United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 112th CONGRESS, SECOND SESSION

Vol. 158 WASHINGTON, WEDNESDAY, MAY 23, 2012 No. 75

House of Representatives

The House was not in session today. Its next meeting will be held on Friday, May 25, 2012, at 10 a.m.

Senate

WEDNESDAY, MAY 23, 2012

The Senate met at 9:30 a.m. and was called to order by the Honorable KIRSTEN E. GILLIBRAND, a Senator from the State of New York.

PRAYER

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

Eternal God, You have made all things well. Thank You for the light of day and the dark of night. Thank You for the glory of the sunlight, for the silver splendor of the Moon, and for the star-scattered sky. Thank You for the hills and the sea, for productive city streets, for the open road and the wind in our faces. Thank You for hands to work, eyes to see, ears to hear, minds to think, memories to remember, and hearts to love.

Thank you also for our Senators and their families who strive to serve You and country. Bless them today with a special measure of Your wisdom, knowledge, and discernment. We pray in Your sacred Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable KIRSTEN E. GILLIBRAND led the Pledge of Allegiance, as follows:

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

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. INOUYE).

The assistant legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 23, 2012.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable KIRSTEN E. GILLIBRAND, a Senator from the State of New York, to perform the duties of the Chair.

DANIEL K. INOUYE,
President pro tempore.

Mrs. GILLIBRAND thereupon assumed the chair as Acting President pro tempore.

RECOGNITION OF THE MAJORITY LEADER

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

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

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

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

The assistant legislative clerk read as follows:

Motion to proceed to Calendar No. 400, S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

SCHEDULE

Mr. REID. Madam President, we are now on the motion to proceed to the FDA user fees bill. Republicans control the first half hour, the majority the second half hour. We are working on an agreement to consider amendments to the FDA bill. We are close to being able to finalize that. We hope to get an agreement and avoid filing cloture on the bill.

MEASURES PLACED ON THE CALENDAR—S. 3220 AND S. 3221

Mr. REID. There are two bills at the desk due for a second reading.

The ACTING PRESIDENT pro tempore. The clerk will read the titles of the bills for the second time.

The assistant legislative clerk read as follows:

A bill (S. 3220) to amend the Fair Labor Standards Act of 1938 to provide more effective remedies to victims of discrimination in the payment of wages on the basis of sex, and for other purposes.

A bill (S. 3221) to amend the National Labor Relations Act to permit employers to pay higher wages to their employees.

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

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

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. REID. The Chair read for the second time a couple of bills. I object to both of them.

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

Printed on recycled paper.

The ACTING PRESIDENT pro tempore. Objection is heard. The bills will be placed on the calendar under rule XV.

Mr. REID. Madam President, when 67-year-old Pamela Gunter started treatment for breast cancer, her doctor knew it would be a grueling fight. He also knew it was a fight she could win. Pamela's doctor put her on Taxol, a common chemotherapy drug. The results were excellent. Her tumor shrank. Her prognosis was good.

Then one day last spring, no more Taxol. The doctor could not get it. It is one of the most popular and effective treatments for breast, lung, and ovarian cancer, and it suddenly disappeared from the markets in Nevada. Doctors couldn't get it; drug suppliers could not say why. So Pamela's doctor was forced to use a much more expensive and much less effective course of treatment. The cancer spread. By the time Taxol was available again, Pamela was dead. She left behind a loving husband, two grown sons, and a grandchild. But with the right treatment she would still be alive today. Her Las Vegas doctor said a shortage of this common generic medicine directly contributed to her death. Had this product been available, she would have been fine. She of course would have suffered; that is what patients on chemo do. But their suffering is worth it because they know it is lifesaving.

Pamela is not the only American affected by a shortage of Taxol and other lifesaving drugs. Every day in hospitals across the country Americans already dealing with devastating illnesses must also face shortages of FDA-approved medications that could keep them alive. Today Taxol is still scarce. And chemotherapy drugs are not the only ones in short supply; supplies of nausea medication. The Capitol physician is, among other things, an oncologist, Dr. Monahan. I have talked to him about cancer a lot in the last year, he and other doctors. My wife would go every week to this place where everybody was hooked up to chemo. Most of them were women, but there were a few men. Just a few years ago that would have been a place where these women were retching by virtue of their vomiting. Sometimes—in fact a lot of the times—they had to hospitalize these women to stop the vomiting from these medicines.

Now we have nausea medication these patients are given to stop their suffering. At least, although they may be going through a lot of nausea, they are not throwing up most of the time. But supplies of nausea medications and other drugs that reduce the side effects of cancer treatment are limited. On Monday, one Las Vegas oncologist said he ordered 10 drugs from his supplier. He could get eight. He said that is typical; doctors never know which drugs will be accessible and which will not.

Last year FDA reported shortages of 231 drugs, including a number of chemotherapy medicines. In the last 6 years, drug shortages have quadrupled, gone up 400 percent. Congress cannot solve every problem in this country, we know that, but this is one problem we can solve with cooperation from the drug manufacturers. It will come about much more clearly if we pass the bill that is before the Senate now.

The Food and Drug Administration Safety and Innovation Act, the one I have talked about several times already today, will help establish effective lines of communication between drugmakers, the Food and Drug Administration, and doctors. When the FDA gets early warning from manufacturers that shortages are coming, it can act quickly to find alternative sources of medication and ease supply problems by, for example, taking from one place where they have a lot of a medicine and moving it someplace where they do not. Drugmakers averted 200 shortages last year by voluntarily notifying the FDA of trouble on the horizon. But many shortages, perhaps all 231 last year, could have been prevented if drugmakers had shared information with FDA.

Our bill would make that necessary and force it to take place. That is why Congress must act quickly to pass the legislation that is now before the Senate, which will ensure the FDA has the resources to approve new drugs and medical devices quickly and efficiently.

Passing this legislation would not bring Pamela back, it would not give her another day to spend with her husband, another week to say goodbye to her sons, or another year to get to know her grandchild. But this legislation will help prevent drug shortages like what took Pamela away from her family far too soon.

As I indicated, we are very close to an agreement, a path forward on this bill, and that would be very good for this country. I hope we can arrive at that by 11 o'clock today.

RECOGNITION OF THE MINORITY LEADER

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

HEALTH CARE

Mr. MCCONNELL. Madam President, yesterday morning I came to the floor to call attention to a quiet and costly PR campaign that President Obama is mounting on the taxpayers' dime. While the President and his surrogates spend most of their time deflecting attention from his record, he has Washington bureaucrats working overtime to try to put on a good face.

I mentioned yesterday the administration is spending yet another $20 million in taxpayer money to promote a health care bill that most Americans would like to see repealed. Let me repeat that—$20 million to promote a health care bill that most Americans would like to see repealed.

There is more. There is a pattern that I, and I am sure many other Americans, find pretty outrageous at a time of trillion-dollar deficits and a near $16 trillion debt. The administration also spent more than $25 million in stimulus funds on grants to public relations firms—PR firms—ostensibly to do public relations related to promoting the stimulus. It spent nearly $20 million on mailings to seniors to tout ObamaCare—a mailer, by the way, that the Government Accountability Office found overstated the law's benefits.

Millions of taxpayer funds were spent on postcards that promote ObamaCare's small business tax credit—a credit the GAO said was ineffective and infrequently used. These are just a few of the ways the administration is quietly promoting its own fatal policies; how it is trying to change people's minds about the President's policies with their own money, and using our tax money to try to promote the President's policies. The campaign is one thing, but using our tax money to promote the President's policies is outrageous.

There is a larger issue than the fact that the President is quietly marketing policies with taxpayer dollars that he is clearly afraid to talk about in public. That is bad enough, but the larger point is the fact that we have a nearly $16 trillion debt, the largest tax hike in history right around the corner, chronic unemployment, and sky-high gas prices, and the President thinks it is a good idea to spend $20 million to promote ObamaCare. We don't have the money to begin with, and he is spending it to market his policies.

The President needs to face the facts. Americans do not want him spending their hard-earned money trying to spin policies they don't like. How about setting some priorities first? How about working with us to lower the deficit and the debt? How about working with us to fund things we actually need? We are more than ready to work with the President, as I said time and time again over the past few years, but he needs to set some priorities and lead.

I yield the floor.

RESERVATION OF LEADER TIME

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

ORDER OF BUSINESS

Under the previous order, the following hour will be equally divided and controlled between the two leaders or their designees with the Republicans controlling the first half and the majority controlling the final half.

SECOND OPINION

Mr. BARRASSO. Madam President, I would like to follow up on the wonderful comments made by the minority leader. Specifically, I want to talk about the health care law and the ways that taxpayer dollars are now being wasted and spent in what appears to be a propaganda campaign by this administration to promote a health care law the American people—at least the majority of them when asked about it—

think should be found to be unconstitutional by the Supreme Court and so many Americans want to see repealed and replaced.

Over 2 years ago, President Obama and Democratic leaders in Congress—in this very body and across the Hall—jammed a health care law through Congress that was drafted completely behind closed doors. We all recall NANCY PELOSI famously saying at the time: First you have to pass it before you get to find out what is in it.

I have come to the floor week after week after that with a doctor's second opinion about the health care law to make sure the American people know what is in it. Week after week there have been more things found out about the health care law that has made it even more unpopular today than it was at the time it was passed and signed into law by President Obama.

Americans knew what they wanted. They did want health care reform. They wanted to be able to get the care they need from the doctor they want at a price they can afford. Yet when I go to townhall meetings and meetings in other communities across my home State of Wyoming and ask the question: Do you think under the President's health care law you will be paying more or less for your health care, the hands go up that they are going to be paying more. Then I ask them: Do you think the quality and availability of your care is going to go down under the health care law? Again, the hands go up.

That is not what Americans want, not to pay more and get less. Yet that is what the American people are receiving under this health care law. So I will continue to deliver this second opinion on the Senate floor so we can continue to talk about what is going to be the impact on Americans' lives as a result of the health care law.

Now, for over 2 years, the news about the law has not been good for those who support it, and the country has had opposition to the law continue to increase. Today 56 percent of Americans oppose the President's health care law.

One may ask: Why is that? Well, there are a number of reasons. One is the health care law is adding to the national debt. We heard the Republican leader talk about the incredible national debt the American people are facing. The health care law has increased premiums that people have to pay for their own insurance directly as a result of the health care law being passed. The President promised: If you like what you have, you can keep it. But actually the health care law has made it harder for workers to keep their employer-sponsored health care coverage.

People want to have choices. They want to have patient-centered care. Yet this health care law established an unprecedented board with unelected bureaucrats who will, by their decisions, have a direct impact on whether patients can get to see a doctor or whether they can receive care.

When I look at the incentives that are part of this health care law, to me, the incentives actually appear to encourage employers to either fire workers or stop providing health care coverage. To me, this health care law is discouraging to students who otherwise might pursue a career in the medical field and potentially provide care for Americans.

In my opinion, this is a law that has actually weakened, not strengthened, Medicare. It has done that by taking $500 billion away from our seniors on Medicare, not to help strengthen Medicare but to start a whole new government program for someone else.

The Medicare Actuary came out with a report last Friday to say that when we actually get into a realistic assessment of the impact of this health care law on Medicare, it weakens it. It shows Medicare going broke sooner than initially thought. This report has a realistic look at the impact of the health care law on Medicare and shows that it will make it that much harder for our seniors on Medicare to get the treatment they need and to actually get to see a doctor to find someone to care for them. The implementation of this law, which takes $500 billion away from Medicare, is not to strengthen or save Medicare but to start a whole new government program for someone else.

So I could go on and on with legitimate complaints about the law. We made it clear for over 2 years that the law is bad for patients, bad for providers, nurses, and the doctors who take care of those patients, and it is terrible for taxpayers.

This week we got a response to our long list of serious issues, responses from the administration and members of the administration. What they are doing is essentially doubling down on the President's failed law. Instead of addressing the serious concerns the American people have about the law and about their own health care, the White House has come to the conclusion they have actually done a bad job of educating the American people about the law. So now, just months before the Presidential election, the 2012 election, the administration has just signed a $20 million contract for a private PR firm to educate the American people about the law.

Of course, this is taxpayer funded. So let me repeat: The Obama administration is not even going to acknowledge any of the real problems with the law. Instead it is going to spend 20 million taxpayer dollars on press releases and more government propaganda.

It is important to remember this isn't the first time the White House has spent millions of taxpayer dollars on trying to spin this law. They realize it is unpopular, but are they addressing the fundamental flaws? No, they want to do more public relations.

In fact, this administration spent $700,000 on an advertisement starring Andy Griffith, the television star, about how the law will impact Medicare. The Internal Revenue Service spent nearly $1 million in taxpayer funds to pay for 4 million postcards to promote tax credits in the law for small businesses. Of course, what we have seen, and what the President would say, and I would say, is fewer and fewer small businesses than anticipated found they were not able to qualify for the so-called benefits of the health care law.

So what we have seen is the President's law continues to be unpopular, and now the administration chooses to spend taxpayer dollars to try a public relations campaign to make it more popular instead of dealing with the fundamental problems.

So here we are millions of dollars later, and it is clear that the White House still has not learned what most Americans understand—good policy is good communication. When a law is good, it sells itself and Americans immediately reap the rewards and appreciate what has been done. But when a law such as this health care law is a bad one, there is no way another slick PR campaign, paid for with taxpayer dollars, can make it look any better.

The American people deserve real solutions to their health care problems, not more Washington spin. Yesterday I called on the President to cancel this program immediately, to retain the taxpayer dollars and use it to pay off the debt, use it as part of lowering the deficit. Don't send it to a PR firm to try to spin this law.

We need to repeal this law. We need to repeal this health care law and replace it with a better plan. Instead of wasting millions of taxpayer dollars on this PR campaign, we need to go back to the drawing board. Americans deserve to be able to get the care they need from the doctor they want and at a price they can afford. That is what I will continue to talk about on the Senate floor as I offer a doctor's second opinion about the significant failure of the law that passed the Senate, was crammed through the House, and was signed by President Obama 2 years ago.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Kansas.

JOB CREATION

Mr. MORAN. Madam President, yesterday a group of four Senators introduced legislation that I would like to highlight in this brief opportunity on the Senate floor. We introduced S. 3217. This legislation is called Startup 2.0 and was introduced by Senator WARNER, Senator COONS, Senator RUBIO, and me to begin the process of trying to create a better entrepreneurial environment in the United States, to create opportunities for entrepreneurials for innovation and to grow the economy and create jobs.

I want to personally thank those three Senators—two Republicans, two Democrats—who decided that this common phrase we hear around Washington, DC—we can't do anything this

year because it is an election year—is nothing that we are willing to tolerate. We didn't get the marching orders and instructions to say we cannot work and accomplish good work for America because there is a November election.

I want to highlight to my colleagues and ask them to join us in this effort to grow the number of Senators who find this kind of legislation valuable and appealing and to commit myself to work with Senator WARNER, Senator RUBIO, and Senator COONS to see that we are successful in 2012. I have talked about this legislation before. In fact, Senator WARNER and I introduced the Startup Act months ago. We then joined with Senator COONS and Senator RUBIO, who had introduced legislation called the AGREE Act. We took the best components of our two pieces of legislation and yesterday, as I said, introduced S. 3217, the Startup 2.0 Act.

This legislation has about five components. In broad terms, it is based upon the Kauffman Foundation Center for Entrepreneurship based in Kansas City, which is the most world-renowned organization that studies and promotes entrepreneurship. Their proposals were based upon their research and are included in many aspects of this legislation. Part of it is dealing with the regulatory environment that a startup company faces and to require that the benefits of that regulation exceed the costs. That kind of requirement has been in the law before but only for the departments, not for the independent agencies. So we know the independent agencies create lots of hurdles and handicaps in regard to the ability of particularly a young company, a beginning company, a startup company to succeed.

In fact, in my view, our legislation is based upon something I was told once by an engineer who said that for an airplane to fly, there are two forces at work: one is thrust and the other is drag. The thrust has to be sufficient to overcome the drag or you could reduce the drag so the thrust is not so necessary. What I like about this legislation is that it is so focused on reducing the drag—getting things out of the way. It is not a thrust program, meaning more government programs, more government spending, more government. This legislation provides aspects that are designed to get government out of the way and to reduce the drag so that the airplane can launch and can fly and can succeed.

One of those, of course, is the regulatory environment. Another is the tax environment. Startup companies face significant challenges in accessing enough capital to get off the ground. We were successful in passing the JOBS Act signed by the President a few weeks ago. This legislation picks up where that legislation left off.

Incidentally, I read this morning that crowdfunding is already beginning to develop a piece—a development that occurs as a result of the passage of the JOBS Act. So once Washington, DC—let me say that differently. Once Washington, DC, gets out of the way so that the private sector can pursue opportunities, those opportunities are pursued. We see that already happening with the passage of the JOBS Act in regard to crowd source funding in which we are gathering capital investments from people across the country to help new businesses commence.

This legislation, the Startup Act, makes permanent the 100-percent exemption on capital gains taxes for investments held at least 5 years in qualified small businesses so investors can provide financial stability at this critical point in their growth. The legislation also includes a limited, targeted research and development tax credit for startups less than 5 years old. So we alter R&D, we alter income taxes, and we alter capital gains in a way that is designed to create better opportunities for access to credit.

We attempt in this legislation to accelerate the commercialization of research. Billions of dollars are being spent—taxpayer dollars—at universities and colleges across the Nation. We want to incent that research to be devoted toward what can be commercialized, that brings new products, new businesses to market. So we take existing resources and utilize those dollars to reward those universities that take their research dollars and use them in ways that are more likely to be commercialized—in other words, create products, pursue dreams, and ultimately create jobs.

In addition, we create competition—at least knowledge of information, knowledge that allows somebody who is thinking about starting a business to decide which States are the most progrowth-oriented and make decisions about their location—where they should locate—based upon information. That then would also encourage States to be very entrepreneurial and progrowth, pro-innovation in their State policies.

Perhaps the most significant portion of this legislation creates two new visas. The first is an entrepreneur's visa to help foreign-born entrepreneurs currently legally in the United States to register their business and to employ Americans. In many instances, foreign-born entrepreneurs, here legally, have an idea and want to begin a company that will employ Americans but are told their visa does not allow them to remain in the United States.

The second visa that is created in this legislation is related to STEM—and this is a topic of conversation I think is so important—to retain foreign students who are studying in the United States, who have a Ph.D. or a master's degree in science, technology, engineering or mathematics. It is silly, it is wrongheaded for us to educate these individuals and tell them we no longer want them in the United States once they receive their degree. So the Startup Act 2.0 makes two important modifications to that current system of visas.

In addition, we include a provision from the legislation introduced by Senators RUBIO and COONS, a provision that eliminates the per-country numerical limit for employment-based immigrant visas, which is another handicap in our system that prevents those who have the greatest skills and talents and intellect from being eligible for a legal visa to remain in the United States.

