)(3), section 803, or part
26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regula-
tion).

(VI) PUBLICATION OF INFORMATION ON NOT-
ICES.—

(I) IN GENERAL.—Through the Internet 
website of the Food and Drug Administra-
tion and a toll-free telephone number, the
Secretary shall readily make available to
the public a list of notices submitted under
clause (i).

(II) CONTENTS.—The list under clause
(I) shall include the date on which a notice is
submitted.

(aa) a notice is under review;

(bb) the Secretary has ordered that im-
portation of the qualifying drug from a per-
mitted country cease, or provide that an order
for the U.S. label drug be vacated;

(cc) the importation of the drug is per-
mitted under subsection (a).

(III) UPDATE.—The Secretary shall
promptly notify Internet website with any
changes to the list.

(C) NOTICE; DRUG DIFFERENCE REQUI-
RING PRIOR APPROVAL.—In the case of a notice
under subparagraph (B)(i) that includes a dif-
ference that would, under section
506A(d)(1)(A), a supplemental application
be required before the difference could be
made to the U.S. label drug the fol-
lowing shall occur:

(i) Promptly after the notice is sub-
mitted, the Secretary shall notify registered
exporters, registered importers, the Federal
Trade Commission, and the State attorneys
general of the determination;

(ii) If the Secretary determines that such
a supplemental application requiring the
U.S. label drug would be approved, the
difference shall be considered to be a variation
provided for in the approved application
for the U.S. label drug.

(E) NOTICE; DRUG DIFFERENCE NOT REQUI-
RING PRIOR APPROVAL; NO DIFFERENCE.—In the case of a notice
under subparagraph (B)(i) that includes a dif-
ference that would, under section
506A(d)(3)(B)(ii), not require the approval of
a supplemental application the following shall occur:

(i) During the period in which the notice
is being reviewed by the Secretary, the
authority under this subsection to import the
qualifying drug involved continues in effect.

(ii) If the Secretary determines that such
a supplemental application regarding the
U.S. label drug would not be approved, the
Secretary shall—

(I) that the importation of the
qualifying drug from the permitted
country cease;

(II) notify the permitted country that ap-
proved the qualifying drug for commercial
distribution of the determination; and

(III) promptly notify registered exporters,
registered importers, the Federal Trade
Commission, and the State attorneys general
of the determination.

(III) APPLICATION UNDER SECTION 505(b).—

(I) there is no qualifying drug in commer-
cial distribution in the permitted country;

(ii) may not order that the importation
of the qualifying drug involved cease;

(iii) shall promptly notify registered
exporters, registered importers, the Federal
Trade Commission, and the State attorneys
general of the order.

(F) DIFFERENCES IN ACTIVE INGREDIENT,
ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.

(IN GENERAL.—A person who manufac-
tures a drug approved under section
505(b) shall submit an application under
section 505(b) for approval of another drug that is
manufactured for distributed in a permitted
country by or for the person that manufac-
tures the drug approved under section
505(b) if

(i) there is no qualifying drug in com-
commercial distribution in permitted countries
whose combined population represents at
least 50 percent of the total population of all
permitted countries of the same active ingred-
ient or ingredients, route of administra-
tion, dosage form, and strength as the drug
approved under section 505(b); and

(ii) each active ingredient of the other
drug is related to an active ingredient of
the drug approved under section
505(b), as defined in clause (v).

(i) APPLICATION UNDER SECTION 505(b).—
The application under section 505(b) required under clause (i) shall—

(iv) If the Secretary determines that such
a supplemental application regarding the
U.S. label drug would be approved, the
Secretary shall—

(II) vacate the order under clause (ii), if any;

(ii) consider the difference to be a vari-
ation provided for in the approved applica-
tion for the U.S. label drug.

(iii) permit importation of the qualifying
drug under subsection (a); and

(iv) promptly notify registered exporters,
registered importers, the Federal Trade
Commission, and the State attorneys general
of the determination.
“(I) request approval of the other drug for the indication or indications for which the drug approved under subsection (b) is labeled; and

“(II) include the information that the person submitting the documentation that was required under paragraph (3) or (4), and the State attorney general of a determination to approve or to disapprove an application under section 505(b) required under clause (i); and

“(VII) related active ingredients.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

“(I) the same; or

“(II) different salts, esters, or complexes of the same moiety.

“(3) SECTION 502; LABELING.—

“(A) IMPORTATION BY REGISTERED IMPORTER.—

“(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Package Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

“(I) directions for use by the consumer;

“(II) the lot number assigned by the manufacturer;

“(III) the name and registration number of the exporter;

“(IV) if required under paragraph (2)(B)(v)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug; and

“(V) if the inactive ingredients of the drug are different from the inactive ingredients of the U.S. label drug the information referred to in clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (i)(II) is submitted to the government of the permitted country.

“(ii) REQUESTED LABELING AND INGREDIENT LIST.—

“(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

“(II) include the proprietary name of the U.S. label drug or any active ingredient thereof;

“(III) if required under paragraph (2)(B)(v)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

“(IV) if the inactive ingredients of the qualifying drug are different from the inactive ingredients for the U.S. label drug, include—

“(aa) a prominent notice that the ingredients of the qualifying drug differ from the inactive ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

“(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e);

“(B) IMPORTATION BY INDIVIDUAL.—

“(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Package Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

“(I) directions for use by the consumer;

“(II) the lot number assigned by the manufacturer;

“(III) the name and registration number of the exporter;

“(IV) if required under paragraph (2)(B)(v)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

“(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug;

“(VI) if the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4), a prominent advisory to people with allergies about this drug in a manner that may affect, the strength, quality, purity, or the drug.