I heard a story from an entrepreneur in California who was ready to hire foreign-born immigrants who were U.S.-educated individuals with Ph.D.s in computer education—computer science, for example—and yet the H–1B visa program failed them. There were no slots available. So, yes, the company hired these 68 Ph.D.s—technicians, highly skilled and educated individuals—but they hired them in Canada, not in the United States. So not only is that a loss of 68 jobs, but many of those people who are now working in Canada will be the next set of entrepreneurs, and they will start their businesses, their startup companies, and grow their companies in Canada, not in the United States. So we lose in both employment today and in opportunity for American jobs in the future because we have a visa system that handicaps our ability to get the highly educated, trained, and technically skilled individuals in the United States.

Today in the local paper I read some statistics that I think are important for us to remember and to know. Research by the Partnership for a New American Economy and Partnership for New York City shows a widening gap between the supply and demand of American graduates educated in the so-called STEM fields of science, technology, engineering, and mathematics. The number of job openings requiring such degrees is increasing three times the rate of the rest of the job market. However, college students majoring in non-STEM fields still outnumber math and science-minded counterparts five to one, according to the National Science Foundation. So five people are majoring in something other than science or mathematics for every one who majors in math or science in the United States.

If this trend continues, American businesses will be looking for an estimated 800,000 workers with advanced STEM degrees in 2018—just 6 years away—but will only find 550,000 American graduates with that type of training. Not only do we need to fill that gap with those who are available to us today, but we also need to encourage education in the United States and educate American students in the STEM field as well. Without easing these restrictions, we will continue to have 60 percent of foreign graduate students in the United States enrolled in science and engineering today. So 60 percent of foreign students are majoring in science and mathematics—not true of American students—and we need to reverse that course.

A study earlier this year showed that half of the Nation's top venture-backed companies have at least one immigrant founder. Three out of four claim at least one foreign-born executive.

The point is that we want the economy to grow, we want to create jobs, and we want to do the commonsense things that get government out of the way to allow the private sector to be entrepreneurial, to be innovative, and to create great opportunities for Americans today and, equally important, for Americans tomorrow. We want our kids and grandkids to have the opportunity to live and work in a growing, exciting economy. That requires the Congress to take actions today to create that environment for the private sector to succeed in creating entrepreneurship in the United States.

When we look at the last few years, we see that the net jobs filled in the United States have been filled by entrepreneurs, by new startup companies, not by existing companies. In fact, the trend is that big companies are often laying off workers while startup companies are the ones obviously hiring individuals.

I ask my colleagues to take a look at the legislation that my colleagues, Senators WARNER, RUBIO, COONS, and I introduced. I look forward to working with the leadership of the Senate to see that it receives appropriate consideration. We ought to do all we can do. We ought not ever use the excuse that we can't do everything; therefore, we can do nothing. These are all commonsense ideas that, in my view, will be supported by at least 80 percent of my colleagues here in the Senate. We ought not use the idea that it is an election year so we can't accomplish anything. The country cannot afford to wait. It needs our action now.

Thank you, Madam President.

The ACTING PRESIDENT pro tempore. The Senator Nevada.

THE HOUSING CRISIS

Mr. HELLER. Madam President, last September I had the honor of coming to the floor to give my maiden speech to my fellow Nevadans and to the American people. In that speech, I quoted a great Nevadan, Mark Twain, who wrote: ''You are a coward when you even seem to have backed down from a thing you openly set out to do.'' I have always said that I ran for office to make a difference, and since my first day here I have set out to provide solutions to fix our current housing problems.

Nevada is the epicenter of our Nation's housing crash. Home prices continue to decline in Nevada. In February of 2006 the average home value was $309,000. Today that has dropped to $120,000. Let me give my colleagues another fact: 5 years is how long Nevada has led the country in foreclosures.

The people of Nevada have suffered far too long because of the recklessness of Wall Street that caused this crash. Many Nevadans are struggling to pay for mortgages or have their homes in foreclosure as a result of the poor job market and the economic downturn. Because of the high rates of foreclosure devastating Nevadans, many are being forced to move, to find a new place to live.

Washington must provide solutions that help those who have been hit the hardest by this tough economy. I have worked on several solutions that I believe will provide some relief for many of those who are struggling.

In February I introduced the Keeping Families in their Home Act or the Home Act. This legislation would allow banks, Fannie Mae and Freddie Mac, to offer long-term leases for foreclosed homes. By doing so, it gives families the opportunity to stay in their homes while also easing the pressure that foreclosures put on home values.

The next month I joined Senator STABENOW to introduce the bipartisan Mortgage Forgiveness Tax Relief Act, which would ensure that homeowners who owe more on their mortgages than their homes are now worth would not be hit with an additional income tax if a part of their mortgage loan is forgiven. The current mortgage relief act expires at the end of this year, and this bill extends this critical safety net for underwater homeowners through 2015.

Today I am proud to announce the introduction of the SOLD Act. Home buyers, sellers, and real estate agents have long observed that banks have been slow to approve home short sales. Current delays in approving short sales are a major challenge to consumers and to realtors. These delays can cause canceled contracts and homeowners being forced into foreclosure. Those short sales are seen as a far better outcome than foreclosure, and finding a way to improve and make this process more efficient has been very difficult.

My legislation, the SOLD Act, would require that mortgage servicers respond to a short sale request within 30 days and make a final decision within 60 days of receiving the purchase offer. By placing a shot clock on these decisions, it will reduce the amount of time it takes to sell property, improve the likelihood that the transaction will close, and reduce the number of foreclosures in Nevada and across this country.

Stability in the housing market is critical for long-term economic growth. As Nevada continues to lead the Nation in unemployment, it is more important now than ever for Washington to provide solutions and address our Nation's biggest problems. Getting Americans back to work and helping families who find themselves in tough economic times should be a priority of every Member of Congress.

I hope my colleagues will join me in supporting the SOLD Act and help those who have fallen on tough times.

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

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

The legislative clerk proceeded to call the roll.

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

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

Mr. REID. Madam President, I ask unanimous consent that execution of the previous order with respect to S. 3187 be delayed until 12:30 p.m. today; that at 12:30, the majority leader be recognized prior to execution of the order, and that all provisions under the previous order remain in effect at that time.

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

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

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

The legislative clerk proceeded to call the roll.

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

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

TOXIC CHEMICALS

Mr. LAUTENBERG. Madam President, I come to the floor today because we dare not stand here while a menace threatens children across our country with too many untested chemicals present in everyday consumer products, products intended for children's use, such as baby bottles and nursery furniture. Many of them contain chemicals that have never been tested for human safety. These chemicals should be tested in industry laboratories, not in our children's bodies. It is time to update the law to protect them.

This picture shows some of the moms, many who traveled long distances yesterday to come to the Capitol with signs demanding ''safer chemicals now.'' Many of the moms had little children with them.

They are pleading with us. They are saying: Senators, understand what is taking place. Threats to our children should not be tolerated in America.

These moms are right to be concerned that their families are not being protected from dangerous chemicals. It is our responsibility, the responsibility of those in the Senate and the House, to fix our broken chemical laws. But until these laws are fixed, toxic chemicals—the word ''toxic'' is a replacement word for poisonous—toxic chemicals will continue to gnaw away at our children's bodies, their health, and their well-being.

Studies by CDC scientists found 212 industrial chemicals, including 6 carcinogens, coursing through America's children's bodies.

''Toxic Chemicals Pose Significant Health Risks.''

This chart tells a very bad, a very sad story: Five percent of pediatric

cancers, 10 percent of diabetes, 10 percent of Parkinson's disease, and 30 percent of childhood asthma are significant health threats to children. And instead of protecting us from harmful chemicals, our current law falls short.

A law called TSCA was designed to eliminate these threats to children's health. It passed in the 1970s. It is so severely flawed that the nonpartisan Government Accountability Office testified that it is a ''high-risk area of the law.'' Imagine that: TSCA, because of the fact that it is so severely flawed, is a high-risk area of the law.

In nearly 35 years, TSCA has allowed EPA to require testing of only 200 of more than 80,000 chemicals. Thousands of new chemicals are introduced every year in industrial and research facilities, but only 200 over that time were tested. What does that say? When you think about the number of children we are trying to protect, 80,000 chemicals, and EPA could require testing for only 200 of them, and only 5 were banned. It is hard to believe the chemical industry fought for years to keep the status quo alive at the expense of our lives, our children's lives, our children's health.

Recently the Chicago Tribune exposed how the industry used dirty tricks and junk science to drive their public misinformation campaign. They wanted to mislead the public about what is going on. Their series detailed how the industry repeatedly bullied and lied to State legislators to prevent commonsense reform. They bankrolled phony experts. A doctor in one instance prominently stood up there and defended a chemical material, a fire retardant. They are brought in there to invent stories that spout the company line, protecting not the health of children but protecting their profits. It is a terrible exchange—all at the expense of safety and health.

It is clear that chemical manufacturers purposefully hid the dangers of toxic flame retardants. We have a chart here that shows the average couch, for instance, has over 2 pounds of flame-retardant chemicals in its foam cushions, chemicals that have been linked to developmental problems and other health risks. The Presiding Officer has cautioned us about this, as well, that there are discharges when these are compressed that release the toxic chemicals into the air. Scientists have warned us about these chemicals since the 1970s, and yet they show up in household furniture, including baby crib mattresses and high-chair cushions.

The Chicago Tribune report said that:

> A typical American baby is born with the highest recorded concentrations of flame retardants among infants in the world.

But we are not here to attack chemicals. We are saying sort out those that are necessary and good for our sustainability, but there are hidden in there products that are dangerous, that are contaminants, that can bring terrible things to children, terrible health threats. Hundreds of useful everyday products contain chemicals, but it is our responsibility to make sure they are all safe, and today we don't know what is in the air, the atmosphere, and is poisonous.

Here is an example. Everybody recognizes what this is, a baby bottle. We have all bought them or seen them used for our kids. But chemicals in some baby bottles have been linked to serious health threats. Imagine, as a child takes nourishment, they are taking in a substance that can be dangerous to their health and make them sick—or worse.

When we use these products, the chemicals in them can end up in our bodies. In essence, the American public has become a living, breathing repository for chemical substances. No one should accept this standoff, and most do not. Those who are aware of what is taking place don't want to hear any excuses. They say: Get rid of these things. Let us know what is in there so we can protect our children and shield them from these threats to their health and their well-being.

Everyone—from some chemical manufacturers to businesses that use chemicals in their products, to environmental, labor, and health groups—has called for reforming our chemical laws, and we will not wait. I ask my colleagues not to wait here. Join us in this quest to save our children's health to make sure they grow up as healthy as we can enable them to do. We will not wait any longer, and we cannot let lobbyists run out the clock.

Lobbyists. Those are people, who for a fee, will represent almost anybody. But in this case, we are looking at not those who bring in good information or a good product, but those who are defending companies that are producing products that are dangerous for all the children who are exposed.

My bill, the Safe Chemicals Act, lays out a vision for strong, effective, and pragmatic regulation of chemicals. The bill simply requires the chemical makers to prove that their products, their chemicals are safe before they end up in children's bodies by being put into a product that children use.

Most of the thousands of chemicals we use every day are safe, but this bill will separate the safe chemicals from the ones that are not—the ones that threaten our children and our families. It will ensure that chemicals are tested and that EPA can take unsafe uses of chemicals off the market.

This bill is common sense. I am sure those who might be listening and those who might read the story from the Chicago Tribune and the research they did will find it very difficult to understand why it is we can't take the steps in here in the Congress to make their children safe. We do it in all kinds of ways to protect our kids. We want them to be able to grow and develop as children should—healthy, healthy kids.

Some chemical industry lobbyists say the cost of testing all these chemicals would be too high. Talk to a parent whose children carry lots of toxins in their bodies already. Talk to the mothers who carry these toxins in their bodies and can transmit them very easily to their children, particularly in pregnancy. So, too high? Too high has to be judged not by the chemical company making a profit and wanting to make more.

We cannot violate our responsibility to the mothers and fathers and the relatives and the families, where little kids live and enjoy life. What about that cost to the damage of their health? What about the cost to them? How high is that cost?

I would like one of these chemical manufacturer executives to stand up to parents who are worried about the health and the well-being of their children and say they are not making enough money and they are going to have to pump more of these threatening materials into the atmosphere without submitting them for testing. What about the cost to the parents who have to pay for their care?

The bottom line is this: If we don't act to protect Americans from thousands of toxic chemicals in everyday consumer products, who is going to do it? It is our responsibility.

Throughout this process we have invited input from all sides of this issue, including the chemical industry. I have extended an open invitation to my Republican colleagues: Think about it. Look at it through the eyes of your children and of your families. Think about it. Or would you rather go to the bank with a larger deposit because you are doing something that is a threat to children of any age and any stage? So I asked colleagues from the Republican side to work with us. Work with me to fix this broken law.

The one thing we will not do—and I know I speak for many others who are cosponsoring this legislation—we will not accept inaction. It is time to act. We want to mark up legislation to reform TSCA and move this legislation to the Senate floor, where decisions can be made. Opinions of individuals who may say, No, we would rather go ahead and enlarge our bank accounts, our cash reserves—let them say it in front of the public. That is when we will be conducting the kind of a test we should be doing here.

We want to move the legislation to the Senate floor and have a vote on it. Hopefully good judgment and good sense will prevail and this will get through and get to the President's desk so he can sign it and start the process of protecting our kids. It is time to come together to finally fix this law and protect our families from toxic chemicals.

With that, I yield the floor.

The PRESIDING OFFICER (Mr. DURBIN). The Senator from New York.

Mrs. GILLIBRAND. Mr. President, I thank Senator LAUTENBERG for his leadership and dedication to protecting

our families. And I know why he is concerned. I know, because I think about these issues every single day.

I washed my son's hair last night in his bath. I want to make sure the chemicals in that baby shampoo are safe. I put sunblock on him this morning. I want to know that I know what the level of that protection of that sunblock actually is.

When my other son was sick last week, he had three different medications. I need to know what those medications will do for him, if they will have side effects, what the impact is.

This is exactly the question every parent asks every single day in their normal daily lives: Are the products, are the chemicals, are the things surrounding my family safe? Will they cause harm? Will they cause disease? These are real questions that we have to have answered. So I thank Senator LAUTENBERG for his leadership on the Safe Chemicals Act.

Yesterday hundreds of mothers gathered here in the Capitol, right in front of the Capitol building, with their kids and with advocates from all across the United States to tell Congress one simple thing: It is time to stop playing politics with the health of our families. They remind us that the effectiveness of our Nation's chemical regulations is an issue that matters to all of us, every single American and every single parent who has children.

Our families are exposed to a variety of chemicals in every aspect of their daily lives, whether it is the soap we wash our hands with, whether it is the shampoo we wash our children's hair with, whether it is the detergents we put in our clothes washer when we are doing our laundry at night, whether it is detergents we use to wash our dishes. Every day we are bombarded with chemicals, and understanding how these chemicals impact our health and the health of our families is a growing concern not just for me but for constituents all across the country. But because of a very broken and ineffective system, our regulatory agencies are not able to provide us with enough information. The challenge our regulatory agencies face is a substantial one. Since the Toxic Control Substances Act was enacted in 1976, the EPA has faced the daunting challenge to investigate more than 84,000 chemicals in commerce, and their track record for success has been poor. Of the tens of thousands of chemicals in the marketplace, only 200 have been identified for further investigations and only 5 have been regulated.

Weekly there are news reports highlighting a new study of chemical concern found in everyday products in our homes, in our schools, and in our places of work. These reports have caused growing concern amongst consumers because we have seen links. There are studies that linked these chemicals to the rising causes of cancer, autism, learning disabilities, diabetes, asthma, obesity, developmental disorders, and infertility. These are the gravest concerns any family is ever going to face—any one of these. So we want to know if these things we were exposed to are affecting outcomes. Is there a relationship?

As a mother of young children, who are most vulnerable to chemical exposure, I am particularly concerned about what chemicals affect them, their well-being, and their development. I have one story of a young girl from Ithaca, Mira Brouwer, who died at the age of 4 because of the complications of her brain cancer treatment. Faced with the loss of her daughter, her mother Christina Brouwer founded Mira's Movement to make sure she could raise awareness about pediatric cancers and to serve as a resource for families facing their own battles with these diseases.

After an exhaustive study and review that identified potential links between chemicals and our environment and cancers such as the one young Mira had, I believe it is time for Congress to take action. We have a number of amendments today that will, again, enhance the work we are doing.

Of the two amendments I care a lot about, one is very simple. It makes sure that parents have as much information as possible when there are disclosures that accompany medicine so we know what are all the impacts there could be of that medication. I know most of my colleagues and certainly most consumers didn't realize the leaflets that come with our prescriptions are not regulated by anyone, and it is usually written by a contractor.

In 1995 the FDA recommended standards to improve the information provided to patients, but by 2008 only 75 percent of the information patients were receiving met the standards for usefulness.

I have to say I met with one mother named Kate, and her personal story about what happened to her son who was suffering from allergies and asthma. When he took a different medication, she saw him go into a depression. She didn't know there could be a relationship. That information was never provided to her. But the pain and loss she goes through every single day, remembering her son, has encouraged her to be an advocate for reform to make sure every parent has basic information that has some level of accountability so they know what the implications of all medicines can be.

The AARP and Consumer Reports have spent years trying to ensure their patients that when they receive FDA approval, standardized and up-to-date information about their medications will be provided. They support this amendment that will make that requirement.

Consumers basically have a fundamental right to know the risks associated with their prescription medications, and my amendment would give them this knowledge.

Last, and quite simply, we use sunscreen every day. In my family my kids have very fair skin. I want to know that the label on that sunscreen is accurate. I want to know if it has the protection it says it does, and this is an area that desperately needs regulation. I support the bill of Senator REED of Rhode Island to finally give consumers the information they need with regard to sunscreen.

Thank you, Mr. President, for this opportunity. All America's families basically have a right to know if these products are safe.

I yield the floor.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. DURBIN. Madam President, it was 10 days ago the Chicago Tribune had a Sunday exclusive investigative report on fire-retardant chemicals, and the report went on for several days. I called the writers and commended them on the wonderful job they did on this report. It was as good as any investigation I have ever seen by a committee of Congress. It raised some serious issues I had never thought about.

We probably have all heard from time to time there are certain chemicals which, when put on fabric, for example, will reduce the likelihood that it will flame and injure someone. I accepted that as truth, and I guess most people would. There was testimony given, even by medical doctors and so-called experts, that said that is a fact.

Well, the Tribune series took a look at the so-called experts, and guess what they found. They were on the payroll of the chemical companies that made the fire-retardant chemicals, and the doctors were actually kind of manufacturing cases of burns to make the case that States should apply these new standards. Over the years this testimony by these people, who had a built-in conflict of interest, ended up being persuasive at many levels in many States. As a result, there were requirements to add fire-retardant chemicals to fabrics in clothing, pajamas, furniture, and the like.

Then a closer look was taken. The Underwriters Laboratories took a look at these chemicals and said: You know what. They don't stop a fire from flaming up. The tests they are using are totally inadequate. These chemicals don't achieve what they are supposed to achieve. But there is another side to the story. The chemicals themselves can be dangerous. These are chemicals that haven't been tested in terms of their exposure to human beings. The Chicago Tribune article said the average couch had 2 pounds of fire-retardant chemicals built into it. They put it particularly in those foam cushions. I will get back to that in a moment. Remember that, the foam cushions.