“(f) The Secretary becomes aware that—

“(I) the drug may be counterfeit;

“(II) the drug may have been prepared, packed, or held under insanitary conditions; or

“(III) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practices;

“(g) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

“(h) The Secretary has under section 505(e) withdrawn approval of the drug.

“(1) The manufacturer of the drug has instituted a recall of the drug;

“(2) the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4);

“(3) the drug is imported or offered for import to an individual by an exporter who issues the prescription, is authorized to administer prescription drugs; and

“(4) the drug is imported or offered for import to an individual by an exporter who issues the prescription, is authorized to administer prescription drugs; and

“(i) the shipping container for such drug does not bear the markings required under subsection (d)(2);

“(ii) The markings on the shipping container appear to be counterfeit;

“(iii) The shipping container or markings appear to have been tampered with.

“(j) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

“(I) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

“(II) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

“(k) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

“(I) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

“(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

“(i) is valid under applicable Federal and State laws; and

“(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

“(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.
"(C) The copies referred to in subparagraphs (A) and (B) are marked in a manner sufficient—

(1) to indicate that the prescription, and the prescription drug, is for the individual in the permitted country in which the importer is located, have been filled and;

(2) to prevent a duplicative filling by another pharmacist.

(3) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the Secretary.

(4) The drug is refused admission to the United States under subsection (a) is dispensed to the individual the following:

(1) The person exporting or importing the drug;

(2) The name and registration number of the importer.

(4) If required under paragraph (2)(B), the drug is refused admission to the United States under subsection (a) is dispensed to the individual the following:

(1) The person exporting or importing the drug;

(2) The name and registration number of the importer.

(5) A registration condition prescribed under paragraph (2)(E) would be required under section 502(e).
(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference as described in subparagraph (G) of paragraph (1) that—

(i) the difference was required by the country in which the drug is distributed;

(ii) the Secretary has determined that the difference was necessary to improve the safety or efficacy of the drug;

(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (b) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

(4) EFFECT OF SUBSECTION.—

(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager, or a covered entity in the drug discount program under section 340D of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

(ii) require that such discounts be made available to other purchasers of the prescription drug; or

(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340D of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary.

(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

(i) prevent or restrict a manufacturer from deducting a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United States, any State, or a governmental entity, or to a government of a foreign country; or

(ii) apply to such donations or supplying of a prescription drug.

(5) ENFORCEMENT.—

(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 1391 of title 28, United States Code.

(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission shall have the right to intervene in any action that is the subject of the notice.

(C) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (A)(ii), the Federal Trade Commission shall have the right to intervene in any action that is the subject of the notice.

(6) ACTIONS BY STATES.—

(A) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

(B) INTERVENTION.—

(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

(ii) ADMINISTRATIVE.—In any action brought under subparagraph (A), the Secretary may—

(I) conduct investigations;

(II) administer oaths or affirmations; or

(III) compel the attendance of witnesses or the production of documentary and other evidence.

(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), the Secretary may not, during the pendency of that action, actuate an action under subparagraph (A) for the same violation, against the same violator, named in the complaint in that action.

(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relative to venue under section 1391 of title 28, United States Code.

(F) SERVICE OF PROCESS.—In any action brought under subparagraph (A), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) may be found.

(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action arising under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable systems or methods as the court may determine.

(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

(8) MANUFACTURER.—In this subsection, the term 'manufacturer' includes, in addition to any affiliate or licensee of that entity, that is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently of means of chemical synthesis, and is intended for extraction and chemical synthesis; or

(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.

(9) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 802.

(2) The sale or trade by an individual of a qualifying drug that under section 804(g)(2)(B) was imported in a usual course of business.

(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or the failure to provide the Secretary, under such section, with such other information as the Secretary may require.

(5) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

(6) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or the failure to provide the Secretary, under such section, with such other information as the Secretary may require.
“(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not an approved drug under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

(1) the drug will be refused admission because the drug was not a lawful import under section 804;

(2) the drug is not otherwise subject to a waiver of requirements of subsection (a); and

(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804, if—

(A) the drug is not shipped by a registered exporter under section 804; and

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(4) the individual can find information about such importing, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.

(2) Establishment registration.—Section 506(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after “import into the United States’’ the following: ‘‘, including a waiver of such application be, importation of the drug was not a lawful import under such section 804’’.

(3) Effective date.—The amendments made by subsection (a) shall take effect on the date that is 90 days after the date of enactment of this title.

(d) Examination.—

(1) in General.—Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

(B) by inserting after subsection (g) the following:

“(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States, or to use, sell, offer to sell, or sell within the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.’’.

(2) Rule of construction.—Nothing in the amendment made by paragraph (1) shall be construed to affect the authority of the owner or licensee to enforce their patent, subject to such amendment.

(e) Effect of Section 804.—

(I) Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this title; and

(B) from permitted countries, as defined in such section 804, by importers registered under such section 804 on the date that is 1 year after the date of enactment of this title.

(2) Review of registration by certain exporters.—

(A) Review priority.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this title will have priority during the 90-day period that begins on such date of enactment.

(B) Period for review.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days relating to approval or reapproval of registrations is, as applied to such entities, deemed to be 30 days.

(C) Limitation.—That an exporter in Canada, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this title shall not serve as a basis, in whole or in part, for disapproving a registration under such section 804 from the exporter.

(D) First limit on number of exporters.—During the 1-year period beginning on the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) Second year limit on number of exporters.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) Further limit on number of exporters.—During the 2-year period beginning on the date that is 2 or more years after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 250, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(G) Limits on importers.—

(A) First year limit on number of importers.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be pharmaceutical groups, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(B) Second year limit on number of importers.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(C) Further limit on number of importers.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 500 (of which at least a significant number shall be pharmacies, to the extent feasible given the applications submitted by such groups) so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(D) Notice for drugs for import from Canada.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this title if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) Notice for drugs for import from other countries.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this title if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that was first completed on the date that is 120 days after the date of enactment of this title; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) Notice for other drugs for import.—

(A) Guidance on submission dates.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this title and that are not required to be submitted under paragraph (4) or (5).

(B) Consistent and efficient use of resources.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under such subparagraph (A) are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on such terms as the Secretary determines appropriate.

(C) Priority for drugs with higher sales.—The Secretary shall establish the dates described under paragraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before those with lower sales in the United States.

(7) Notices for drugs approved after effective date.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this title shall be submitted to and reviewed by the Secretary as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) Beginning of first fiscal year after date of enactment of this title.—Beginning with the first full fiscal year after the date of enactment of this title, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice under paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the
progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).  

(9) User Fees.—When establishing an aggregate total of fees to be collected from exporters and importers under subsection (f)(2) of this section 804, the Secretary shall, under subsection (e)(3)(C)(ii) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during the fiscal year during which this title is effective to be $1,000,000,000 as the number of days in such fiscal year during which this title is in effect.  

(B) Importers.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—  

(i) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and  

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.  

(C) Reestimate.—(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during the 4-month period from October 1 through January 31 of such fiscal year.  

(ii) REESTIMATE.—Notwithstanding subparagraph (A), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall equal to—  

(i) the total price of qualifying drugs imported by each importer as reported under clause (i), multiplied by  

(ii) 3.  

(iii) ADJUSTMENT.—The Secretary shall adjust the total price of drugs during the fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year equals the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during such fiscal year as estimated under clause (ii).  

(D) Failure to Pay Fees.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.  

(E) Annual Report.—(i) Food, and Drug Administration.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year, such report being prepared by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.  

(ii) Customs and Border Control.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary, in consultation with the Senate Committee on Finance, the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred or otherwise payable to the United States Customs Service and designated for use by this title, including an analysis of the expenses incurred in the use and disposition of such fees.  

(iii) Review Regarding Importation by Individuals.—(A) In General.—Notwithstanding any provision of this title (and an amendment made by this title), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Government of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.  

(B) Timing and Criteria.—The Secretary shall designate such additional countries under subparagraph (A) not later than—  

(i) 120 days after the date of the action by the Government of Canada described under such subparagraph; and  

(ii) 120 days after the date on which the Secretary determines that the drugs should be preserved as evidence or potential evidence of a violation of any provision of Federal food, drug, and cosmetic law.  

(C) Notice of Proposed Rulemaking.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.  

(D) Final Rule.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.  

(E) Implementation of Section 804.—(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.  

(2) Notice of Proposed Rulemaking.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary of Homeland Security to the Secretary under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.  

(3) Final Rule.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.  

(4) Coordination with Food and Drug Administration.—The Secretary shall carry out activities that educate consumers—  

(A) in regard to the availability of qualified drugs for personal use from an exporter registered and approved by the Food and Drug Administration and the toll-free telephone number required by this title; and  

(B) in regard to the suspension and termination of any registration of a registered importer or exporter under section 804; and  

(C) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration shall, to the extent that such provisions are not modified, be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.  

(3) Objection of Procedures.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, the delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 804(d)(1)-(3).  

(4) Certain Procedures.—(a) In General.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 804(d)(1)-(3).  

(b) Effect on Administration Practices.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration shall, to the extent that such provisions are not modified, be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.  

(5) Effect on Administration Practices.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration shall, to the extent that such provisions are not modified, be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.
"(f) Rule of Construction.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.

(b) Procedures.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this title.

(c) Effective Date.—The amendments made by subsection (a) and subparagraph (A) and by subsection (b) shall take effect on January 1, 2010.

SEC. 806. WHOLESALE DISTRIBUTION OF DRUGS: STANDARDS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) Striking of Exemptions; Applicability to Registered Exporters.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking "and who is not the manufacturer, distributor, or an authorized distributor of record of such drug";

(B) by striking "to an authorized distributor of record or"; and

(C) by striking paragraph (B) and inserting the following:

"(B) The fact that a drug subject to subparagraph (A) is dispensed from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statements described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug."

(2) Section 806(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(2)) is amended—

(A) in paragraph (1)—

(i) by striking the words "and which may be distributed through";

(ii) by inserting at the end the following:

"(ii) each place of business of the person with respect to whom the person is authorized by law to dispense prescription drugs;

(iii) by striking subparagraph (C) did not, when paragraph (2), a person may not dispense a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

(1) are not intended to be accessed by purchasers or prospective purchasers; or

(2) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5))."