Madam President, in your wonderful State last November my daughter gave birth to twins. November 15 was a source of great celebration. It still is. My wife and I were there with our son-in-law and daughter to welcome this little boy and little girl into the world. After a couple of days we brought them home from the hospital to the condo where my son-in-law and daughter live. We were so careful. I think about it now. We used hand sanitizers. We never had that when we were raising our kids, but we were careful to make sure we washed our hands. Every single thing these kids would come in contact with, the little onesies and the blankets that had to not only be cleaned but cleaned with the right detergent—we wanted to get the right detergent so it wouldn't cause any problems with these children.

Of course, when we are giving them formula, we are sterilizing everything in sight to make sure it is perfectly clean. Then I recall at that moment when I had that tiny little baby, and I was going to give this baby a bottle—and see if I still remembered how to do it—they said get a comfortable place. Why don't you sit down on the couch? It never crossed my mind as I sat down on the couch and pressed that cushion on the couch that I was releasing a spray of toxic dust from fire-retardant chemicals. That never crossed my mind at one moment.

When we went to buy a little cradle with a cushion for each of the kids, we took the subway to Columbus Circle to Babies ''R'' Us. It never occurred to me to think about whether the cushion on that baby's cradle or crib had fire-retardant chemicals in it that might, in fact, be sprayed every time someone sat on it or the baby was put on it. It never crossed my mind.

Well, I can say that as a result of the Chicago Tribune article, I think about it all the time now. I also think about this: How many American families can make that judgment when they buy a couch or a chair or children's furniture? They cannot. They cannot physically do it. I am a political scientist, but that doesn't count; I am not a real scientist. I can't judge what is safe and what isn't.

Who can we trust? Can we trust the company making the product? We want to think so, but sometimes not. Can we trust the spokespeople for the chemical industry? Unfortunately, they come into this with a conflict of interest.

So Senator FRANK LAUTENBERG of New Jersey created legislation that calls on the chemical industry to take care with the chemicals they put into everything we use every single day. It is also to make sure that Americans and families have peace of mind when they buy products to know the Environmental Protection Agency is at least reviewing the chemicals that are being put in those products that cite they are safe.

If the Environmental Protection Agency doesn't do this, who will do it? Can we trust the chemical industry to do it? I don't think so. Can we trust the furniture industry? I am not sure. We know if the EPA does it, it can make a difference. There are 80,000 different chemicals out there now. Many of them are critically important for our safety and health. There are safe chemicals we can be exposed to every single day without concern, but there are others that are not. The flame-retardant chemicals are a good example of that.

As the Presiding Officer said when she was speaking on the Senate floor, over the years they have reviewed 200 of these chemicals out of 80,000, and at the end of the day, they banned 5. What about the rest of them? Have they taken a look? Where does the first level of responsibility start?

Senator LAUTENBERG's bill says it starts with those who put the chemicals in the marketplace and that there be a certain level of safety established before they can be sold across the board. I think that is essential.

We are on a bill that will not bring up the toxic chemical issue, but I hope that will come up in and of itself soon. We are on a bill dealing with the Food and Drug Administration, and I heard about the amendment, and I support it. I think it is a good one.

Let me tell you something else we should know. The Food and Drug Administration is a small agency with big responsibility. Literally before any drug can be sold as a prescription drug in America, the Food and Drug Administration has to establish, No. 1, it is safe, and No. 2, it is effective. If it says it is going to do certain things, it has to accomplish those things. So there is lengthy testing in terms of these drugs before they will actually be licensed and allowed legally in America. The drugs that make it through all of these tests can generate millions, even billions, of dollars in profits for the pharmaceutical companies, but many don't make it through the testing process. But the FDA is there to establish that those drugs are safe and effective, and of course the consumers rely on them. When the doctor writes a prescription, we feel pretty certain this is going to be something the doctor knows is good for you and it has already been tested through the FDA.

There is a whole other category of goods, though, that we buy every single day that are treated differently and they are called dietary supplements. They include things such as vitamins and minerals that you take in the morning. I take a multivitamin every day. I don't know for what reason, but I do.

Dietary supplements also include things such as energy drinks. Heard about energy drinks lately? We can hardly escape them. The 5-hour Energy drink, the Monster drink. There are all of these different drinks we can buy that turn out not to be the same as soda or soda pop, but they are dietary supplements with small print on the back of the label. What is the difference? The difference is this: If you wanted to sell a bottle of cola, for example—and I won't give any proprietary names—there is a limitation by the FDA about how much caffeine can be put in each bottle of cola. If they decide they are not going to sell cola, which is classified as a beverage or food, and instead sell Monster Energy Drink and call it a dietary supplement, there is no regulation on the amount of caffeine that can be included.

Yesterday I met a woman who came here with her parents and her daughter to be in the gallery as I talked about her late daughter. Her late daughter's name was Anais Fournier from Hagerstown, MD, 16 years old. This young girl, with no history and no warning, drank two 24-ounce Monster Energy Drinks in a 24-hour period of time, and it killed her. There was almost 500 milligrams of caffeine in those two drinks. It was too much for her. She died of cardiac arrest. Those were billed not as beverages or sodas but as dietary supplement energy drinks.

Here is what it comes down to. I have a simple amendment I am going to offer, and this amendment will come up, I hope, on the Food and Drug Administration. Here is what it says: Every dietary supplement manufacturer that wants to sell their product in America has to register with the FDA. They have to tell the FDA the name of the product, the ingredients of the product, and a copy of the label. That is it. There is no requirement for testing, just so we know what is out there.

Let me add, dietary supplements are coming from all over the world into the United States. When we walk into that vitamin store or nutrition store and we think everything in there has been tested, no, virtually nothing has been tested. Do we still have a right to buy it? Yes, and I will fight to defend our right to buy it, but I also think we have a responsibility too. If people get sick and die because of a dietary supplement, we ought to do something about it, and the people across America expect us to. It starts with registration, simple registration, so the Food and Drug Administration knows what is out there.

A few years ago there was a pitcher for the Baltimore Orioles who, in an effort to lose a few pounds before the season, took a dietary supplement that included a compound called ephedrine. Ephedra is a stimulant. He died as a result of that compound he took. We ended up basically banning ephedra from dietary supplements as a result. I think it is important for the Food and Drug Administration to have lists of the dietary supplements and their ingredients in what they are selling, and a copy of the label, so that some future ephedra, some future compound that we find can be dangerous could then be traced to the actual dietary supplement product in order to protect American consumers and families.

The dietary supplement industry hates my amendment like the devil

hates holy water. The notion that they would have to register and disclose the name of their product and its ingredients? No way. They say: You can't do that. It is a violation of basic rights.

I say: Baloney. If they want to sell in America, then sell what is safe or at least tell us what they are selling. If a seller lives in China, for goodness' sakes, and wants to sell in the United States, is it too much to ask that they register with the FDA and tell us what they are putting on the shelves across America? That is basic.

So we will have a choice. I am fighting now to put this amendment on this bill. Let's have a choice. Let's have a vote: Should the dietary supplement industry have to register their products? It is pretty basic.

This amendment is based on a recommendation from the 2009 GAO report which said the FDA has insufficient information to regulate dietary supplements and analyze adverse event reports. That is what happens when people get sick or die from dietary supplements. The amendment requires facilities which manufacture, package, or hold dietary supplements to register the products with the FDA, provide a description of each dietary supplement, a list of ingredients, and a copy of the label. Facilities notify the FDA within 30 days and provide the required registration information when a product is introduced or removed from the market. So they have 30 days to do it.

Any product that is not registered is to be considered misbranded and illegal to sell. In other words, they have to do it. It is a real law.

That is it. Just register. They have to tell us what they are selling to Americans. Give us the name, give us the ingredients, and give us a copy of the label.

Well, get ready, because the industry is coming in to say this is an outrage. I think it is outrageous that they would not comply with this basic amendment. I say this to them: I am not opposed to people buying vitamins. I have gone to these nutrition stores, and about every other month they say: Stop the latest Durbin amendment. Well, I buy vitamins. I take vitamins. It is OK. I think it is fine. We shouldn't have to have a prescription for it. But Americans have a right to know what they are taking, and they have a right to know what, if anything, the government is doing to protect them.

I hope my colleagues will support the amendment.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. FRANKEN). The Senator from Missouri.

Mr. BLUNT. I thank the Presiding Officer for the time to speak on the Senate floor.

I am supportive of the bill that has come out of the HELP Committee to reauthorize user fees for the Food and Drug Administration. We have tried these user fees in the past, and under this bill they would be reauthorized for prescription drugs and for medical devices. This seems to be a way to help get these items to the consumer faster, to get them through the approval process more quickly, and to allow the companies that develop new medical devices or new prescription drugs to recoup their investment in a quicker way, which also allows them to get to the generic market in a quicker way.

I think it serves the purpose of health care well, and the community that pays the user fees appears to be in support of their continued use, and I am too. This bill provides for faster verification of generics. It also adds a product called biosimilars to the process where fees would be paid. For all of the same reasons, it seems that those fees would also make sense for health care and make sense for health care costs. Again, it allows for recouping the investment that is made to develop a new drug quicker. That allows it to go to the generic market quicker.

I hope this bill can be approved, and I hope it will be approved even before we leave for the Memorial Day work period.

I think Senator HARKIN, Senator ENZI, and their committee, the HELP Committee, have worked hard. I don't serve on that committee. I am on the appropriating committee for the Food and Drug Administration—for agriculture, rural development, and FDA. I am glad to be on that committee, and I have the contacts I have with FDA because of that. But, certainly, I support this bill.

There will be amendments, and we will look at those amendments as they are offered; although I think the committee has worked hard in a bipartisan way to bring a bill to the floor that is legislated the way we should legislate wherein the committees do their work and there is a bipartisan approach. That approach seeks input, continues current policies, and improves on those policies in a way I hope the Senate and then the House can be supportive of.

I know one of the areas where we are likely to have amendments will be the debate we have had over and over on whether prescription drugs can be imported into the country. If that amendment is brought up, I would have the same position I have had in the past, which is it is fine as long as someone from our government is willing to say those prescription drugs are what they appear to be. They have been out of the chain of custody, out of the closed pharmaceutical chain supply system that we believe is always essential to be sure that the drug one is getting is the drug one is getting.

Senator DURBIN spoke about vitamins earlier. I don't know what is in that capsule and neither does he unless someone has verified what is purported to be in there is really in there. It is very easy for that not to be the case. There are all kinds of examples of that all over the world. We want to be sure that American consumers who are taking a health product take that product for a good cause.

The Senator from Illinois even mentioned that he thought dietary supplements should be filed with the FDA. Certainly anyone who would think that should also think the same for prescription medicines, pharmaceutical medicines—that someone would need to verify that a prescription medicine is the medicine one believes it to be because a person is not taking it for some additional dietary reason; a person is taking it because their doctor has told them it is a medicine they need to take. It means there must be some medical reason they are taking it, and they must be certain, in my view, that a specific health care reason is being met.

Also, I read this week that in a time of trillion-dollar deficits, the Department of Health and Human Services announced it was going to go forward with a provision in the affordable health care act that apparently allows the department to spend $20 million of taxpayer money to launch a PR campaign to convince Americans they should like the affordable health care act better than they apparently do.

We are spending $20 million at a time when we have trillion-dollar deficits, at a time when, in fact, the health care law is even being challenged in Court. We will find out within the next month what the Court thinks about the potential constitutionality of the health care law.

This is the same Department of Health and Human Services that, during the health care debate, told insurance companies they could not tell their customers—they could not communicate with their customers in any way that suggested any possible negative impact this law might create. I thought that was an incredible position for the government to take at the time, so maybe I shouldn't be surprised that now the government would spend $20 million on a PR contract to convince people they should like this health care plan better than they do.

In fact, poll after poll shows the more people know about the health care proposal, the less they like it. Two years after its passage, opposition to the health care law, I believe, is stronger than it has ever been. The recent Rasmussen poll said 56 percent of voters favor a repeal of the affordable health care act, believing that it is perhaps neither all that affordable or all that good for health care.

According to a USA Today Gallup poll, 72 percent of Americans think this bill will make things worse or would not help their family health care situation. They believe it would not make things better or it will even make things worse. It is clear, in my view, that this is a bad law that we can't afford—bad for families, bad for seniors, bad for job creators. I guess maybe that is why the government is going to spend $20 million to convince me and others that it is not nearly as bad as we think it is.

This is not the first time the administration has used taxpayer money to

roll out publicity initiatives or to move forward in a way that will try to encourage the use of this law. Last year, the Department of Health and Human Services asked Congress to quadruple the budget for its public affairs office to $20 million. So the request was, let's have $20 million in public affairs to double the staff, quadruple the budget. Let's have another $20 million to hire a PR firm to convince the American people that the affordable health care act is going to be good for them. Let's sway seniors by using $3 million for an ad campaign featuring Andy Griffith, who is one of my favorite actors of all time, who took on the role to convince people the health care law is good for seniors.

The nonpartisan factcheck.org concluded that the ads used—they said ''weasel words'' to mislead seniors. I certainly would not imagine that Andy Griffith would use weasel words, but I do know they used taxpayer dollars—taxpayer-paid-for words—to talk about how this plan is going to be good for them.

Then the administration recently decided to spend $8.35 billion—now we are talking about real money; we are not talking about $20 million or $3 million. We are talking about $8.35 billion to postpone the vast majority of the Medicare Advantage cuts until after the end of this year, which is, coincidentally, after Election Day as well. This supposedly comes out of money that would usually go for a demonstration project.

As I understand demonstration projects, it is to take an idea and prove whether it will work. Well, apparently, this demonstration project is merely to not allow these provisions of the affordable health care act to go into effect until after the election. I think we can all see what that demonstrates. It demonstrates there must be something the administration believes the American people and seniors would not like if they found out before the election that $8.35 billion was scheduled to be taken out of Medicare and put into another health care program. In fact, the affordable health care act will spend $500 billion that will come out of Medicare at a time when Medicare, we all know, is about to be in real trouble.

If someone made this argument anywhere but Washington, DC, I think they would be laughed out of the room. We have one fund that is about to be in big trouble, so we are going to take money from it and start another program that we also don't quite know how we are going to fund.

The Government Accounting Office has said this demonstration project—I think they have identified it as a sham demonstration project because it doesn't demonstrate anything.

This is not a health care system proving that if you take care of seniors on a per capita basis, you do a better job keeping them well than if you wait until everybody gets sick for them to be able to see a doctor under Medicare. This just simply demonstrates that the administration would not like people to know what the impact of the law is going to be during this even-numbered year.

Government spending is out of control. Federal debt is at a record high. It is unacceptable to me that the administration has decided to waste money on a PR campaign or to waste money to see that the impact of the law is not evident until after election day. Instead of spending time and taxpayer dollars to try to convince people that unpopular things should be liked, I would like to see the President work with the Congress to help us get the 23 million men and women who are either unemployed or underemployed back to work. If we are going to spend money, let's spend money for purposes like that.

I yield back and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. GRASSLEY. Mr. President, today we will be considering and are considering a vital piece of legislation that not only includes all four user fee agreements but also includes policy proposals to improve the Food and Drug Administration review and approval of medical products, particularly in the pharmaceutical supply chain.

In 2008, when Senator Kennedy was still in the Senate, he and I introduced the Drug and Device Accountability Act. This legislation was largely in response to the extensive oversight I conducted on the Food and Drug Administration. During these investigations, I identified serious problems at the FDA that included severe weaknesses in the inspection process, delays in informing the public of emerging safety problems, and lack of enforcement authority.

Based on these findings, the Kennedy-Grassley legislation included provisions to ensure the safety of drugs, including foreign-manufactured drugs. It would have expanded FDA's authority to inspect foreign manufacturers and importers on a risk-based schedule. It would have required all manufacturers to register with the agency so they can properly identify the number of manufacturers and where they are located. This would have ensured that when a crisis occurs, we can quickly locate the questionable facility. And it would have increased civil and criminal penalties with respect to violations.

Unfortunately, Senator Kennedy and I never had an opportunity to debate this legislation, let alone cast a vote on it. However, roughly a year ago Senators HARKIN and ENZI forged a bipartisan working group to address these challenges. The group has worked tirelessly to produce a bipartisan bill that modernizes FDA's authority to ensure that drug products coming into the United States are safe for American patients.

This bill incorporates many provisions in the Drug and Device Accountability Act Senator Kennedy and I introduced. It increases penalties for knowingly and intentionally counterfeiting drug products. It requires electronic submission of certain key information by a drug importer as a condition to grant entry.

I would like to have seen additional enforcement tools included in the legislation. For example, granting FDA the authority to destroy unsafe products that are refused admission into our country would enhance FDA's ability to protect the public from tainted products.

Likewise, I think FDA should have been granted subpoena authority and have it on a par with other Federal law enforcement authorities because currently FDA lacks subpoena authority and has to go through the Department of Justice, which is time-consuming and burdensome.

Ultimately, this legislation is a needed step in the right direction toward securing our supply chain. This legislation did not address a top priority of mine; that is, ensuring whistleblowers have adequate protections. Four months ago, my office learned of an abusive treatment by the Food and Drug Administration toward whistleblowers due to their protected communications with Congress, more specifically with the office of this Senator. Once the agency learned of the communications, it began actively monitoring and observing employees' personal e-mail accounts for 2 years until the agency was able to have the employee fired.

Regrettably, I was not shocked to learn that the FDA was mistreating whistleblowers within this agency as it has done on more than the one occasion in the past that I have identified. What makes the example different and worse is that the FDA intentionally went after an employee because they knew that employee had no protection under the Whistleblower Protection Act.

The employee in question happened to be a member of the Public Health Service—the title is the Public Health Service Commissioned Corps. Because of the decision from the Court of Federal Claims, those employees are, in the Public Health Service, along with other members of the uniformed services, not covered by Federal employee whistleblower protections.

In 2009, the Court of Federal Claims held in Verbeck v. United States that an officer in the Public Health Service Commissioned Corps is a member of the uniformed services and as such is not covered under the Civilian Whistleblower Protection Act nor the Military Whistleblower Protection Act. This

same logic extends to the commissioned corps of NOAA. So under this precedent, officers of the Public Health Service and NOAA currently have no whistleblower protection under Federal law.

This is particularly problematic when we consider that the Public Health Service and NOAA officers can be detailed to agencies such as the Food and Drug Administration or the Centers for Disease Control. That is the case here where that Public Health Service officer was working with FDA. At FDA they have to work side by side with civilian employees doing critical work to review and approve drugs, oversee medical devices, and even work on infectious diseases. However, unlike their civilian colleagues sitting right beside them, if these employees uncover wrongdoing, waste, fraud, and abuse, they can be retaliated against by the agency and have no recourse for it.