(b) Additional Requirements.—

(3) The preceding sentence with respect to the furnishing of any prescription drug, for which the person provides the statements described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug, fails to meet the requirements, referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies as follows:

(1) Each page of the site shall include either the following information or a link to a page that provides the following information:

"(i) The name of such person.

(ii) Each State in which the person is authorized by law to dispense prescription drugs.

(iii) The address and telephone number of each place of business of the person with respect to whom the person is authorized by law to dispense prescription drugs through the Internet, other than a place of business that does not mail shipment purchases to purchasers.

(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

(v) If the person provides for medical consultations through the site for purposes of purchasing prescription drugs, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type and purpose of such consultations for which the individual provides such services, and whether the individual is responsible for fulfilling any such service.

(2) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'."

(b) Internet Sales Without Appropriate Medical Relationships.—

(1) In general.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet; or

(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for a drug that is valid in the United States;

(2) Secured to such communications, the person provided the information of a prescription for a drug, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

(3) The person was required to know, that the practitioner or the individual referred to in subparagraph (C) did not, when

SEC. 807. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) In General.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

"SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) Requirements Regarding Information on Internet Site.—In general, a person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

(A) the purchaser of the drug submitted the prescription order for such drug, and each other provision of the Federal Food, Drug, and Cosmetic Act, as added by section 806 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)) is amended—

(1) in paragraph (1)—

(A) by striking "and who is not the manufacturer, distributor, or an authorized distributor of record of such drug";

(B) by striking "to an authorized distributor of record or"; and

(C) by striking paragraph (B) and inserting the following:

"(B) The fact that a drug subject to subparagraph (A) is dispensed from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statements described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug."

(2) Section 806(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(2)) is amended—

(A) in paragraph (1)—

(i) by striking the words "and which may be distributed through";

(ii) by inserting at the end the following:

"(ii) each place of business of the person with respect to whom the person is authorized by law to dispense prescription drugs;

(iii) by striking subparagraph (C) did not, when paragraph (2), a person may not dispense a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

(1) are not intended to be accessed by purchasers or prospective purchasers; or

(2) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5))."

(b) Additional Requirements.—

(3) The preceding sentence with respect to the furnishing of any prescription drug, for which the person provides the statements described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug, fails to meet the requirements, referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies as follows:

(1) Each page of the site shall include either the following information or a link to a page that provides the following information:

"(i) The name of such person.

(ii) Each State in which the person is authorized by law to dispense prescription drugs.

(iii) The address and telephone number of each place of business of the person with respect to whom the person is authorized by law to dispense prescription drugs through the Internet, other than a place of business that does not mail shipment purchases to purchasers.

(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

(v) If the person provides for medical consultations through the site for purposes of purchasing prescription drugs, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type and purpose of such consultations for which the individual provides such services, and whether the individual is responsible for fulfilling any such service.

(2) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'."

(b) Internet Sales Without Appropriate Medical Relationships.—

(1) In general.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet; or

(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for a drug that is valid in the United States;

(2) Secured to such communications, the person provided the information of a prescription for a drug, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

(3) The person was required to know, that the practitioner or the individual referred to in subparagraph (C) did not, when
issuing the prescription, have a qualifying medical relationship with the patient; and
"(E) the person received payment for the dispensing or sale of the drug.
For purposes of subparagraph (E), payment is received if money or other valuable con-
sideration is received.
"(2) EXCEPTIONS.—Paragraph (1) does not apply if—
"(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices
sponsored by—
"(i) a hospital that has in effect a provider agreement under title XVIII of the Social
Security Act (relating to the Medicare pro-
gram); or
"(ii) a group practice that has no fewer than 100 physicians who have in effect pro-
vider agreements under such title; or
"(B) the dispensing or selling of a prescription
drug pursuant to practices that promote the public health, as determined by the Sec-
retary by regulation.
"(3) QUALIFYING MEDICAL RELATIONSHIP.—
"(A) IN GENERAL.—With respect to issuing a
prescription for a drug for a patient, a practitioner has a qualifying medical rela-
tionship with the patient for purposes of this section if—
"(i) at least one in-person medical evalua-
tion of the patient has been conducted by the practitioner; or
"(ii) the practitioner conducts a medical evalua-
tion of the patient as a covering prac-
titioner.
"(B) IN-PERSON MEDICAL EVALUATION.—A medical evalua-
tion by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the phys-
ical presence of the patient as part of con-
ducting the evaluation, without regard to whether portions of the evaluation are con-
ducted by other health professionals.
"(C) COVERING PRACTITIONER.—With respect to a practi-
citioner referred to in section 503(b)(1) with-
termination drug in violation of section 503B.
"(i) IN GENERAL.—The term 'practitioner' means a prac-
titioner who has conducted at least one in-per-
sion medical evaluation of the patient and is
temporarily unavailable to conduct the eval-
uation of the patient. A practitioner is a cov-
ering practitioner for purposes of this section if the
practitioner conducts a medical evalua-
tion of the patient at the request of a practi-
citioner who has conducted at least one in-per-
sion medical evaluation of the patient and is
temporarily unavailable to conduct the eval-
uation of the patient. A practitioner is a cov-
ering practitioner for purposes of this section if the
practitioner has conducted any in-person medical evalua-
tion of the patient involved.
"(4) RULES OF CONSTRUCTION.—
"(A) DEFINITION OF COVERED PERSON.—The term
'covered person' has the meaning assigned to it under section 503(a).
"(B) STANDARD PRACTICE OF PHARMACY.—
Paragraph (1) may not be construed as pro-
hibiting any conduct that is a standard prac-
tice in the practice of pharmacy.
"(C) APPLICABILITY OF REQUIREMENTS.—
Paragraph (3) may not be construed as hav-
ing any applicability beyond this section, and
does not affect the authority of State law en-
pforcement of State law, concerning the prac-
tice of medicine.
"(D) ACTIONS BY STATES.—
"(i) IN GENERAL.—The Secretary of Health
and Human Services (referred to in this sub-
section as the 'Secretary') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of matching funds under paragraph (1), except that on the
expiration of the 12-month period described in subparagraph (A), the Secretary shall not make an award under such paragraph unless the Secretary finds that there will be a significant increase in the number of patients who benefit from services that are available to such patients.
"(ii) PROHIBITION OF CERTAIN ACTIONS.—
No Federal, State, or local government, or any
individual engaged or otherwise affiliated with such government or individual, shall take any action to prohibit, discourage, or otherwise impair the ability of any person to obtain services provided under paragraph (1) if such action is taken in violation of any State law, notwithstanding any provision of Federal law.
is amended by adding at the end the following:

"(g) Restricted Transactions.—

"(1) In General.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

"(2) Payment System.—

"(A) In General.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in whole or in part, or by any other means that may be used by another person, to effect a credit transaction, an electronic fund transfer, or a money transmitting service.

"(B) Persons Described.—A person referred to in paragraph (A) is—

"(i) a creditor;
"(ii) a credit card issuer;
"(iii) a financial institution;
"(iv) an operator of a terminal at which an electronic fund transfer or money transmitting service is authorized to be used by a consumer; and
"(v) any other system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

"(B) Persons Described.—A person referred to in subparagraph (A) is—

"(i) a credit card system;
"(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service; and
"(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

"(3) Restricted Transaction.—The term 'restricted transaction' means a transaction or transmittal, on behalf of any individual who was engaged in the introduction of restricted transactions into a payment system or was centrally managed and is primarily engaged in the transmission and settlement of restricted transactions, on behalf of any individual for the purpose of the unlawful drug importation request, including credit extended through the use of a credit card;

"(4) Money Transmitting Business or Transmittal.—The term 'money transmitting business or transmittal' means any electronic fund transfer, or money transmitting service that involves the use, in whole or in part, of the Internet, phone, or electronic mail, or by a means that is not a registered electronic fund transfer service.

"(f) Enforcement.—

"(1) In General.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

"(2) Policies to be Considered.—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulator shall consider the policies and procedures of the payment system and the Federal Trade Commission shall consider the following:

"(I) The extent to which the payment system or person knowingly permits restricted transactions.

"(II) The history of the payment system or person in connection with permitting restricted transactions.

"(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

"(4) Transactions Permitted.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7).

"(5) Timing of Requirements.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is not subject to the requirements promulgated under subsection (a), not later than 90 days after the date of enactment of this Act.
SEC. 809. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking “not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance” and inserting “import into the United States not more than 10 dosage units of all such controlled substances.”

SEC. 810. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

SEC. 811. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public’s health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid upon the table. The title amendment which is at the desk is agreed to, and the motion to reconsider is considered made and laid upon the table.

The title was amended so as to read:

‘‘Sec. 809. Importation Exemption Under Controlled Substances Import and Export Act. ’’

The PRESIDING OFFICER. With no objection, it is so ordered.

Mr. ENZI. Mr. President, I ask unanimous consent that Senator KENNEDY and I have a few minutes here to thank some of the people involved. I have checked with the people who would be involved with the judges, and they have no objection.

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

Mr. ENZI. Mr. President, I do want to take a few minutes to thank the leaders, particularly the majority leader, who, after some difficulties last week, helped to smooth some things out and make it possible for us to move on a little bit on the bill. His coordination and leadership were indispensable.

I thank the Republican leader for the way he handled the bill and, again, made sure we were working across the aisle and getting difficulties smoothed out.

I definitely wish to thank the chairman of the committee for the outstanding work he did through the entire process. As we mentioned a number of times, it has been a very lengthy process, but he has always been so forthright and knowledgeable and willing to work under all kinds of circumstances and difficulties. Because of his dedication and abilities, I have learned a lot about running the committee from him and I have learned a lot about getting a bill passed from him and have enjoyed working with him over the last 2 years on a number of bills.

I thank the staff people who have worked so hard. They have spent many evenings and even weekends away from home. I especially want to thank John Underwood, who worked through the night to get some of these issues worked out. The way we work a bill, it is a work in progress until it is finished. It is not finished yet; we have got to work with the House side yet, and we will do that.

This is such an important bill for the country. My HELP team worked overtime to get this bill to the floor and passed in the Senate.

I would first like to thank my health policy director, Shana Christrup. Shana was promoted to her leadership position in January of this year. She took aloof of the reins, has incredible knowledge, dedication, and negotiating and drafting skills that helped bring this bill to fruition.

I also want to greatly thank Amy Muhlig, our crackerjack expert who knows all things FDA. Her knowledge and drafting skills were central to this bill.

I thank Keith Flanagan for his work on the children’s statutes in this bill, and Dave Schmickel, who is our resident drug patent expert, for his ongoing work on follow-on biologics.

Others on the team I would like to thank include Todd Spangler and Brittany Moore, who provided the required backup that goes with moving a bill of this magnitude.

Finally, I thank my staff director, Katherine McGuire, whose steady hand in negotiating and communication skills and ability to juggle a number of issues at the same time and tap dance skills and ability to juggle a number of issues at the same time and tap dance and do all sorts of things that make these bills possible provided the cement for the entire process.

I would also like to thank Ilyse Schuman, Flip McConnaughy, who was good at putting out brushfires throughout the process and kind of maintaining the core to our whole process.

On Senator KENNEDY’s staff, I would like to thank Michael Myers, David Dorsey, Missy Rohrbach, Jeff Teitz, David Noll, and Tom Kraus. Senator KENNEDY’s staff were reasonable negotiators throughout the process and open and patient to hearing all sides of any issue.

As I mentioned before, Senator HATCH was responsible for the first FDA Revitalization Act, and I would like to thank him and his staff, Patty DeLoatche and Trish Knight, for helping me with the second FDA Revitalization Act.

With Senator GRIZZL’s office, and for his assistance with the health IT for drug safety, I thank Dave Fisher and Liz Wroe.

Stephanie Carlton from Senator COBURN’s staff and Jenny Ware with Senator BURR were also integral to many parts of the bill.

I would like to thank my colleague from Kansas, Senator ROBERTS, and his staff Jennifer Swenson, Kate Anderson, and Mike Seyfert, for their incredible work on our direct-to-consumer advertising.

I also thank my colleague, Senator HARKIN, and his staff, Mike Woody, for his hard work on the bill.

I thank Meghan Hauck, who is with Senator MCCONNELL, for her great assistance throughout the process and her tireless hours.

I thank Isaac Edwards, Amanda Makkki, Tyler Thompson, Jennifer Claypool, and Mary-Sumpter Johnson. Finally, there is a group of people without whom none of this would have happened. They work behind the scenes and make the rest of us look good. I am talking about the dedicated folks at legislative counsel, Stacy Kern-Scheerer, Bill Baird, Amy Gaynor, and the rest of the legislative counsel team. They have drafted forever on this, and redrafted, helped make this law become a reality. They did it with class, grace, patience, and I cannot thank them enough.

I yield the floor.

The PRESIDING OFFICER (Mr. BROWN). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, one of the great joys of serving in the Senate has been working with my friend and colleague from Wyoming, Senator ENZI, on different legislation. He does it the old-fashioned way. He believes that what we ought to do is have the hearings on the problem and then listen to various alternatives and then try to work out a solution and carry the process forward. That is the old-fashioned way. Today people look at different issues, file bills, and think about interventions. He has a deep-seated conservative philosophical commitment. He and I differ on some matters, but we always try to find common ground. We have been able to find it certainly on this legislation and many other pieces of legislation. I look forward to continuing this tradition. I am personally grateful to him for all his help in guiding us. You can see the closeness of these votes. This is enormous. I think this legislation to bring the Food and Drug Administration into the 21st century. But there are strong feelings, strong opinions, strong arguments on different ways to do so. We have legislation. It is solid legislation. We are proud of it. I think the overwhelming, virtually unanimous vote of the Senate on both sides is a vindication of the efforts our committee has made. It starts with Senator ENZI. I am grateful to him.

Mr. BROWN. Senator BROWN, the Senator from Ohio, was kind enough yesterday to stand in for me when I had the great honor to witness the coming together in Northern Ireland after 400 years of
conflict and the establishment of democratic institutions in a very momentous historical moment. When I left Monday night, there was a certain element of chaos surrounding this bill, and coming back early this morning, under the leadership of Senator Enzi and Senator Brown, we had an orderly path to proceed. He is knowledgeable about health issues and had a very distinguished record on health policy before he came to the Senate. He has not missed a beat in working through the issues. He has been invaluable to me personally and to our committee. I thank Senator Brown for all of his good work.

Quickly: I would like to thank my friend, Senator Dodd for his work on all of the issues that affect kids’ drugs and devices; Senator Clinton for her work on drugs and devices; Senator Mikulski for her work on the issues of transparency, enormously important provisions on which this legislation depends; Senator Hatch for his work on antibiotics; Senator Gregg for his work on the databases and Web portal; Senators Roberts and Harkin for their work on the direct to consumer advertising issue, which involves a lot of different, important policy issues and a lot of emotion and feeling. They worked very hard with the staff, we had very solid recommendations on this; Senator Stabenow for her work on the citizens’ petitions in order to help get products to patients more quickly; I would also like to thank Senator Brown and Senator Brownback, for their enormously creative innovative idea with regard to neglected diseases. This is something the United States should be doing more of, and they have been very creative in coming up with an idea; Senator Coburn on the doctor-patient relationship, a subject matter he feels intensely about and has been helpful to us on the legislation; Senator Hatch on safety provisions, which are very important and helpful; Senator Alexander on the children’s drugs; Senator Allard on food safety issues; Senator Lincoln on food safety including the raising-fish issue.