This is wrong and needs to be fixed. Whistleblowers point out waste, fraud, and abuse when no one else will. They do so while risking their professional careers. Whistleblowers have played a critical role in exposing government failures, and retaliation against whistleblowers should never be tolerated whether they are in the Public Health Service or otherwise.

For this reason, I will offer an amendment that expands whistleblower protection for uniformed employees of the Public Health Service. It corrects the anomaly pointed out in the Court of Federal Claims and ensures that officers in the Public Health Service have some baseline whistleblower protection. It expressly includes the commissioned corps of the Public Health Service within the protections of the Military Whistleblower Protection Act. This is consistent with the structure of the commissioned corps functioning like a military organization and matches the fact that these officers receive military-like benefits and retirement.

All Federal employees should feel comfortable expressing their opinion both inside the agency and to those of us in Congress. The inclusion of this language will ensure those opinions receive appropriate protections. I want to take this opportunity to express my appreciation to Senator HARKIN and Senator ENZI for their commitment and effort over the years to reform and improve the Food and Drug Administration.

We have to do what we can to protect whistleblowers. They know where the skeletons are buried. They and enterprising journalists come to us in Congress so we can investigate. We need those sources of information.

I yield the floor.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Mr. President, I ask unanimous consent the execution of the previous order with respect to S. 3187 be delayed until 2:15 today; that at 2:15 p.m. the majority leader be recognized prior to the execution of the order, and that all provisions of the previous order remain in effect at that time.

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

Mr. REID. Mr. President, we are close to a way to move forward on the FDA bill. I do say this, however: On this side we have cleared everything. So the disputes now are with the Republicans on the Republican amendment. We are willing to do whatever is necessary on that amendment. So I hope we can get this worked out. It would sure be helpful. We have heard all the speeches about this important bill. It really is important, as I indicated today in talking about some of the shortages we have had in Nevada where people die as a result of not having the medicines.

We are nearing a time where we cannot prolong this any more. This legislation is necessary because the bill—the information we have in this bill, everything we need expires at the end of this month.

The PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, I rise today to talk about the importance of passing the Food and Drug Administration Safety and Innovation Act, more commonly known as the user fee reauthorization bill. This bipartisan legislation would reauthorize the user fee program for the medical device industry, incredible important in my home State of Minnesota, as well as the pharmaceutical industry.

This bill represents over 1 year of negotiations between the FDA, Congress, and the industry. I believe we have achieved a good balance in terms of the improved performance, incentives through increased accountability, more meaningful goals, important process improvements, better metrics, and additional resources.

Not only does this legislation include the user fee agreements negotiated between the industry and the FDA, it also includes several reforms that will benefit the entire health care system and improve public health. The bill will make medicines safer for children. It will protect the global drug supply chain. It will improve access to safe, innovative medical devices and treatments, and it will tackle the drug shortage crisis that is spreading across the country.

On Monday I talked about the work I did leading the effort on drug shortages. I am so pleased that Senator HARKIN and Senator ENZI included this provision in this bill. But I also believe it is important to talk about the guts of the bill; that is, the improvements with the FDA and the work that needs to be done.

I commend the HELP Committee, on which the Presiding Officer serves, and specifically Chairman HARKIN and Ranking Member ENZI for being dedicated to ensuring that this process was open, transparent, and bipartisan.

At a time when Congress has been deeply divided, this legislation shows we can still overcome our differences and address the needs of the country through strong bipartisan cooperation.

For the State of Minnesota, passing this bill is vital to our continued economic growth and strength. With strong institutions such as the Mayo Clinic and the University of Minnesota and innovative companies such as 3M and Boston Scientific and Medtronic and St. Jude's, Minnesota's job numbers have fared better than the national average, with our unemployment rate now more than 2½ points below the national average; that is, 5.6 percent compared to 8.1 percent.

That is also attributed to the fact that Minnesota has one of the largest and most dynamic pockets of medical device companies in the country. I mentioned a few of the big ones, but there are also many small thriving companies. Many of our biggest innovations have come from the small companies, adding up to about 400 firms employing over 35,000 people across our State.

We cannot forget that it was Minnesota that brought the world one of the biggest innovations in the country. I am not talking about the Post-It note, although it is true that did come from our State. I am talking about the pacemaker, which we give thanks to a company called Micronic that started out in a garage in Minneapolis.

So our roots run deep in this industry. But medical technology is just not important to Minnesota, it is important to our country, putting billions of dollars in our economy each year. It is important to the world. The devices we make in the United States do not just save lives locally, they save lives globally.

As we look at potential exports and how we are going to reach the President's goal of doubling our exports in 5 years, and how we are going to get out of the economic rut we have been in, a lot has to do with exports, new markets, and a rising middle class in countries such as China and India where people are finally going to the hospital, will use our medical devices, and will bring jobs to the United States.

But that only works if these medical devices get approved and if we are able to make them, have the skilled workers to make them, and can beat our competition, basically, of companies in other countries that may be growing unless we make sure we have a proper approval process here that keeps things safe but also moves smoothly and quickly. The kind of meaningful, innovative work that our country needs more of is this kind of work. It is high-tech manufacturing, and that is what we need more of in this country.

As cochair of the bipartisan Med-Tech Caucus in the Senate, I have had several conversations with FDA about ways to improve this regulatory environment. I have introduced bills, as has the Presiding Officer, and looked at the

importance of putting in things that guarantee safety but also make sure we improve the process so we get more innovation and more jobs in this country.

If we are not careful, as we know, continents such as Europe—if they move faster than us, as they have in some instances, then we have a problem because then the venture capital money goes to Europe. With China requiring country-of-origin approval, we can have a situation where companies decide they can get things done quicker if they move their business to a place such as Europe and then get the approvals in place so they can sell in China. We do not want that to happen.

The FDA will now be responsible for total review time goals. That is an important part of this bill. This measures the time from submission of a new application to the time the technology is available to patients. Putting the FDA on the hook for this measure will streamline the approval process and help get innovative and lifesaving devices and treatments to patients.

In addition to improved review times and performance standards, the one aspect I hear about the most from our medical device companies, both small and large, is they need better communication between the FDA and industry. This agreement takes significant steps to address this issue by opening clear lines of discussion before a submission is made. This helps provide companies with clear direction and requires the FDA to stick to their commitments.

It also requires interaction between the FDA and the applicant during the review process to keep everyone on the same page and avoid miscommunication and costly delays. The agreement also requires the FDA to work with companies to find the best path forward if goals are not met. Most importantly, this legislation will give the FDA the tools necessary to meet these goals.

This agreement provides for $595 million in user fees over the next 5 years. This is meant to provide for additional reviewers, enhanced training, and increased efficiencies to help improve FDA performance and help patients get access to the most innovative and safest products available.

But a positive user fee agreement does not guarantee success. We must also focus on the execution and administration of these new resources and new guidelines. That is why I introduced a bipartisan bill with RICHARD BURR of North Carolina, a Republican, and MICHAEL BENNET of Colorado, a Democrat, that would significantly improve the regulatory process.

It would tackle three important things related to the approval process: First, it would increase efficiency by strengthening the agency's least burdensome principle, which has been continuously overlooked by FDA's reviewers. The average time to approve an application has increased 43 percent from the 2003-to-2007 time period to 2010. This simply is unacceptable.

Second, it would improve conflict-of-interest provisions making it easier for the FDA to recruit top-line experts to take part in the review process.

This would allow the FDA to protect the integrity of the review from undue conflicts of interest but also take advantage of available expertise.

Third, it would require the FDA to use an independent consulting organization to assess the management processes at the Center on Devices. This would encourage the agency to consider the impact of its decisions on innovation, while also considering the balance between the risk and benefits of the new devices.

I am thankful that, in working with Senators HARKIN and ENZI, we were able to include these improvements in this bipartisan legislation.

Equally as important to improving the regulatory process at the FDA, this legislation also includes my provision on drug shortages. I have come to the floor several times in the past year to talk about the crisis as it has impacted individuals all across our country. There is the story of a little 4-year-old boy who was going to get treatment for his leukemia, and his parents were put in a panic. He was a little bald boy with a smile on his face. They found out that the drug he needed, Cytarabine, was missing in action; it was not in the hospital, not in the pharmacy. They were actually looking into booking flights to Canada so that he could get the drug treatment he needed. At the last minute someone located the drug.

Sadly, that doesn't happen in many cases across the country, where we have had people come forward and talk about missing breast cancer treatments and people who have died because drugs were not available. The fact that physicians, nurses, and pharmacists are spending hours and hours of their time, which should be spent with patients, looking for pharmaceuticals is an outrage.

We know there are many reasons for this. We are glad the industry was willing to work with us to come up with at least a short-term patch here, where the FDA will be alerted as a result of the provisions in this bill when the pharmaceutical companies believe there is going to be a shortage. Right now, they are only required to do it for orphan drugs. Now they will be required to do it for all drugs. These can be shortages as a result of raw materials that are not there, as a result of mergers in the pharmaceutical industry, or shortages as a result of a decision not to produce a drug because it may not be as profitable or shortages because of all kinds of things that could happen in the course of commerce.

The key point here is that when the FDA finds out early, they have been able to avert drug crises. They can find another manufacturer in our country or abroad, and they get the drugs in; they have done it over 200 times in 2 years. This will give them more tools to be able to avert what is an escalating crisis in this country where we are seeing more and more shortages of drugs on a weekly basis.

As I said, I am glad this bipartisan provision—and Senator CASEY introduced it originally with me, and we have had support from Senator COLLINS and others, and our working group worked out an agreement to get this provision in the Senate bill, with good prospects in the House under the leadership of Congresswoman DEGETTE from Colorado.

I thank my colleagues for their work for two reasons. One, this is important for medical devices and pharmaceuticals in terms of getting fast approval, and that is better for patients and for jobs in America as we become a country again that makes products and invests in goods that we export to the world. To do that, you need the regulatory process working.

Second, this bill is good because it contains a drug shortage provision to finally get at something that is long overdue, and that is the escalating crisis of drugs that have gone missing, which should be in the hands of patients across this country. Now we put them in a much better position in terms of being able to find alternative drugs in either our country or others, so we don't have these shortages we are seeing every day. That is why I think it is very important that we get this bill done soon.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

THE DISCLOSE ACT

Mr. WHITEHOUSE. Mr. President, I rise today to speak about a subject that I know is dear to the heart of the Presiding Officer, which is the sorry state of our campaign finance system and the need for the DISCLOSE Act of 2012, which we call DISCLOSE 2.0.

The Supreme Court's 2010 decision in Citizens United v. Federal Election Commission opened the floodgates to unlimited corporate and special-interest money in our elections, bringing about an era in which corporations and other wealthy interests can drown out the voices of individual voters in our political system. Worse still, much of this spending is anonymous, so we don't even know who is spending millions to influence our elections.

Here is how my State's newspaper, the Providence Journal, explained it when the ruling came down:

> The ruling will mean that, more than ever, big-spending economic interests will determine who gets elected. More money will especially pour into relentless attack campaigns. Free speech for most individuals will

suffer because their voices will count for even less than they do now. They will simply be drowned out by the big money.

The Providence Journal had a lot of foresight with that warning. What has happened since then has proven them right. Senator JOHN MCCAIN recently said this:

I predicted when the United States Supreme Court, with their absolute ignorance of what happens in politics, struck down the law—

Referring to the McCain-Feingold campaign finance law

—That there would be a flood of money into campaigns, not transparent, unaccounted for, and this is exactly what is happening.

Senator MCCAIN, is it ever. In the 2010 midterm election, the first after Citizens United, there was more than a fourfold increase in expenditures from super PACs and other outside groups compared to 2006, with nearly three-quarters of political advertising coming from sources that were prohibited from spending money in 2006. Also in 2010, 501(c)(4) and (c)(6) not-for-profit organizations spent more than $135 million in unlimited and secret contributions. This anonymous secret spending rose from 1 percent of outside spending in 2006 to 44 percent in 2010.

We are already seeing the influence of money on the 2012 elections. Super PACs and other outside groups have spent around $140 million in this election cycle. That is about twice what was spent over the same period in 2008 during the last Presidential election. In the 2 weeks leading up to Super Tuesday, outside PACs that supported the Republican Presidential candidates spent three times as much on advertising as the campaigns did themselves.

There are already signs things are going to get even worse. The Washington Post reported:

Groups that do not reveal their funding sources have spent $28.5 million on advertising related to the November presidential matchup, or about ninety percent of the total.

Ninety percent. And these are groups that don't reveal their funding sources.

Our campaign finance system is broken. Action is required to fix it. Americans of all political stripes are disgusted by the influence of unlimited, anonymous corporate cash in our elections, and disgusted by campaigns that succeed or fail depending on how many billionaires the candidates have in their pockets. More and more, people believe their government responds only to wealthy and corporate interests.

As they see their jobs disappear and their wages stagnate and bailouts and special deals for the big guys, they lose ever more faith their elected officials are actually listening to them. Over the deafening roar of secret special interest spending, they get harder and harder to listen to.

This growing consensus across the political spectrum was reflected in the brief Senator JOHN MCCAIN and I filed with the Supreme Court last week in American Tradition Partnership v. Bullock. In that brief, we urged the Court to reconsider the flawed central premise of its decision in Citizens United: the proposition that independent expenditures do not lead to corruption or the appearance of corruption.

As the statistics about anonymous spending and public perception make clear, this premise is discredited. I am proud to have worked on the brief with Senator MCCAIN, who has long been a leader in Congress on campaign finance issues. I hope our partnership will mark the beginning of greater cooperation across party lines on this issue of vital importance to the integrity of our great American democracy. I also hope the Supreme Court will take heed of the nearly universal opinion that the system they have unleashed in Citizens United puts our very democracy in jeopardy.

Until the Court acts, or until we enact a constitutional amendment to repair what they have done, we are left with one weapon in the fight against the overwhelming tidal wave of money from special interests—and that is disclosure. At least make them fess up to who they are.

That is why I stand here today in support of the DISCLOSE Act of 2012 or, as I said, DISCLOSE 2.0, in recognition of Senator SCHUMER's great work on the DISCLOSE Act. This legislation will shine a bright light on these powerful interests and their spending. With this legislation, which now has 43 cosponsors in the Senate, every citizen will know who is spending these great sums of money to get their candidates elected and to influence those candidates.

I would like to give particular thanks to the previous Presiding Officer, Senator FRANKEN, and the current Presiding Officer, Senator TOM UDALL, as well as Senators CHUCK SCHUMER, MICHAEL BENNET, JEFF MERKLEY, and JEANNE SHAHEEN for their hard work on developing this legislation. Senator SCHUMER, as we all know, has been leading the charge for disclosure since Citizens United upended and fouled our campaign finance system.

In 2010, with Senator SCHUMER's leadership, we came within one vote of passing the original DISCLOSE Act. Since then, the problem of anonymous, unaccountable special interest money has become much worse. We must redouble our efforts and pass DISCLOSE 2.0.

DISCLOSE 2.0 says two very simple things: First, if you are an organization, such as a corporation, a super PAC, or a 501(c)(4), and you are spending money in an election campaign in support of or in opposition to a candidate, you have to tell the public where that money came from and what you are spending it on in a timely manner.

That should not be a controversial idea to anyone, at least to anyone who is not seeking secret special influence. This chart shows how easy it is under our current system for wealthy interests to anonymously spend millions on election ads. This amounts to a form of legalized money laundering or identity laundering. Super PACs are supposed to disclose their donors under current law. But if someone wants to avoid that disclosure, they can set up a shell corporation, which may be nothing more than a P.O. box, and send the money to the super PAC through that.

Worse still, instead of using a shell corporation, they can pass the money through to a 501(c)(4), a so-called ''social welfare'' organization set up just for the purpose of spending money in elections. Think about that. The IRS gives nonprofit status to groups whose primary purpose in many cases is to shield billionaires and corporations spending money in elections from having their identities disclosed. In many cases, these 501(c)(4) groups are so closely affiliated with their super PACs they have all the same staff and all the same office space, and the (c)(4) groups still don't have to disclose the identities of their donors.

On this chart we see the money raised through the end of 2011 by two political groups started after Citizens United by Republican political operatives. These two organizations have the same staff and the same office space, and they run negative ads against many of the same candidates. One, American Crossroads, is a super PAC and is supposed to disclose its donors. The other, Crossroads GPS, is a 501(c)(4) group and doesn't have to disclose donors. Guess which one has raised more money. Of course it is the 501(c)(4) group which doesn't have to disclose its donors. That group has raised $76.8 million as compared to only $46.4 million by its sister super PAC.

This is, by no means, a unique situation. For corporations trying to buy influence through spending in elections, ''nondisclosure is always preferred,'' as an unnamed corporate lobbyist recently told Politico. Why? Well, for one thing there is no accountability—not to the company shareholders, not to their customers, and not to the public. Nondisclosure is ''preferred'' because it makes it impossible for the public and for law enforcement to track the corrupting influence of the money these corporations spend in elections. DISCLOSE 2.0 would put an end to using 501(c)(4) groups and shell corporations to shield the identities of big campaign contributors.

One thing that shouldn't be lost in this discussion of anonymous spending is the fact there is one person to whom this spending is certainly not anonymous, and that is the candidate—the elected official. The donors manage to hide their identities from the public, but they can sure tell the candidate how much money they put into that candidate's super PAC and what positions they want the candidate to take on issues. What this creates is a perfect

formula for corruption: wealthy corporations and individuals spending millions of dollars to influence a candidate without any oversight or public accountability or scrutiny.

Also, as a former Attorney General—and I know the Presiding Officer, the Senator from New Mexico, can appreciate this as well—a well-heeled donor doesn't have to make the contribution necessarily, doesn't have to launch the ad necessarily. They can also secretly threaten a massive expenditure against a candidate if the candidate doesn't vote right on their issue. Political scientist Norm Ornstein recently said:

> I have had this tale told to me by a number of lawmakers. You're sitting in your office and a lobbyist comes in and says, ''I'm working with Americans for a Better America. And I can't tell you who's funding them, but I can tell you they really, really want this amendment in the bill.'' And who knows what they'll do? They have more money than God.

If the candidate complies and does the right thing by the amendment or the right thing by the bill, the expenditure is never made. There will be no paper trail; no trace of the threat that drove that vote—that corrupted that vote—was ever made.

The whole rationale for unlimited spending was that it was going to be done independently of the candidate's campaign. That has proven false. The reality is that super PACs are anything but independent. Campaigns and super PACs share fundraising lists, donors, former staff, and consultants. Candidates appear at fundraisers for their super PACs, and super PACs recycle ads originally run by the candidates. They are free to act as the ''evil twins'' of candidate campaigns, as one FEC Commissioner put it, raising unlimited, anonymous money and then spending it on massive amounts of advertising—most of it negative—which further hides the identity of the interest behind the ad because if all you are doing is trashing a candidate, you don't even have to show what your interest is, let alone your identity.