These are some of the items. Again, we thank staff members: From my staff, Dave Bowen, David Dorsey, David Noll, and Caya Lewis, all who have spent a great deal of time and effort over these past weeks, Michael Myers and Paul Martin, and Misky Rohrbach, Tom Kraus, I thank them enormously.

I express appreciation to Senator Enzi’s staff. If people try to find solutions, rather than perpetuate differences, it makes an enormous difference. That was certainly true of all the staffs on our committee. I thank Amy Muhlb erg and David Schmickel and Keith Flanagan and Katherine McGuire, Shana Christrup; Senator Brown’s staff: Ellie Dehoney; Senator Dodd’s staff: Nan McGraw; Senator Mikulski: Ellen-Marie Whelan; Senator Hatch’s staff: Patty DeLoache, and Trisha Knight; Mike Woody from Senator Harkin; Senator Gregg: Liz Wroe; Senator Roberts: Jennifer Swenson, Mike Seyfert, and Kate Anderson; Senator Clinton’s staff: Ann Gavaghan and Andrea Palm. I am sure I might have missed someone, but we will make sure they are included in the RECORD.

We thank colleagues and friends. We look forward to meeting with the House and reflecting the Senate’s best judgment on the legislation.

Mr. President, over the past 10 days we have had a good debate about important issues affecting the safety of our Nation’s citizens, about the drugs they use when they are ill, and about the food they eat every day.

S. 1062 will reauthorize two important user fee programs at the FDA. First among these is the prescription drug user fee program. In 2008, the program is projected to supply the FDA with nearly $400 million to help support new drug reviews and monitor the safety of drugs once they are approved. Finally, the bill will reauthorize the medical device user fee program, which subsidizes the medical device review process. Both these programs speed new medical products to patients by enhancing the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening the agency’s science-based culture, and improving transparency, strengthening

A clinical trials registry would enhance patient enrollment and provide a mechanism to track the progress of clinical trials.

Finally, the legislation would establish the Reagan-Udall Foundation for the improvement of the public health research projects, among the FDA, academic institutions, and industry intended to improve medical product development and evaluation.

I appreciate Senator Dodd and Senator Clinton’s leadership to promote the safety of drugs and devices used to treat children.

I thank Senator Roberts and Senator Harkin for working with Senator Enzi and me to design constitutionally sound, effective, and feasible controls on DTC advertising. The amendment we produced will ensure the information that ads provide is accurate, clear, and conspicuous without imposing a moratorium.

I applaud Senators Stabenow, Brown, Lott, Thune, Coburn, and Hatch for coming to a solution on the issue of citizens’ petitions. They were able to craft an amendment that ensures that only citizens’ petitions with meritorious claims could delay approval of a generic drug and that frivolous petitions will not lead to unwarranted delays in the approval of new generic drugs.

I also applaud Senator Brownback and Senator Burr for their proposal to encourage investment in new medicines for neglected tropical diseases. Their proposal entitles companies that develop new therapies or vaccines to a voucher allowing them a priority review at the FDA for a product of their choosing. It would provide pharmaceutical manufacturers a significant incentive without raising costs to consumers or relaxing the safety standards applied to the drug given priority review.

I would also like to draw attention to the essential amendment introduced by Senator Hatch, with important contributions from Senators Brown, Burr, Stabenow, and others. The amendment would close a loophole that did away with the incentive to bring old but never approved antibiotics to market. It would also establish a process to identify drug-resistant infections that are orphan diseases and that could be treated with orphan drugs. Additionally, the amendment makes certain molecules that are a part of old active ingredients eligible for recognition as new active ingredients, provided they will be used for a new indication. This provision includes limits that would prevent pharmaceutical manufacturers from abusing the process to extend the life of old active ingredient drugs.

Finally, I am grateful to my friend, Senator Enzi, for his leadership and commitment to addressing prescription drug safety. We have worked together for over 2 1/2 years to develop this legislation, and I am proud of where we are today.
I have already thanked a number of people, and I would also like to thank, on Senator Enzi's staff, Ilyse Schuman, and on my own staff, Stacy Sachs, Molly Nicholson, Jeff Teitz, and Charlotte Burrows, and two of my interns, Ashley Hartnett and Lara Mounir. I would also like to thank the many other staff members, both on and off the committee, who did such great work on this bill: Carmen Green, Nancy Hardt, Paula Burg, Lisa German, Jessica Gerrity, Dora Hughes, Ed Ramirez, Jim Escarce, Laura Lazarus, Lisa Layman, Jenny Ware, Mary-Sumpter Johnson, Stephanie Carlton, and Jennifer Claypool.

I would also like to thank the legislative counsel's Bill Baird, Amy Gaynor, and Stacey Kern-Scheerer for all of their hard work on this bill.

Mr. ROBERTS. Mr. President, today the Senate voted to approve S. 1082, the Food and Drug Administration Revitalization Act. I am very pleased to note that the Senate has voted by voice vote to approve this bill, and I now look forward to its consideration in the House.

Unfortunately, I was not present to vote for the bill, but I would like the record to reflect that I had planned to vote in favor of this legislation. Just last night, as many of us experienced a horrible disaster when a tornado devastated an entire community and took the lives of several Kansans.