About 70 percent of ads in this election cycle have, as a result, been negative ads, up from only 9 percent in 2008. This brings us to the second thing DISCLOSE 2.0 does. If someone is a top executive or a major donor of an organization spending millions of dollars on campaign ads, they have to take responsibility for their ads, just the way we do as candidates. These are reasonable provisions that should have wide support from Democrats and Republicans alike. As Trevor Potter, a Republican former Chairman of the Federal Election Commission, said in a statement submitted to the Rules Committee of the Senate:

> [DISCLOSE 2.0 is] . . . appropriately targeted, narrowly tailored, clearly constitutional, and desperately needed.

We have made every effort to craft an effective and fair proposal while imposing the least possible burden on covered organizations. Passing this law would remove a dark cloud of unlimited, anonymous money from our elections, and it would prove to the American people that Congress is capable of fairness, equality, and following the fundamental principle of a government ''of the people, by the people, and for the people.''

I urge my colleagues to support the DISCLOSE Act of 2012.

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

The PRESIDING OFFICER (Mr. UDALL of New Mexico). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. UDALL of New Mexico. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. UDALL of New Mexico. Mr. President, I was just listening to the Senator who is now in the Chair, and I want to congratulate him on filing that amicus brief with Senator MCCAIN in the Supreme Court. I believe the Supreme Court should heed the good advice both Senator MCCAIN and Senator WHITEHOUSE have given them, and I think if they do not heed that advice, the authority they have undertaken themselves will be taken away from them by the people who are urging a constitutional amendment to give this back to the Congress and back to the State legislatures.

I join my colleagues today to highlight what I consider a significant problem in our country—the unprecedented flow of money into our democratic elections.

Over the past several months, a group of us have been working together to address this problem. We have asked the FEC, IRS, and the FCC to take actions that would help curb the impact of money on our elections.

Led by Senator WHITEHOUSE, we have introduced the DISCLOSE Act. This bill would shine a light into the dark corners of the campaign finance system. Senator BENNET and I have introduced a constitutional amendment, which currently has 22 cosponsors, to overturn the disastrous judicial opinions that have led to the broken system we have today.

In January 2010, the Supreme Court issued its opinion in Citizens United v. FEC. Two months later, the DC Circuit Court of Appeals decided the SpeechNow v. FEC case. These two cases gave rise to the super PACs.

Millions of dollars now pour into negative and misleading campaign ads, and often without disclosing the true source of the donations. But our campaign finance system was hardly a model of democracy before these disastrous opinions. The Citizens United and SpeechNow decisions renewed our concerns about campaign finance, but the Court laid the groundwork many years ago.

We can go all the way back to 1976. That year, the Court held in Buckley v. Valeo that restricting independent campaign expenditures violates the first amendment right to free speech; in effect, that money and speech are the same thing.

The damage is clear. Elections become more about the quantity of the cash and less about the quality of ideas; more about the special interests and less about public service.

We cannot truly fix this broken system until we undo the flawed premise that spending money on elections is the same thing as exercising free speech. That only can be achieved in two ways: The Court could overturn Buckley and subsequent decisions based on it, something the current Court seems highly unlikely to do, or we amend the Constitution to not only overturn the previous bad Court decisions but also to prevent future ones. Until then, we will fall short of the real reform that is needed.

In Federalist No. 49, James Madison argued that the U.S. Constitution should be amended only on ''great and extraordinary occasions.'' I believe we have reached one of those occasions. In today's political campaigns, our free and fair elections—a founding principle of our great democracy—are for sale to the highest bidder.

I know amending the Constitution is difficult. And it should be. But we didn't start this effort last year or even in the last Congress. Others before us have urged that this longstanding problem needs a long-term solution. Many of our predecessors understood the corrosive effect money has on our political system. They spent years championing the cause.

Senator Fritz Hollings introduced bipartisan constitutional amendments similar to our amendment in every Congress from the 99th Congress to the 108th Congress. Senators SCHUMER and COCHRAN introduced one in the 109th Congress. And those were all before the Citizens United decision—before things went from bad to worse. The out-of-control spending since that decision has further poisoned our elections, but it has also ignited a broad movement to amend the Constitution.

I participated in a panel discussion in January with several activists in this movement. One of the panelists, Maryland State Senator Jamie Raskin, was asked about overcoming the difficulty of amending the Constitution. Jamie said that:

> A constitutional amendment always seems impossible until it becomes inevitable.

I think we are finally reaching the point of inevitability.

Across the country, more than 200 local resolutions have passed calling for a constitutional amendment to overturn Citizens United. Legislators in four States—Hawaii, Vermont, Rhode Island, and my home State of New Mexico—have called on Congress to send an amendment to the States for ratification. Many more States

have similar resolutions pending. Over 1 million citizens have signed petitions in support of an amendment, and more than 100 organizations under the banner of United for the People are advocating for constitutional remedies.

This grassroots movement is yielding progress. In addition to our amendment, several other campaign finance-related amendments have been introduced in the House and the Senate. Senators LEAHY and DURBIN recently announced that Senator DURBIN's Judiciary Subcommittee on the Constitution will hold a hearing on the Senate proposals in July. I thank them for their support. The hearing will be a great opportunity to examine the different approaches, to solicit input from constitutional experts, and to have a national discussion about the need to return our elections to the American people.

I hope this dialogue will convince some of my Republican colleagues to join me. Fixing our campaign finance system is only a partisan issue in Washington. A recent Washington Post-ABC News poll found that nearly 70 percent of registered voters want super PACs to be illegal. Among independent voters, that figure rose to 78 percent. But the Court, in its misguided reading of the first amendment, told the Congress that we can't rein in super PACs. In doing so, it gave millionaires and billionaires unchecked power to influence our elections. It has allowed a flood of PAC money to drown out the voices of average Americans. This is a fatal misreading of the real world of political campaigns, and it is wrong. Supporters of super PACs and unlimited campaign spending claim they are promoting the democratic process. But the public knows better. Wealthy individuals and special interests are buying our elections. Citizens United has meant citizens denied. Our Nation cannot afford a system that says ''come on in'' to the rich and powerful, and says ''don't bother'' to everyone else.

The faith of the American people and their electoral system is shaken by big money. It is time to restore that faith. It is time for Congress to take back control.

I know the Senator from Rhode Island, as Senator WHITEHOUSE, has worked very hard on this issue, and has pulled us together. I believe we are going to have others join us in this hour. The crucial thing we are trying to say is we need reform, we need disclosure. We need to get to the bottom of what is happening in this broken system and get our democracy back for the American people.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. WHITEHOUSE. I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. UDALL of New Mexico). Without objection, it is so ordered.

Mr. WHITEHOUSE. Mr. President, while we are waiting for the next speaker to arrive, I wanted to take a moment and discuss the brief Senator MCCAIN and I filed in the Supreme Court last week. It can be found at http://www.whitehouse.senate.gov/download/?id=e3ba7f1b-d132–4aef-b5bc-c49fd711fc51.

The Supreme Court in the Citizens United decision was in a difficult situation. No member of the Court had ever run in an election for office. It may be the first time in the history of a country that no member of the Supreme Court had ever run for office, so it is a Supreme Court that as a corporate group was uniquely inexperienced in the actual ins and outs of elections and politics.

Moreover, the way the Citizens United case came up to the Court, the question they ended up deciding is one that they asked for additional briefing on. It is a question that, in many respects, the Court raised itself. And so the Court did not have the benefit of the usual process of a case beginning in the trial court and amassing a record of evidence, of testimony, of witnesses, of a review of all of that at the appellate court level, and then final review at the Supreme Court. So they did something very unusual. They actually made a finding of fact.

A finding of fact is not something Supreme Courts are supposed to do in the first instance. That is the job of the trial judge and the jury, if there is a jury trial. Those are the fact-finders in our system of law. And certainly for a Supreme Court that has an appellate tribunal between it and the trial branches, as our Federal system does, it is very unusual for them to be making findings of fact. They made findings of fact in this case. And, unfortunately, because they had no experience in elections, any of them, and because they had no record, they made a finding of fact that was not in fact a fact. They made a finding of a false fact.

The mistake they made was to determine that no amount of corporate spending in an election could create either the risk or the appearance of corruption, and I think the practical facts of that are pretty easy to rebut.

They stood that finding of fact, that premise, on two subordinate premises and we rebut both of them in the brief. If I have further time, I will come back to that, but I see that the Senator from New Hampshire is here and I do not want to cut into her time, so I yield to the distinguished Senator from New Hampshire, and I appreciate her great work through the long period of discussion and draftsmanship that brought 2.0 to the floor with its now 43 cosponsors.

Mrs. SHAHEEN. Mr. President, I am pleased that I could be here today to join you, to join Senator WHITEHOUSE and our colleagues who have been working to try to bring to light for the public the serious and ongoing problem of excessive campaign spending. I congratulate Senator WHITEHOUSE for all of his work in leading this effort. It has been very important.

This excessive spending has been a problem for the last 2 years, since the Supreme Court's decision in Citizens United, because their decision has allowed for the formation of what has been called super PACs, which are really organizations that can spend unlimited amounts of money without ever having to disclose where that money came from. So the public doesn't know who is spending the money, doesn't know how the decisions about spending are made.

We are actually in the middle of the first Presidential election since that Supreme Court decision, and we can see the dramatic impact of that spending. There are now more than 500 super PACs registered with the Federal Election Commission. They are permitted to raise and spend unlimited amounts of secret money to fund political advertisements.

Again, I want to emphasize the fact that we do not know where this money is coming from. We do not know if it is coming from corporations. We have heard a lot of stories and seen a lot of stories that there are very wealthy individuals who are putting up money for these super PACs. But the amount of money that has been spent by these super PACs so far this election cycle alone has just topped $100 million. Nearly $80 million of that came from just five groups.

As we are looking at this money being spent, it is important for all of us to reflect on our national priorities. What does it say about our country that we allow this kind of deluge of money to flood our electoral process? Who is really being represented? Are average voters in America being represented in this process?

To provide some perspective, I think it might be useful to examine what else this amount of money could pay for. In the past few weeks we have been discussing the importance of providing survivors of domestic violence and sexual assault with the resources they need by reauthorizing the Violence Against Women Act. What has already been spent so far by these super PACs, $100 million, could fund all of the domestic violence and sexual assault assistance in the State of New Hampshire for 20 years. It could serve more than 320,000 victims.

The New Hampshire job training program provides workers with valuable instruction at community colleges across our State. It prepares workers for high-skilled jobs and creates a stronger economy. With the $100 million that has been spent by these super PACs, we could train 288,434 workers in New Hampshire. Mr. President, $100 million would provide low-income heating assistance to more than 135,000 households. That is enough to keep

New Hampshire's neediest families warm for three winters.

The starting salary for a police officer in the city of Manchester, the largest city in New Hampshire, is $50,000. With $100 million we could put an additional 2,000 police officers on the street. Instead, this money is being spent on political advertisements, millions of dollars from groups that refuse to disclose their donors. Most of these expenditures are being made on attack ads. According to a study by the Wesleyan Media Project, at this point during the last Presidential campaign in 2008, just 10 percent of the ads were negative. Now, in this Presidential campaign, 70 percent of those ads are negative. It is no wonder that Americans are becoming increasingly disillusioned with our political process.

The challenges confronting this country are significant. We need Americans to be engaged and invested in our political process, not throwing up their hands in frustration as the attack ads pile up. We need campaign finance reform.

I have been pleased to work with the Presiding Officer, with Senator WHITEHOUSE, and with all of our colleagues in developing the DISCLOSE Act, which makes some important changes to our system. Senator WHITEHOUSE described the DISCLOSE Act very well. It will make sure voters know who is paying for all of these campaign ads. It does not eliminate super PACs, but it is a very important step in the right direction.

I urge all our colleagues to join us in calling for change and urging reform of our campaign finance system. I urge everyone in this body to support the DISCLOSE Act.

I yield the floor.

Mr. MERKLEY. Mr. President, I ask unanimous consent to ask a question of my colleague from Rhode Island.

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

Mr. MERKLEY. Mr. President, I was very engaged by the comments Senator WHITEHOUSE was making a short time ago. I was very struck, as I have been all along, by the substantial challenge posed by Citizens United. My colleague was speaking to the impact on our constitutional system. When I think about this, I often think about those first three words of our Constitution, ''we the people.'' Is it the Senator's sense that this phrase, ''we the people,'' that starts out the Constitution is more than simple window dressing? Does it go to the heart of who and what we are as a society, as a nation?

Mr. WHITEHOUSE. The great experiment that the Founders of this country embarked upon when they founded this country was to allow for a democratic form of government that was governed by the people—not kings, not lords, not pharaohs, by the people. It has been a consistent thread throughout our history at important times.

As the Civil War came to a close and our beloved President Lincoln stood at Gettysburg to give his great address, he talked about the importance of a government ''of the people, by the people, and for the people.'' That has always been the core, heart, and hallmark of the American form of government.

It has lit a blaze that has illuminated the rest of the world as well. It is not just an American value. People from around the world look at this and say: You know, it can be that way.

Mr. MERKLEY. So I think if any three words would summarize the heart of our Constitution, it would be those three words. It would be ''we the people.'' Yet we have a Supreme Court decision, Citizens United, that essentially unleashes a flood of special interest money. Is that fundamentally in conflict with the notion of ''we the people''?

Mr. WHITEHOUSE. I believe it is. We operate in a modern world in which we are bombarded by media. The average person, the average, ordinary member of ''the people,'' does not have much access to that media, cannot get his or her voice much heard in that bombardment. But if someone has enormous amounts of money, either because they are a corporation with a vast treasury or because they are a billionaire, they can take a big chunk of that media and can use it to broadcast their view. That will drown out other voices that do not have that power. So it really does attack the basic premise of ''we the people.''

Mr. MERKLEY. So Citizens United goes right against the very heart of our Constitution. How is it possible that the Supreme Court found, in this 5-to-4 decision, that this has no corrupting impact on our electoral process?

Mr. WHITEHOUSE. I think three things went wrong. First of all, this is a Supreme Court that, unlike most if not all other Supreme Courts, has no political experience. None of them have ever run for office, so they do not have a practical sense of how politics engages in an election.

Second, because they sort of invented this question, they did not have a record where people who did know about politics and did know about elections and did know about corruption could assemble a record from which they could then learn. So they were operating in a much greater vacuum than the Supreme Court usually does.

Finally, they made two presumptions that supported it. One was that the super PACs and all these big entities would be independent from the candidates. We have seen that was a false assumption. That was a wrong premise. Now the super PACs are connected to a candidate. They have one purpose: to get the candidate elected. They have funds raised by the candidate, they share staff with the candidate, they share consultants with the candidate. They use the same footage as the candidate. The idea that they are independent has been made preposterous by the facts.

The second was that there would be disclosure so the public could at least evaluate, OK, this is the coal mining industry coming after somebody who is fighting for climate change. We get that. We can make an appropriate judgment about that use of corporate money to attack a candidate. They were wrong about that as well. That is why we are here on this DISCLOSE 2.0, and we have been working so hard to make sure this bill has gotten to the floor in the good shape it has been.

Mr. MERKLEY. So the Supreme Court envisioned this steel wall, this high, impenetrable wall between an independent campaign and the candidate's campaign, and thereby saw fit to unleash unlimited money on one side of the wall while saying the other side has campaign caps, and that made sense together but their fundamental premise was wrong?

Mr. WHITEHOUSE. Absolutely dead wrong, as proven by reality. It is not just a theoretical wrongness, it is a factual, actual wrongness.

Mr. MERKLEY. Most of our campaigns for the Senate involve millions of dollars—some are $2 million, some are $20 million, some more. There are super PACs that have that much money and can bring that much money to bear in a single race. Did the Supreme Court wrestle with the type of intimidation, that precensorship, the precensorship impact on this body when somebody thinks about what should I say? Do I want to offend someone who has, not just $1 million but millions and millions of dollars to bring to bear? Did they wrestle with the impact on corrupting the debate and dialog and decisionmaking of this body?

Mr. WHITEHOUSE. Not only did they not wrestle with it, it is not clear they even thought about it. When there are people who have come out of the judicial monastery—not quite the right word because they are men and women alike—but out of the separate province of high-end adjudication, they are not familiar with this. They did not think of this. They didn't think of that, and the other thing they didn't think of was that the threat of launching a multimillion-dollar negative attack against a candidate could have a corrupting effect, even if no dollars were ever spent.

If the threat is successful, if the scheme works, there is no trail left to it. Before Citizens United, if someone wanted to make a threat, their threat was limited to a big PAC contribution, having a big fundraiser, things like that. It was not a real threat in the sense it could knock somebody out of their office.

Now the idea that a corporate identity can hide its identity, can launder its identity through 501(c)(4)s and then launch a multimillion-dollar attack in somebody's State is a credible threat, and I think that is a threat, among others, they overlooked completely.

Mr. MERKLEY. I thank my colleague from Rhode Island very much for

championing this bill and for what he has done helping folks to understand this issue.

I will make a few comments on this issue. My friend from Vermont is standing by and, I think, wants to make some remarks as well.

I wanted to have the key words we are talking about put up before us. This is a picture of the Constitution, or at least the top of the front page, if you will. I was always struck that our Founders saw fit to start this document that lays out the framework for our Nation, the framework for our system of government, with three simple words, ''we the people.'' They got to it right from the very beginning. They did not put in three paragraphs of polite this and that and then get to the heart of it. They started with the heart: ''We the people.'' They did not put it in small print, they put it in super-sized print. We can see it is written in a font that is probably 10 times the size of the rest of the Constitution. They deliberately said this is the premise on which our Nation will operate. This is the foundation on which we stand.

These words are not ''we the powerful.'' There is a huge distinction between ''we the people'' and ''we the powerful.'' But the Supreme Court, in Citizens United, attacked the very heart of our Constitution—by saying the most powerful companies with vast sums of money can flood our political system, can buy up the airwaves, and completely dominate the conversation.

Free speech wasn't about one side buying up the airwaves. Airwaves didn't exist then. It wasn't about one side buying up the airwaves. It was about all ideas being able to compete in the marketplace of ideas so citizens could hear the pros and cons and decide who they wished to elect and how they wished to vote based on their understanding of what would work best for ''we the people.''

The Supreme Court did not benefit from seeing the Republican primaries of this year in operation. They didn't see how a super PAC would sweep into a State, buy up the airwaves, dominate the conversation, and determine the outcome. No, they had some other vision. My colleague has referred to the fact that none of the members of the Supreme Court had the political experience to understand the impact of this flood of money.

You may be thinking to yourself: Well, how much money can we be talking about? Well, money beyond an amount that a working man or woman could ever envision. If it were in dollar bills and stacked in a room in your house, it would fill the room in your house, plus. All of those dollar bills would not fit into a room. We are talking about such an enormous amount of money that it completely controls the sound in the airwaves.

Let me give you an example. In 2008, if one of the rather well-off companies in America—I will use one as an example. ExxonMobil made a lot of money that year. If they had spent just $3 out of $100 of their net profits on the Presidential race, they would have spent as much as the rest of America put together. That is the type of flood of money we are talking about washing across the cities and the countryside of America, buying up the newspapers, buying up the airwaves, and dominating the debate. That is not a competition of ideas envisioned in our Constitution. That is the power. That is not ''we the people.''

It is my hope that the members of the Supreme Court will stand back and realize their findings of fact were wrong, and their findings of fact that there was no corruption from this flood of money were wrong, their argument that they didn't attack the heart of the Constitution was wrong, the fact that they didn't consider the precensorship this type of flood of money creates was in error, and that they will change their decision.

But we can't be sure this activist rightwing Court will consider the facts and reach a finding consistent with the very heart of the Constitution. We can't be sure of that. We have to do what we can in this Chamber, and that is the DISCLOSE Act, the DISCLOSE Act that at least says at a minimum this huge flood of money will be identified by the donor, and it will be identified promptly so citizens will be able to find out where it came from; also that the advertisements purchased by this money will have disclaimers that will say who the major contributors are so the citizens can see it in real time, so when that group says they are the group for America's green forests and blue skies, and it is really by a very powerful group against blue skies and green forests, we can find out who it is. That is the heart of this. Citizens United is a dagger poised at the heart of the American Constitution. We must reverse it, and we must use every tool at our disposal to make that happen.

I encourage citizens to summon their full instincts about what they value in our democracy and make their voices heard. Let's get this DISCLOSE Act passed and let's go further to reverse Citizens United.

Thank you very much.

I yield the floor to my colleague.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. SANDERS. Mr. President, I thank Senator WHITEHOUSE and Senator MERKLEY and everybody else for the very hard work they have done on this monumentally important issue. It is hard for me to think of an issue that is more important.

A moment ago Senator MERKLEY used the word ''precensorship,'' which is an interesting concept. I want to give an example of this.

Mr. President, I would ask unanimous consent to have printed in the RECORD an article that appeared in the ''American Banker'' fairly recently.

(See exhibit 1.)

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

[From the American Banker, May 23, 2012]

BANKERS FORM SUPERPAC FOR 'SURGICAL' STRIKE AT INDUSTRY'S ENEMIES

(By Barbara A. Rehm)

Frustrated by a lack of political power and fed up with blindly donating to politicians who consistently vote against the industry's interests, a handful of leaders are determined to shake things up.

They have formed the industry's first SuperPAC—dubbed Friends of Traditional Banking—that is designed to target the industry's enemies and support its friends in Congress.

''It comes back to the old philosophy of walking softly and carrying a big stick,'' says Howard Headlee, the president and chief executive officer of the Utah Bankers Association. ''But we've got no big stick. And we should. We have the capacity to have one, we just aren't organized.''

Think of it as an Emily's List for bankers and their allies.

''Congress isn't afraid of bankers,'' adds Roger Beverage, the president and CEO of the Oklahoma Bankers Association. ''They don't think we'll do anything to kick them out of office. We are trying to change that perception.''

Unlike traditional banking PACs, which target hundreds of House and Senate races, the SuperPAC instead is focusing on making a big difference in just a handful of close elections.

SuperPACs are the latest campaign finance innovation, made possible by two 2010 court decisions. They are officially known as ''independent-expenditure only committees'' because they are not allowed to coordinate their activities with candidates. SuperPACs are attractive because there are no limits on contributions or expenditures.

With a regular political action committee, like the American Bankers Association's BankPAC, an individual may donate no more than $5,000 a year. Then the PAC may contribute up to $10,000 to any one candidate in an election—cycle $5,000 for the primary and another $5,000 for the general election.

But Friends of Traditional Banking can direct as much money as it can raise to certain races without such restrictions. Matt Packard, the SuperPAC's chairman and president and CEO of $670 million-asset Central Bank in Provo, Utah, views the SuperPAC as a complement to BankPAC.

''BankPAC is much broader and covers lots of different candidates. This is much more surgical,'' Packard says. ''If someone says I am going to give your opponent $5,000 or $10,000, you might say, 'Yea, okay.' But if you say the bankers are going to put in $100,000 or $500,000 or $1 million into your opponent's campaign, that starts to draw some attention.

''That's why I think this is much more instrumental than BankPAC in a close race.''

Friends of Traditional Banking will ask contributors to pledge from $150 to $500 to two congressional races each election cycle. An advisory council will research races and select the candidates to be targeted. A board of directors will sign off on the selections, and then information will be sent to those who pledged funding explaining how to donate to a particular candidate.

The SuperPAC itself will not touch the money. Unlike Emily's List, which raises money for female candidates, Friends of Traditional Banking will merely point its supporters toward the races and the candidates considered key to the future of traditional banking.

If 10,000 supporters sign up at the minimum pledge level—not a high bar considering 2.1 million people work in the banking industry—Friends of Traditional Banking would be channeling more than $1 million. That's enough to make a difference in a tight race.

''My short-term goal is to get to the $1 million mark,'' Headlee says. ''I have a lot of confidence that once we get there we will get way beyond there. People will see how effective it is and they will jump on board.''

SuperPACs are considered pretty cutting-edge, which is not a place a lot of bankers feel comfortable. Headlee says the first question most bankers ask him is, ''Is this legal?'' Friends of Traditional Banking got Federal Election Commission approval last September and federal banking regulators have been briefed on the effort.

But SuperPACs are still relatively rare. As of early April, 407 had been formed and just 18 had raised more than $1 million.

''It would be nice to sit on the sidelines or sit on our hands and say, 'Oh we don't get involved in that stuff,' but that just means you get run over,'' says Don Childears, the president and CEO of the Colorado Bankers Association. ''We need to get more deeply involved as an industry in supporting friends and trying to replace enemies.''

Childears says he's seen SuperPACs in action, citing a credit union that donated $50,000 to an independent expenditure committee and defeated a candidate in Colorado. ''Regretfully that is our world these days,'' he says. ''Everyone from the Realtors to the credit unions to the consumer groups are playing more hardball. It would be nice not to have to engage in that, but we do.''

[The Credit Union National Association, the industry's largest trade group, does not operate a SuperPAC. But it does accomplish many of the same goals by marshalling both institutions and their customers to donate to specific races. PACs are allowed to make these ''independent expenditures,'' or donations that are not coordinated with a campaign, and according to the Center for Responsive Politics, CUNA's PAC spent $837,000 to influence six tight races during the 2010 elections.]

The ABA's BankPAC has spent $1.146 million so far in the 2011–12 election cycle, which ranks it 9th overall, just behind CUNA at $1.184 million, and well behind the second-ranked National Association of Realtors at $1.629 million, according to the Center for Responsive Politics. BankPAC expects to raise $3.5 million during this election cycle.

Gary Fields, BankPAC's treasurer, says it will contribute to 380 House races and virtually all the Senate races this year. Fields says the ABA is considering an effort that would parallel Friends of Traditional Banking loosely dubbed the ''Chairman's Club.''

''For those bankers who want to do more than just contribute to the PAC, Howard has his Friends of Traditional Banking and we're looking at something, the Chairman's Club, which would be a pledge program that would complement Friends of Traditional Banking,'' Fields says. ''But it's only on the drawing board and nothing has been rolled out to the public on that yet.''

Fields, however, sounds more focused on the traditional PAC. Asked if he is excited about the prospects for Friends of Traditional Banking, Fields says, ''I'm more excited about the ABA BankPAC . . . What we would like to see is more bankers participate in the PAC.''

Why isn't ABA, the industry's broadest trade group, or the Independent Community Bankers of America, the group devoted to Main Street banking, involved in Friends of Traditional Banking?

''We didn't ask the ABA or ICBA to participate,'' Headlee said. ''I don't think they want to have any kind of control over this because we may piss some people off inside the Beltway. We fully intend to. They have to work back there.''

ICBA President and CEO Cam Fine is enthusiastic about the effort.

''I am for any PAC that is going to defeat our enemies,'' Fine says. ''I agree with Howard on this. More power to him. I hope he raises a lot of money and hammers these guys.''

Beyond Utah, Oklahoma and Colorado, the advisory council currently includes members from eight other state associations: Arizona, Colorado, Idaho, Kansas, Michigan, Minnesota, New Jersey and Vermont.

Headlee and the other state association leaders see Friends of Traditional Banking going beyond bankers to tap shareholders and customers and anyone else who sees the value in preserving Main Street banking.

''Clearly there are Members of Congress who have absolutely no reservations about kicking traditional banks in the teeth, and we are tired of it,'' says Headlee. ''We've got to be able to defend the folks who have the courage to stand up for us as well.''

The vehicle now exists. The potential is there. It's up to bankers to make it happen.

Mr. SANDERS. Let me read what this article says. This is a member of the banking industry who contrasts what the old rules would have allowed, and that is under the old rules where there are limits as to how much people can contribute into a PAC, and that is $5,000 before the primary, $5,000 after, for a total of $10,000.

This is what this gentleman, Mr. Packard, from the banking industry, says:

> If someone says I am going to give your opponent $5,000 or $10,000, you might say, ''Yea, okay.'' But if you say the bankers are going to put in $100,000 or $500,000 or $1 million into your opponent's campaign, that starts to draw some attention.

What that gentleman is saying, and what this whole issue is about, is that if a Member of Congress is prepared to stand up to Wall Street, they better watch out. If they are going to vote for a bill that protects consumers, they better watch out because—as this banker said—there may be $500,000 or $1 million going to your opponent and going into television and radio ads.

So when Members of the House and the Senate are thinking about how they want to address the recklessness and irresponsibility on Wall Street—if they are thinking, as I am thinking, about the need to break up these huge banks which have so much power and have done so much harm to our country; if they want to bring about reform of the Fed so we don't have representatives of the largest banks in America sitting on regional Feds—guess what. They are going to think twice about going forward because they are going to worry that when they go home on the weekend, there are going to be all kinds of ads from the banking industry.

Maybe they are concerned as to why in America we spend almost twice as much per person on health care as any other Nation. Maybe they want to move, as I do, to a single-payer health care system. Well, the private insurance companies are not going to like that. They are going to pour huge amounts of money into advertising.

Maybe they are concerned that in America we pay the highest prices in the world for prescription drugs. Are they going to take on the pharmaceutical industry if they now have the ability to spend unlimited sums of money?

I come to the Senate floor this afternoon to express my profound disgust with the current state of our campaign finance system and to call for more disclosure until we can finally overturn Citizens United. I know the Presiding Officer from New Mexico has a very good constitutional amendment to do just that. I have one. There are other good amendments. Long term, there is no question in my mind that we need to overturn Citizens United. In my view, it will go down in history as one of the worst decisions ever to come from the Supreme Court by a 5-to-4 decision. Five members on the Court came to the bizarre conclusion that corporations should be treated as if they were people and that they have a first amendment right to spend as much money as they want in elections, even though corporations cannot vote.

On election day, the average American, after studying the issues, goes out and with pride votes for the candidate of his or her choice. There are many people in this country who make campaign contributions. Maybe they will contribute $25, maybe they will contribute $50. If they have a lot of money, maybe they will contribute $1,000 or $2,000. But what Citizens United is saying is that a small number of people who run large multinational corporations can spend as much as they want on campaigns. And if that is what American democracy is supposed to be about, you surely could have fooled me, and I think many of the Americans who have put their lives on the line to defend American democracy. American democracy is one person, one vote. We are all in this together. You may be rich or you may be poor, but under our Constitution you have one vote.

This country has had to go through a very rocky process to ensure one person, one vote. In the beginning poor whites could not vote, women could not vote, African Americans could not vote. We struggled and struggled, and we said in America every citizen of this country is going to have their say on election day. That is what we learned when we were in elementary school. That is what democracy is about. And by a 5-to-4 Supreme Court vote, the Supreme Court said: Everybody has one vote, but if you are rich or if you are the head of a corporation, you can go into corporate treasuries and spend as much money as you want. For the average Joe, it is one vote. Corporate America can spend unlimited sums of money buying the airwaves, and we are seeing this today.

This is no academic or intellectual debate. People all over America are

seeing the results of Citizens United today on their television stations and on their radio stations. In the past few months the American people have seen what Citizens United means.

According to the Center for Responsive Politics, super PACs alone have spent over $112 million on this election, and we are still more than 5 months away from election day. If 2 weeks before the election there is a billionaire out there or the head of some corporation, who is to say that person cannot take hundreds of millions of dollars out of a large corporation and spend it on an election? It is totally legal but not what America is supposed to be about.

Mr. President, I know you are aware of it, once again, because of your excellent constitutional amendment. What we are seeing throughout grassroots America is that people are beginning to stand and they are saying: No, we don't want Citizens United. We want to overturn it. We want real democracy in this country.

I am very proud that in the State of Vermont, and in four other States, State legislatures have gone on record saying: Overturn Citizens United. There are 209 cities that have passed resolutions to that effect, including some 50 or 60 in the State of Vermont, and people are organizing all over America on this issue.

I thank Senator WHITEHOUSE and others for the work they are doing on this DISCLOSE bill. This is the very least we can do, and I am eagerly waiting to hear the arguments from those people who oppose it.

If I put an ad on as a candidate or if Senator WHITEHOUSE puts an ad on as a candidate, we have to say: I approve this ad. If you are saying something nasty or dishonest, the viewers have a right to know you are behind that ad, you are not hiding. Right now the ads that are going out over this country—who is paying for them? We don't know who is paying for them. We don't see that pretty face on TV saying: I am the CEO of this corporation, and I approve this ad. We don't get the immediate disclosure we should as to who is paying for that ad. That is all this DISCLOSE legislation does.

Long term, no question, we need a constitutional amendment to overturn Citizens United. It would be awfully nice if maybe our friends on the Supreme Court realized the error of their ways and acted accordingly. But at the very least here in the Congress, we need to pass a DISCLOSE piece of legislation and minimize the severe damage that Citizens United is doing to our democracy.

I yield the floor.

The PRESIDING OFFICER. The Senator from Kansas.

Mr. ROBERTS. It is my understanding I am to be recognized at 2 p.m. for 10 minutes. I understand the majority leader has something to say at about 2:15 in regard to the progress of this bill.

The PRESIDING OFFICER. The Senator from Kansas is recognized.

Mr. ROBERTS. Mr. President, I rise today to speak on the legislation that is actually before us as opposed to the topic before, the Food and Drug Administration Safety and Innovation Act that we are currently debating. In addition to reauthorizing the user-fee agreements, this legislation includes many other important provisions. Members should know what is in this bill and how important these provisions are.

There is language to permanently reauthorize pediatric research incentives, programs to incentivize antibiotic research and development, and more transparency and accountability for the FDA and stakeholders, which we hope will help to address drug shortages. That is a big problem not only in urban areas but in the rural health care delivery system in every State. Every Senator ought to be aware of that, and I am sure they are hearing about it.

In May I joined with Senators REED, MURRAY, and ALEXANDER in introducing the Better Pharmaceuticals and Devices for Children Act, the BPDCA. I don't think that makes a very good acronym, so I am not even going to try it. Back in 1997 Congress passed the Best Pharmaceuticals for Children Act, which acknowledged the importance of ensuring medications were effective and safe for children by providing an incentive for pharmaceutical companies to invest in pediatric research. In 2003, with the passage of the Pediatric Research Equity Act, Congress required the pharmaceutical companies to engage in these studies.

These bills are often referred to as the carrot-and-the-stick approach for pediatric drug development. I prefer carrots to sticks around here, especially mandates, but they have proven over time to work—the carrot-and-the-stick approach. Since the enactment of these laws, approximately 426 drug labels have been revised with important pediatric information, and the number of off-label drugs used in children has declined from 80 to 50 percent. That is certainly good news.

In 2007 a complementary initiative to promote the development of pediatric medical devices; that is, the Pediatric Medical Device Safety and Improvement Act, was enacted. This law has resulted in a fivefold increase in the number of small-market medical devices designated for pediatric use.

The Better Pharmaceuticals and Devices for Children Act will permanently extend these worthwhile programs, while providing some real predictability and accountability for pediatric drug and medical device development.

The legislation also includes the Generating Antibiotic Incentives Now Act that I joined with Senators BLUMENTHAL and CORKER in supporting last year. This title contains provisions that aim to boost development of products to treat serious and life-threatening infections—something that is a growing problem in all of our hospitals. It provides meaningful market incentives and reduces—get this—reduces regulatory burdens. Glory be. Here is a bill that actually reduces regulatory burdens to encourage development of new antibiotics. Why? Well, the antibiotic pipeline has slowed to an alarming rate. According to the FDA, the approval of such drugs has decreased by 70 percent since the mid-1980s. This is unacceptable. The development of just one new antibiotic can take upwards of 10 years. We must act now to avoid a potential health care crisis.

When I am back in Kansas—and I know when other Senators are back in their States—talking to folks about health care, I often hear about the problem with drug shortages. When a problem exists in an urban setting, simply multiply that 10 times, and that is what we have in our rural areas. This is never more true than on the issue of drug shortages. This is a crisis. As difficult as it is to hear from my hospital administrators and pharmacists in Kansas about the difficulties they are having in getting drugs to fill prescriptions for patients, nothing compares to the patients and the families of patients who can't get their drugs, who can't get their treatment, who are already scared about their future and they can't get their lifesaving medication due to shortages. This is unacceptable. That is why I joined with a number of my colleagues on the HELP Committee to work together to see if we could come to a bipartisan consensus on a way to alleviate at least some of the burden drug shortages create. The legislation now requires reporting on drug shortages, but it also provides some transparency and accountability in the hope that we can get to the root cause of this problem.

Not everything in this legislation is what I would have done if I had my choice—that is obvious and probably the case with every Senator and every major bill on which we must make decisions. I am certain many of my colleagues on the HELP Committee are thinking the same thing. However, I think we are all pleased we were able to come to a bipartisan consensus on this legislation and in addressing many of the issues that are affecting Kansans and the rest of Americans.

I talked with a fellow last night who said: Why can't you all work together? Why can't you pass something in a bipartisan way?

This legislation is a good example of exactly what that gentleman was talking about and what a lot of Americans are concerned about. In that regard, I thank Chairman HARKIN and Ranking Member ENZI for all of their work and for all of the work by their staff and our staff over the past years and months in putting together this important piece of legislation. This took a long time. It took a lot of effort. It took a lot of hard work. Their commitment to a bipartisan process and their willingness to communicate with all

the members of the HELP Committee has led us through a relatively noncontentious markup, and I hope the same will happen as we consider this legislation on the floor.

I yield the floor.

The PRESIDING OFFICER (Mr. CARDIN). The Senator from New York.

CAMPAIGN FINANCE REFORM

Mr. SCHUMER. Mr. President, I thank my friend from Kansas for finishing his speech in a timely manner.

I come to the floor to talk a little bit about the DISCLOSE Act and Citizens United. For the last 2½ years, Americans have heard us talk about the need for full disclosure of money donated to campaigns. It is time for Congress to stop stalling and let the American voters find out where the money being spent on elections is coming from once and for all.

All of our predictions in the aftermath of the flawed Citizens United decision unfortunately are coming true. This decision handed a megaphone to the wealthiest voices among us and strapped a muzzle on every other American. Sure, average Americans can talk to one another, but they are not spending $10 million on TV ads, and we know what kind of an effect that has. If anything, the situation is even worse than we could have possibly anticipated because unlimited spending by just a handful of the wealthiest Americans has put true democracy in danger—a true democracy of one person, one vote, of true equality. This is worrisome when we have such huge amounts of money being spent by so few people who seem to speak with one voice and one conservative point of view.