Late last Friday evening, the town of Greensburg, KS, was literally wiped off the map by an enormous tornado. As a result of this and storms associated with the system, 12 Kansans are confirmed dead, and all of the 1500 residents of Greensburg have been displaced. What we have experienced in Greensburg is unlike any other event in recent Kansas history. The hospital is gone, the schools are gone, every church is gone, virtually every business in the community is gone, including all of Main Street. Estimates are that at least 95 percent of the structures in the town are damaged or destroyed. Because of this devastation, I invited President Bush to come to Greensburg, KS, and view the damage from this unspeakable disaster. Today, President Bush is in Greensburg, and I, along with other members of the Kansas congressional delegation, are showing him the devastation this community has experienced, so I could not be present to vote for S. 1082.

However, I want my colleagues to know that I support this legislation and would have voted in favor of the bill if I were present. I believe S. 1082 will give FDA the tools to ensure drug safety and will renew some very important prescription drug and medical device programs. I am also pleased that the bill includes an amendment I sponsored with Senators Harkin, Burr, and Coburn to improve the drug advertisement provisions in the underlying bill. This amendment was accepted unanimously by the Senate.

Our amendment addresses the first amendment concerns with the advertising provisions in the original bill and gives the FDA the tools they need to protect the public from false or misleading prescription drug advertisements. We believe this amendment is a more commonsense approach to dealing with prescription drug advertisements and ensures the public will get truthful information about new prescription drugs.

I especially want to thank Chairman Kennedy, Ranking Member Enzi, and Senator Harkin for their leadership and hard work on this issue. I also want to thank Senators Burr and Coburn for their cooperation and cosponsorship of my amendment. This amendment represents the result of our efforts to achieve an outcome that is acceptable to all of us. The agreement that was accepted today is a fair compromise that addresses the concerns of all of the Members involved.

Mr. BYRD. Mr. President, I voted against Senator Durbin’s amendment because the amendment would have retained the removal of the best scientific minds from the oversight of the safety of our Nation’s food and prescription drug approval process. Though well intentioned, the Durbin amendment would have limited the advice available to the Food and Drug Administration for critical decisions pertaining to consumer safety. I will support the efforts to ensure that conflicts of interest do not interfere with the safety of the American people, and I will work to ensure that the country’s best experts continue to secure our medications and food supply.

I suggest the absence of a quorum. The PRESIDING OFFICER. The clerk will call the roll. The legislative clerk proceeded to call the roll.

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

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

EXECUTIVE SESSION

NOMINATION OF DEBRA ANN LIVINGSTON TO BE UNITED STATES CIRCUIT JUDGE FOR THE SECOND CIRCUIT

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider Executive Calendar No. 104, which the clerk will report.

The legislative clerk read the nomination of Debra Ann Livingston, of New York, to be United States Circuit Judge for the Second Circuit.

The PRESIDING OFFICER. Under the previous order, there will be 3 hours for debate equally divided between the chairman, Senator Leahy, and the ranking member of the Judiciary Committee or their designees.

The Senator from Vermont is recognized.

JACK VALENTI

Mr. LEAHY. Mr. President, in the time allotted to me, I will talk about some other things. Later this afternoon, a wonderful American man who had a life that epitomizes what is best in our country will be buried in Arlington. I am speaking about Jack Valenti. Jack and his wife Mary Margaret first took my wife Marcel and I under their wing when we were in our 30s. They were known 34-year-old Senator from Vermont. We had so many wonderful times with both of them. There would be times, obviously, as many of us did during Jack’s years as president of Motion Pictures Association, when we would gather for a dinner at the MPAA, always with at least one Italian dish, and then watch a first-run movie. Jack would be greeting everybody by name. For those of us who sometimes have to remember the names of our own families, he was remarkable. But the remarkable thing was, he greeted everybody. He knew about you and was interested in what you were interested in, but also on the points that he wanted to get across, he would do so in a way with integrity, with brilliance, and with the respect of both Republicans and Democrats, as he would go through the halls of the Senate and the House.

On a personal basis, with Ray and Mary Margaret, he was my single her out at national gatherings of them, on a soft summer evening, sitting outdoors and talking about kids and, in that case, their pending grandchild. I could not help but think about this man, who by all rights never should have made it through World War II. He was a highly decorated fighter bomber pilot. He went through battles where there were enormous casualties. He received the Distinguished Flying Cross and just about every other bravery medal one could, and he survived.

He came back to a career that ranged from being somber, as we all know, in Texas at the time of President Kennedy’s death, to being on the plane with President Johnson, and sharing those Texas roots and working with him.

From a personal point of view of view, I think of the time he spent with my late mother, who was an Italian American. They had that bond. He would single her out at national gatherings of Italian Americans. She loved it. She called me once and said: I saw that nice young man on television. I said: Mother, whom are you talking about? She said: Jack Valenti, that nice young man. I said: Mom, Jack is almost 20 years older than I am. She said: Really? Well, he doesn’t look it. And then came the killing shot. She said: Patrick, you should take better care of yourself. When Jack had one of his many retirement parties—I will speak to that in a moment—I told that story.

I am afraid more than one person in the audience agrees with my mother. It is one of many retirements." He never retired. He continued to write books. He had one that he just finished before a stroke silenced him a few

May 9, 2007

CONGRESSIONAL RECORD — SENATE