The list of the top donors to super PACs reads like a who's who of the richest people in America. The contributions to super PACs that were released in the most recent disclosure reports are truly astonishing. Six-figure sums seem like pocket change now compared with today's trend of seven- and eight-figure donations.

Let's take Bob Perry, for instance, top donor to Mitt Romney's super PAC, Restore Our Future. People may know him as the former top donor to Swift Vets and POWs for Truth, the group that ran smear ads questioning JOHN KERRY's military service in 2004. When we add up his donations to super PACs this cycle, we have almost $14 million of political influence from just one man. Another example is Harold Simmons. When we combine his personal donations with the corporation he owns with his wife, we get contributions of over $17 million to six different super PACs.

Because disclosures to the FEC are only made publicly available once a month, this paints a mere fraction of the picture of total super PAC spending. The reports don't even address spending through so-called nonprofit organizations. As we all know, 501(c)(4) organizations are able to serve as conduits for huge sums of anonymous funding that are never publicly disclosed. I call them ''so-called'' because they function the same as the super PACs, except they can't say ''vote for'' or ''vote against,'' but their effect on campaigns, obviously intended, is just as real.

It doesn't stop at the Federal level. We are also seeing the concern over corporate spending at the State level through the Montana case, American Tradition Partnership v. Attorney General Bullock. This case hinges on a challenge to Montana's century-old campaign finance law by special interest groups that want to take advantage of the anonymous political spending made possible by Citizens United. In fact, the fundraisers in this case, a group called American Tradition Partnership, solicits contributors by actually bragging about their secrecy. In their promotional literature, they promise potential donors:

> We're not required to report the name or the amount of any contribution that we receive. So, if you decide to support this program, no politician, no bureaucrat, no radical environmentalist, will ever know you helped make this program possible.

It is no surprise, given mounting concerns about the corruptive effects of unlimited and often anonymous campaign spending on our democracy, that so many individuals and groups have filed amicus briefs to this case—including Senators WHITEHOUSE and MCCAIN, several House Democrats, and dozens of others—urging the court to uphold Montana's 100-year-old law.

We cannot sit idly by and watch our democracy put up for sale to the highest bidders. Full disclosure—the kind the DISCLOSE Act of 2012 requires—is still necessary to shed light on which groups and individuals are funding our elections, to keep some modicum of faith that the voters at least know what is going on.

In 2010 the original DISCLOSE Act passed the House and had widespread support in the Senate and from the President but failed to gain cloture by one vote because not one Republican was willing to step across the aisle and do what the American people clearly regard as the right thing. Well, now there is no excuse. We have removed the original provisions my Republican colleagues most objected to. All that remains is disclosure and disclaimer, plain and simple.

The time to act on campaign finance reform is now. While America's richest billionaires can afford to keep contributing millions of dollars to super PACs and 501(c)s, America cannot afford to be kept in the dark any longer.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

The majority leader is recognized.

FLOOD INSURANCE

Mr. REID. Mr. President, the first thing we are going to talk about—I have had conversations in the last few days—in fact, a longer period of time than that—with Senator VITTER, Senator COBURN, Senator JOHNSON, Senator SHELBY, and others on flood insurance.

Like a lot of things that happen, it has become critical that we do something on flood insurance. It affects almost 6 million people. We need to get something done on a more permanent basis.

There has been a general agreement—we do not have it in writing yet, but I want to make sure the record on the floor is clear what my intention is—that we would have a 60-day short-term extension. In that extension there would be language for the duration of 60 days that would include in that the second-home subject that is part of the underlying bill on which Senator COBURN is focused. That would be for 60 days. Then I would be happy to make a statement here on the floor today that during the next work period we will move to that bill, the flood insurance bill, so we would have the opportunity to make it permanent. It is very important we do that. With the economy being such as it is, we cannot, in this area—and probably others but in this one—we cannot have these short-term extensions. It does not allow people to do what they need to do. Mr. President, 40,000 homes a day go through a process where they have to have flood insurance. If there is no flood insurance, that is 40,000 loans every day that will not be approved.

Senators JOHNSON and SHELBY have done good work to narrow down the list of amendments we would have to consider when the Senate takes up this long-term flood insurance bill. It is my understanding there are a dozen or so amendments—six, eight on each side. But I hope we can do that. If we cannot do that, we are going to have to go to the bill anyway.

I wanted to make sure Senator VITTER, who is on the floor today, understands that is my understanding of things he and I have talked about in the last couple weeks.

I appreciate the work that Senators JOHNSON, TESTER, SHELBY, COBURN, and VITTER have put into working out an agreement on flood insurance.

As Senators have noted, this program that provides insurance coverage to 5.5 million people is set to expire next week.

If the program were to expire, new housing construction would stall, real estate transactions would come to a halt, and taxpayers would be on the hook for future disasters. So this is something that we have to do.

I understand that Senators JOHNSON and SHELBY have done good work to narrow down the list of amendments that we would consider when the Senate takes up a long-term flood insurance bill. I believe that they have made

good progress. And we could consider eight or even fewer relevant amendments per side on a long-term bill.

And thus I believe that the Senate can consider a long-term bill in the next work period. And I am committed to turning to a long-term bill in June.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. Mr. President, I thank the distinguished majority leader very much for this important announcement and this plan. It certainly meets two—

Mr. REID. Mr. President, it is my understanding he was going to ask me a question, because I do not want to lose the floor.

The PRESIDING OFFICER. The majority leader has the floor.

Mr. VITTER. Yes. I have no intention of his losing the floor. I just want to thank him for the announcement. From my perspective, it meets the two main goals we have been in search of: first of all, making sure in the short term there is not a lapse of the program; that would be disastrous; that would cancel, as the majority leader suggested, thousands of good closings, really put a hiccup in the economy for no good reason—and, in addition, getting to a permanent bill in the next work period. So I appreciate the leader's announcement.

I would also note, as he did, that there has been great work and great progress in narrowing the field of relevant amendments. I certainly hope that leads to a limited and reasonable number of amendment votes, as he does, on the floor. I understand what he said about, if that becomes unwieldy, we will just proceed with the bill as is. But that certainly it is my expectation. I will continue to work on that amendment list so we can have a reasonable opportunity for relevant amendments.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Mr. President, I am glad the Republican leader is on the floor. We have worked very hard to arrive at this point where I am going to ask for this consent agreement. I appreciate everyone's help, and it takes everyone's help to get to where we are. That is why we call them unanimous consent agreements.

I ask unanimous consent that the only first-degree amendments in order to the bill that is now pending before the Senate be the following: Bingaman No. 2111; McCain No. 2107——

The PRESIDING OFFICER. Will the majority leader suspend for one moment.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

The PRESIDING OFFICER. Under the previous order, the motion to proceed to S. 3187 is agreed to and the clerk will report the bill by title.

The bill clerk read as follows:

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

AMENDMENT NO. 2122

(Purpose: In the nature of a substitute)

The PRESIDING OFFICER. Under the previous order, amendment No. 2122 is agreed to.

(The amendment is printed in the RECORD of Monday, May 21, 2012, under ''Text of Amendments.'')

The PRESIDING OFFICER. The majority leader.

Mr. REID. Thank you very much, Mr. President. I am sorry I got ahead of the Chair a little bit.

I ask unanimous consent that the only first-degree amendments in order to the bill be the following: Bingaman No. 2111; McCain No. 2107; Sanders No. 2109; Murkowski No. 2108; Cardin No. 2125; Cardin No. 2141; Grassley No. 2121; Grassley No. 2129; Manchin No. 2151, as modified; Portman No. 2146, as modified; Portman No. 2145, as modified; Reed No. 2126; Coburn No. 2132; Coburn No. 2131; Durbin No. 2127; Paul No. 2143; and Burr No. 2130; that there be no second-degree amendments in order prior to the votes in relation thereto; that there be no motions or points of order to the amendments or the bill other than budget points of order and the applicable motions to waive or motions to table; that there be up to 30 minutes of debate on each of the amendments, with the exception of the McCain amendment, which will have 2 hours of debate, and 60 minutes on the bill, with all time equally divided in the usual form; that at 2 p.m. on Thursday, May 24, all debate time be considered expired and the Senate proceed to votes in relation to the amendments in the order listed above; that there be 2 minutes of debate equally divided in the usual form prior to each vote; that all after the first vote be 10-minute votes; that the following amendments be subject to a 60 affirmative vote threshold: Bingaman No. 2111, McCain No. 2107, Sanders No. 2109, and Murkowski No. 2108; that upon disposition of the amendments, the bill be read a third time and the Senate proceed to vote on passage of the bill, as amended.

That upon disposition of S. 3187, the Senate proceed to the consideration of Calendar No. 365, S. 2343; that the only amendment in order to the bill be an amendment from the Republican leader or his designee, the text of which is identical to S. 2366; that there be 10 total minutes of debate on the amendment and the bill equally divided between the two leaders or their designees prior to a vote on the McConnell or designee amendment; that no amendment be in order to the McConnell or designee amendment; that no motions or points of order be in order to the amendment or the bill other than budget points of order and the applicable motions to waive; that upon disposition of the amendment, the Senate proceed to vote on passage of the bill, as amended, if amended; that the amendment and the bill be subject to a 60 affirmative vote threshold; that if the bill does not achieve 60 affirmative votes, S. 2343 be returned to the calendar; and finally, that the motion to reconsider with respect to the cloture vote on the motion to proceed to S. 2343 be withdrawn.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. REID. So, Mr. President, we are going to have votes on these amendments. It is my understanding that there is time, 30 minutes per amendment. We need to get as much of that done today as possible. We have an event for spouses tonight, so we are not going to be working late into the night. We have tomorrow to finish this. We should be able to do that. I hope we can. I hope it does not spill and there is no reason it should spill over until the next day. We are going to also have votes on the Republican student loan legislation and ours. That is what we are doing in the next 36 hours.

The PRESIDING OFFICER. The Republican leader.

Mr. MCCONNELL. Mr. President, let me just add that I think this is a good agreement that allows us to go forward on the FDA bill with appropriate amendments and also allows an opportunity for the Senate to express itself on the issue of the student loans.

I would join the majority leader in encouraging people to do their debate today or in the morning because once we get into the votes tomorrow afternoon, they will be dealt with in rapid succession.

I yield the floor.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I rise to discuss my amendment that would repeal the costly and counterproductive medical device tax in President Obama's health care law. In the mad scramble to find money to pay for his $2.6 trillion health spending law, the President and his Democratic allies created a number of new taxes that serve no purpose other than to fuel this new spending. Economically, these taxes are a disaster. They will undercut job creation, and they will increase costs for patients.

The new 2.3-percent tax on medical device manufacturers, which kicks in at the beginning of next year, is particularly onerous. For that reason, last year I introduced legislation to repeal it. That bill, the Medical Device Access and Innovation Protection Act, S. 17, has been cosponsored by 25 of my colleagues.

They understand that all of ObamaCare needs to go. The President's health care law is now over 2 years old. It is not aging well. Even before ObamaCare became law, the American people made themselves absolutely clear they wanted nothing to do with this Washington takeover of the Nation's health care system. The President and his advisers refused to face reality, telling reluctant Democrats all

was well in spite of the tea party townhalls.

According to the President and his congressional Democratic leadership, as soon as the legislation became law, Americans would come to embrace the wonderful benefits bestowed on them by the Department of Health and Human Services. It has not quite turned out that way.

Poll after poll shows that substantial majorities of Americans continue to oppose the law and favor its full repeal. A majority of Democrats think the law is unconstitutional. In a matter of weeks, the Supreme Court might issue a coup de grace to President Obama's misguided adventure in big government.

Whatever the Supreme Court does, I want to be clear about something. All of ObamaCare needs to go. It needs to be pulled out root and branch. The entire thing needs to be repealed. That said, some part of the law stand out for their wrongheadedness. The individual mandate and Medicaid expansions are flat out unconstitutional.

The IPAB, the CLASS Act, the Medicare cuts, and the employer mandate all deserve honorable mention for being bad public policy. Among the most counterproductive parts of the law are its over $500 billion in new taxes and penalties.

The medical device tax sits at the top of the list of foolish new ObamaCare taxes, and my colleagues who have supported S. 17 and this amendment understand the critical importance of eliminating it. I thank in particular my colleagues, Senator BROWN from Massachusetts, and Senator TOOMEY from Pennsylvania, who have spoken on this issue and understand completely the devastation this tax will create for patients and for employers who provide good jobs for communities in their States.

Thanks to ObamaCare, medical devices will get hit with a $28 billion tax. So we are clear about what these medical devices are, they include surgical tools, bed pans, wheelchairs, stethoscopes, and countless other products that patients and doctors rely on every day. Surgical masks, gloves, blood pressure monitors, scissors, needles, cribs, trays, lights, stents, pacemakers, scales, scalpels, inhalers, and ankle, knee, and hip braces, and a lot more.

The cost of all of those products is going up thanks to this tax. Somebody is going to have to pay for it, and that someone is the already overburdened American taxpayer and middle-class breadwinner.

The President and his supporters seem to think we can simply tax corporations and individuals with impunity and face no adverse economic consequences. Yet economists understand when we tax these companies, employees will pay for it in lower wages, the unemployed will pay for it with a job that was never created, and patients will pay for it with higher health care costs.

Whatever our economic circumstances, this tax is bad news. But it is particularly foolish given the precarious state of our economic recovery. The President once liked to tout all of the jobs created or saved by his over $800 billion stimulus bill. Yet by supporting the medical device tax, the President and his allies have shown a real disregard for good high-paying American jobs.

Medical device companies employ nearly half a million people. They pay a salary that is nearly 40 percent higher than the national average. These manufacturers are small businesses we must be cultivating if our economy is going to recover and we are going to be successful in bringing down unemployment.

Roughly 80 percent of medical device companies have fewer than 50 employees; 98 percent have fewer than 500 employees. ObamaCare's $28 billion tax hike on these manufacturers will do nothing to improve health care, but it will do plenty to undercut the viability of these companies that provide good wages and good opportunities for American families.

According to one recent analysis, the medical device industry provided jobs to 409,000 employees in 2009. Yet this tax could result in job losses in excess of 43,000. It will hit certain States harder than others: California, Florida, Illinois, Massachusetts, Minnesota, New Jersey, New York, Ohio, Pennsylvania, Wisconsin, and my State of Utah. The presence of medical device manufacturers is significant in all of these States.

This new tax will roughly double the device industry's total tax bill and raise the average effective corporate income tax to one of the highest effective tax rates faced by any industry in the world. The President and his allies frequently attack industries that choose to move their operations overseas. But they do not seem to grasp that their policies are driving these industries to do just that. With the onset of this new tax, U.S. device manufacturers are increasingly likely to close plants in the United States and replace them with plants in foreign countries.

According to another report by the Lewin Group, the medical technology industry contributes nearly $382 billion in economic output to the U.S. economy every year. President Obama, in the middle of a weak economy, facing high rates of joblessness, has decided to attack that industry. It is bewildering to me. An industry that pays workers on average $84,156 has become a victim of the President's desire to pay for his new health spending law or, better put, those workers and the families they support become the victims of the President's health spending law.

In my own State of Utah, the device tax is an issue of great importance. There are over 120 medical device companies in Utah. As the Utah Technology Council wrote in a letter to me, these companies ''are a vibrant part of the Utah economy providing high-paying, high-tech jobs for citizens of our great state.''

They certainly are all of that, and they are under assault as a result of this tax, targeted for nothing other than their success and the fact that they were a so-called stakeholder that could pay a so-called fair share to subsidize the President's health spending bonanza.

I ask unanimous consent that letter be printed in the RECORD.

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

JANUARY 25, 2011.

Hon. ORRIN G. HATCH,
U.S. Senate,
Hart Office Building,
Washington DC.

DEAR SENATOR HATCH: As you are aware, the Utah Technology Council represents the life science community in Utah. There are over 120 medical device companies in Utah that are part of that community. They are a vibrant part of the Utah economy providing high-paying, high tech jobs for citizens of our great state. Many of these companies you would recognize immediately including Merit Medical, Dynatronics, WorldHeart, Aribex, Utah Medical, Edwards Life Science, Becton Dickinson, Watson Laboratories and Fresenius Medical Care.

The Governor of the State of Utah as part of his long-range economic plan has identified the life sciences, including medical device companies, as a targeted area of growth for the state of Utah. The state's economic growth initiatives recognize the importance of these industries to our future and the rich resources our state offers to companies operating in this market. The industry-specific taxes imposed by the 2010 Patient Protection and Affordable Care Act are of great concern to us as an industry association because of the impact these taxes could have in slowing economic growth in this targeted area.

Therefore, we strongly support the Medical Device Access and Innovation Protection Act that you are introducing. The removal of this unfair and onerous tax will assure the continued growth of jobs and innovation in this important market sector. We appreciate the fact that you have recognized the need for this statutory change. The imposition of an excise tax is particularly burdensome for our small companies here in Utah that operate on less than average profit margins. To take 2.3 percent of sales as an excise tax would render some companies unprofitable and significantly reduce the profitability of most—not to mention the catastrophic effect this tax would have on companies that are already not profitable. If a medical device company is operating on a 5 percent net profit margin, the excise tax represents the equivalent of a 50 percent income tax. Such a tax takes money that would otherwise be deployed in new jobs, R&D, capital equipment and reinvestment in product lines and redirects it to an entitlement program. It may seem a small percentage of sales, but as a percentage of pre-tax profits, this could range from 25 percent to well over 100 percent. That is simply unacceptable and unwise tax policy—especially in the current environment that is already struggling to produce jobs and economic vitality.

Just as important as the effect on current companies is the impact on investment capital. This new tax will have a chilling effect on investors who will likely redirect their capital to other industries not so burdened with industry-specific taxes. Few investors

will appreciate the fact that the government gets paid tax dollars from sales before investors can be paid from profits. It is a paradigm that creates significant disincentives for investment. Without capital investment, job creation and innovation suffer.

We not only support this legislation to repeal the medical device tax imposed by the 2010 Patient Protection and Affordable Care Act, we feel it is essential to protecting an industry vital to Utah's present and future economic growth. We lend our full support to your efforts.

Sincerely,

RICHARD R. NELSON,
Founder & CEO,
Utah Technology Council.

Mr. HATCH. Just yesterday, the Governor of Utah, the Honorable Gary Herbert, sent a letter to Congress addressing the negative impact this tax will have on our State. He wrote:

As a Governor of a state with a significant concentration of medical technology manufacturers, I believe this tax could harm U.S. global competitiveness, stunt medical innovation and result in the loss of tens of thousands of good paying jobs.

Now, there is little doubt the President's medical device tax, one that unfortunately received the vote of every Democrat in the Senate, will do just that—kill jobs and undercut our economy.

I ask unanimous consent that Governor Herbert's letter be printed in the RECORD.

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

STATE OF UTAH,
OFFICE OF THE GOVERNOR,
Salt Lake City, UT, May 22, 2012.

Speaker JOHN BOEHNER,
U.S. Capitol,
Washington, DC.
Minority Leader NANCY PELOSI,
U.S. Capitol,
Washington, DC.
Majority Leader REID,
Hart Senate Office Building,
Washington, DC.
Minority Leader MCCONNELL,
Russell Senate Office Building,
Washington, DC.

DEAR SPEAKER BOEHNER, LEADER REID, LEADER PELOSI, AND LEADER MCCONNELL: On behalf of the State of Utah, I am writing to express my concern over the impact of the 2.3% excise tax on medical devices set to begin in 2013. As a Governor of a state with a significant concentration of medical technology manufacturers, I believe this tax could harm U.S. global competitiveness, stunt medical innovation and result in the loss of tens of thousands of good paying jobs.

As you know, America is the global leader in medical technology, one of our only manufacturing sectors in which the U.S. is a net exporter. The United States annually exports $5.4 billion more medical technology than we import, and accounts for 40 percent of the global medical technology market. However, our lead has shrunk dramatically in the last decade, and we stand to lose further ground.

One of my priorities as Governor is creating an economic environment in which business can grow and thrive. As part of this effort, I supported a comprehensive tax reform strategy that reduced sales, income, and corporate taxes in the State of Utah by nearly $400 million. In order for our nation to remain economically competitive, it is time to also reform our country's tax system.

The United States has not undertaken major business tax reform since 1986. While the world's economy has changed, our tax system has not. The medical device tax is an example of a policy that runs counter to efforts to make American manufacturing industries more competitive. In fact, the medical device tax will make our tax system even less competitive. Worse still, it is already causing layoffs as companies prepare to absorb its impact.

At a critical time for both the U.S. economy and state economies, the new tax will undoubtedly stifle economic growth and job creation. We must have a national tax strategy that encourages growth, investment, and export industries, to help create jobs and expand the economy. Therefore, I strongly urge you to consider legislation that would repeal the medical device excise tax before it takes effect.

Sincerely,

GARY R. HERBERT,
Governor.

Mr. HATCH. The President's health care law is a travesty. The American people know it. They think it is fundamentally illegitimate, unconstitutional to its core, and enacted over the deep and loud objections of citizens and taxpayers.

All 2,700 pages of that law must be stricken from the U.S. Code one way or another. Eliminating its medical device tax is absolutely essential. It is critical for our States, for our economy, and for America's families and workers. I ask my colleagues join the repeal effort, and I thank my colleagues who have already joined as cosponsors.

I would like to briefly touch on one other issue that is of great importance to me and to the people of Utah and others all over the country. Over 150 million Americans regularly consume dietary supplements as a means of improving and maintaining their health.

The passage of the Dietary Supplement Health and Education Act, or DSHEA, in 1994 brought clarity, predictability, and a better understanding of what the FDA expected from industry and vice-versa. DSHEA provides an appropriate structure that balances the risks and benefits to consumers, with continued access and affordability.

Unfortunately, my colleague from Illinois, Senator DURBIN, has filed an amendment to the current bill that would undo that well-balanced approach. As the author of DSHEA, along with my dear friend and colleague, Senator HARKIN in the Senate, I strongly oppose his amendment. It would require facilities engaged in the manufacturing, processing, packing, or holding of dietary supplements to register with the FDA, provide a description with a list of all ingredients, as well as a copy of the labeling for each dietary supplement product. Additionally, the facilities must also register with respect to new, reformulated, and discontinued dietary supplement products.

While I appreciate my colleague's commitment, his amendment is based on the misguided presumption that the current regulatory framework for dietary supplements is flawed and that the FDA lacks authority to regulate these products. This is simply not the case. Previously FDA Commissioners, including Drs. Jane Henney, Mark McClellan, Les Crawford, and Andy von Eschenbach, as well as the former Deputy Commissioner, Dr. Josh Sharfstein, have all agreed DSHEA provides an appropriate and sufficient level of oversight of this industry.

Under DSHEA, Congress set out a legal definition of what could be marketed as a dietary supplement and safety standards that products have to meet. It allowed the FDA to develop good manufacturing practice standards and clarified what types of claims could be made. It provided the Secretary of Health and Human Services with the authority to impose an immediate ban on any dietary supplement that poses an imminent risk to public health.

DSHEA already provides the Secretary with enforcement tools of seizure, injunction, or criminal prosecution for ingredients that pose an unreasonable risk of illness or injury, are poisonous or deleterious, contain unapproved drugs or food additives, or fail to meet good manufacturing practice standards.

Furthermore, under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, a manufacturer, packer, or distributor whose name appears on the label is required to report a serious adverse event related to the use of a supplement within 15 business days to HHS; submit any related medical information received within 1 year of the initial report within 15 business days; maintain records related to each report for 6 years; and permit inspection of such records.

To me, that sounds like a whole lot of regulation. The FDA already has a tremendous amount of regulatory oversight and enforcement tools when it comes to dietary supplements. Yet instead of urging FDA to use its current enforcement authority to find and punish those companies that are not following the law, Senator DURBIN's amendment serves to punish all responsible companies with its overreaching mandates.

Finally, I would be remiss if I did not mention another obvious point. Senator DURBIN's amendment would have the devastating effect of piling on more work for an underfunded agency already struggling to keep above water with its current core responsibilities.

Now, let me just say this: Before we passed DSHEA, there basically was no regulation over this industry. We brought together, Senator HARKIN and I, the whole dietary supplement industry to get behind DSHEA. They are behind it. It took over 10 years to get the good manufacturing practices completed by FDA—more than 10 years, as a matter of fact. But we provided for them in that agreement. We provided all the tools that are necessary to supervise and regulate dietary supplements. To now add other obligations

onto this industry is just plain not right, and I hope my colleagues in the Senate and the House of Representatives will recognize this is an overreach and not put up with it. We are not going to put up with it. I will be voting against Senator DURBIN's amendment, and I urge all of our colleagues to do the same.

At this point, I pay tribute to my colleague, Senator HARKIN from Iowa. Senator HARKIN worked tirelessly on this bill along with me. We worked all the way through the Senate on a number of occasions on various things. We have improved the bill from time to time. We have gone along with the improvements. We have done everything we can to protect the American citizens with everything that should be done. Nothing further needs to be done.

This is an industry that deserves support, not condemnation. Senator HARKIN has been there every step of the way. He is a champion for the dietary supplement industry, as am I, and a lot of others in this body. I think it is time to quit trying to overregulate everything to death and cause costs to go up by leaps and bounds. Dietary supplements are not inexpensive today, although they are a lot less expensive than they would be if we keep piling on these regulations.

Frankly, we believe we have all of the necessary language in the law today to protect the American public regarding dietary supplements. We have given the Food and Drug Administration all the authority they need, and every FDA Commissioner has met with me, as I recall, since DSHEA was passed in 1994, and has said they have enough tools to be able to supervise this industry properly and they don't need anything more.

To make a long story short, again, this is an overreach by a colleague, sincere though he may be, and as important as he believes it to be. I hope he will withdraw his amendment so we don't have to go through this again. If he won't, I hope our colleagues on both sides of the aisle—and this is a bipartisan effort—will rise and say we have had enough of this and let's vote these kinds of amendments down.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I thank the Senator from Utah for his concluding remarks regarding the amendment that I assume will be offered by the Senator from Illinois, as it is cleared to be offered.

I thank Senator HATCH for his great leadership on the issue of making sure the American people can have access to healthy, life-supporting vitamins, minerals and supplements, without having it go through untold processes and reviews and approvals by the FDA, and all that kind of regulation.

Senator HATCH was the leader on the DSHEA bill when we passed it in 1994. I was happy to work in tandem with him on that. It has proven, through the years, to be a great success for the American people. The American people all over this country take vitamins and other supplements, and they are living healthier because of this.

I say to my friend that I heard the Senator from Illinois on the floor yesterday give an impassioned speech about a very sad case about a young woman who evidently consumed some energy drinks with a lot of caffeine in them and had heart arrest and died. It is a very sad story. But as sad as that is, you can't keep people from abusing things. People also die every year from aspirin poisoning, where they took too many aspirin.

Reasonableness has to enter into this. We have worked together to make sure the labels are good on all of these things, so that people know what is in them. The FDA has the authority—as the Senator said, every Commissioner has said they have the authority to keep dangerous products off the shelf and to remove them from the shelf. They have all that authority. These cases, as I said, that Senator DURBIN brought up are very sad, and you wish it were not so. I don't think it lends itself, though, to overturning what has been working now for 17, going on 18, years and working well for the American people.

I join the Senator from Utah, and I hope the amendment might not come up. But if it does, it does. I am sure there will be some debate on it. I join with the Senator from Utah in urging all Members of the Senate to vote that amendment down. If it comes up, I will move to table that amendment. Hopefully, we can approach this in a much more judicious, responsible, thinking manner.

I say to my friend from Utah—and I know he agrees—we are not taking the position that nothing has ever been changed. We have changed DSHEA in the past to make it work better. We did it after due deliberation, committee hearings, and going through the process to see what it means in terms of access to these products by the American people, to make sure we keep the intent of DSHEA there.

Again, I am more than willing, as chairman of the committee—and the Senator used to be chairman of the committee at one time, and then ranking member—we are always willing to look at these things and have a hearing on them and get more information. Again, I thank the Senator from Utah, who has been a great leader on this issue.

Mr. HATCH. I thank the Senator from Iowa. I know Senator DURBIN is sincere, but, my gosh, there is enough regulation and regulatory authority in this bill, including the amendments we have added voluntarily, to resolve any problem that exists. Frankly, I hope everybody will vote against the Durbin amendment.

Mr. HARKIN. Mr. President, how much time does this side have on the bill?

The PRESIDING OFFICER. For general debate, 24½ minutes.

Mr. HARKIN. I reserve the remainder of my time on the bill. If the Senator from Illinois wishes to bring up his amendment, we can bring it up.

Mr. President, again, I understand I have 24 minutes left.

The PRESIDING OFFICER. That is correct.

Mr. HARKIN. I will make a short general statement about the bill. I talked about it in the past. I want every Senator to know that we are now on the FDA reauthorization bill. This is reauthorizing the prescription drug user fee, the medical device user fees, and then we are authorizing a new program, the generic drug user fee, biosimilar user fee, and so we are on the bill now. There is 30 minutes for debate on each amendment that has been listed. Senators know who they are and what the amendments are.

I want to make it clear that the unanimous consent we just adopted says that all debate time will expire at 2 p.m. tomorrow. So I say to Senators, if you want to take your 30 minutes and debate your amendment, now is the time to do it. If you wait too long, 2 o'clock will come tomorrow, you won't have the time, and you will be limited to 1 minute. There will be 2 minutes on each amendment after that. Those who have amendments and wish to discuss them, you are guaranteed at least 30 minutes, but all time runs out at 2 p.m. tomorrow. If you want to talk on your amendment and make your point, now is the time to do it this afternoon.

I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois.

AMENDMENT NO. 2127

Mr. DURBIN. Mr. President, I call up amendment No. 2127.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Mr. BLUMENTHAL, proposes an amendment numbered 2127.

The amendment is as follows:

(Purpose: To require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration)

At the end of title XI, add the following:

SEC. 11___. REGISTRATION OF FACILITIES WITH RESPECT TO DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended by adding at the end the following:

''(6) REQUIREMENTS WITH RESPECT TO DIETARY SUPPLEMENTS.—

''(A) IN GENERAL.—A facility engaged in the manufacturing processing, packing, or holding of dietary supplements that is required to register under this section shall comply with the requirements of this paragraph, in addition to the other requirements of this section.

''(B) ADDITIONAL INFORMATION.—A facility described in subparagraph (A) shall submit a registration under paragraph (1) that includes, in addition to the information required under paragraph (2)—

''(i) a description of each dietary supplement product manufactured by such facility;

''(ii) a list of all ingredients in each such dietary supplement product; and

''(iii) a copy of the label and labeling for each such product.

''(C) REGISTRATION WITH RESPECT TO NEW, REFORMULATED, AND DISCONTINUED DIETARY SUPPLEMENT PRODUCTS.—

''(i) IN GENERAL.—Not later than the date described in clause (ii), if a facility described in subparagraph (A)—

''(I) manufactures a dietary supplement product that the facility previously did not manufacture and for which the facility did not submit the information required under clauses (i) through (iii) of subparagraph (B);

''(II) reformulates a dietary supplement product for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B); or

''(III) no longer manufactures a dietary supplement for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B),

such facility shall submit to the Secretary an updated registration describing the change described in subclause (I), (II), or (III) and, in the case of a facility described in subclause (I) or (II), containing the information required under clauses (i) through (iii) of subparagraph (B).

''(ii) DATE DESCRIBED.—The date described in this clause is—

''(I) in the case of a facility described in subclause (I) of clause (i), 30 days after the date on which such facility first markets the dietary supplement product described in such subclause;

''(II) in the case of a facility described in subclause (II) of clause (i), 30 days after the date on which such facility first markets the reformulated dietary supplement product described in such subclause; or

''(III) in the case of a facility described in subclause (III) of clause (i), 30 days after the date on which such facility removes the dietary supplement product described in such subclause from the market.''.

(b) ENFORCEMENT.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a dietary supplement for which a facility is required to submit the registration information required under section 415(a)(6) and such facility has not complied with the requirements of such section 415(a)(6) with respect to such dietary supplement.''.

Mr. DURBIN. Mr. President, this amendment is very straightforward. I will not ask for a show of hands among Senators, staff, or those who are following this debate, about how many of them got up this morning and took a vitamin pill. I did, and I didn't have a prescription. I bought it voluntarily. I don't know if it does any good, but it was my decision, right? I voluntarily made that decision. I think that is a good thing.

The FDA is an agency that looks at what we buy and consume. It has an important responsibility. When it comes to certain things, such as prescription drugs, they test them—maybe the pharmaceutical companies do the testing, but the FDA monitors it to make sure what is given to you by your doctor is safe, won't kill you, and is effective. The same thing is true for over-the-counter drugs. The FDA has that responsibility.

When it comes to the ingredients and the dosage, those things are established through the FDA based on disclosures by the companies, testing, experience—it is all there. But there is another world out there, a completely different world called dietary supplements, which includes the vitamin I took this morning. That is a much different world, a world with less disclosure, less transparency, and far less regulation. In fact, there is no requirement in the law today—none—that the people who sell us dietary supplements have to register with the FDA the name of their product, the ingredients it contains, and a copy of the label.

That is what my amendment says. We don't require any testing by a dietary supplement company. We don't require any assertions of safety. It would require simply that they register with the FDA that they are selling it in America. That, to me, seems pretty basic. It is not my original idea. It comes from a report of the General Accountability Office in 2009. They recommended this after they made a review of the safety issues with the FDA:

To improve the information available to FDA for identifying safety concerns and better enable FDA to meet its responsibility to protect the public health, we [the GAO] recommend that the Secretary of the Department of Health and Human Services direct the Commissioner of FDA to request authority to require dietary supplement companies to identify themselves as a dietary supplement company as part of the existing registration requirements and update this information annually; provide a list of all dietary supplement products they sell and a copy of the labels and update this information annually, and report all adverse events related to dietary supplements.

In other words, did you take the pill and get sick? Does that seem like an onerous, heavyhanded, big government overregulation of an industry? Remember, the dietary supplement companies are not all based in the United States. Products are sitting on the shelf which you may not know come from other countries, including China. Do we want to know that? Would you want to know the company that is selling you whatever it is is at least registered in the United States? Is that too much to ask if you are going to sell the product in the United States, that they have to register with the FDA and tell us what the ingredients are? That seems pretty basic to me. I bet that 99 percent of the American people thought they already had to do that. No. Let me tell you that dietary supplements go beyond vitamin pills.

Yesterday I told the story on the floor about a 16-year-old girl in Hagerstown, MD, who drank two Monster Energy Drinks. When you go to the store, you see Coke and other things there. There are all kinds of them out there. She drank two of those Monster Energy Drinks and died of cardiac arrest. I met with her mom yesterday. She stopped breathing while watching TV. She was dead on the floor. They took her to the hospital and barely got her back to life for a little while, and then she died a few days later.

Is it too much to ask of a dietary supplement company that is making that to tell us what ingredients are in that drink? Is that the heavy hand of government? I don't think so.

Here is what we have found. Sometimes ingredients that may appear to be benign and OK today turn out to be dangerous when you look at them more closely, and maybe more dangerous for people who are younger, pregnant, or in a compromised immune situation.

This amendment basically says that American consumers have the right to know the dietary supplements sitting on the shelf have at least been registered with the FDA. I heard Senators HATCH and HARKIN say this goes too far, it is too much to ask. I think they are wrong.

Manufacturers, some say, voluntarily provide product labels to the National Institutes of Health. That is true, and it is a voluntary system. Good actors share their labels with the FDA, but the bad actors don't do that. The NIH is in the process of developing a label database that currently has 7,500 dietary supplement labels. Do you know how many products are on the market? They have 7,500 labels, with 75,000 products—75,000. So 10 percent are volunteering this information. So to say the NIH already has the information is 90 percent wrong.

Requiring registration, they say, of these labels is just too much work for the FDA. No, as a matter of fact, the FDA responded to the GAO recommendation and said: We agree the agency's ability to ensure the safety of dietary supplements used by consumers would be improved if FDA had more information on the identity of firms marketing dietary supplements as well as the identity and compositions of the products they market. The FDA responded by saying: We want this information to keep Americans safe.

So to argue this is a burden we shouldn't put on the FDA, well, they asked for it. The other thing is about how many supplements are being sold in the United States. I said 75,000. That was the estimate in 2008. The number, I am afraid, is much larger. In terms of how many come on the market each year, it is just a wild guess because it is the Wild West. It is an open market. Any country that wants to export their dietary supplement to the United States—whether it is from China or India or Africa or Europe or Mexico—be my guest. They don't even have to show up and register with the FDA.

This is a simple amendment. It just says any company wishing to do business in the United States, to sell their dietary supplement, must tell us who they are and what they are selling and what their label looks like. That is not too much to ask to protect families from some harmful consequences.

I reserve the remainder of my time.

Mr. President, I ask unanimous consent that the time Senator HATCH used

be counted retroactively against the time in opposition to my amendment, No. 2127.

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

The Senator from Wyoming.

Mr. ENZI. On this amendment, I appreciate the concern, the interest, and the effort the Senator from Illinois has gone to on this bill. But in looking at it, there is still a couple of steps missing if this were to become law. Yes, it would provide a lot of information to the FDA. It would, in fact, flood them with information, and I think we would flood them with more information than they could possibly process.

But that part doesn't even bother me. What bothers me is how we get that information to the consumer. It is the consumer that needs to know what they are drinking, eating, and everything else. That is why we provide labeling on a lot of things. But even the things we already provide labeling on, the consumer doesn't necessarily pay attention to it. Probably the people who need to pay the most attention to it don't pay any attention to it. So just making this information available to the FDA doesn't get it to the point where the consumer can know. Of course, anytime we start talking in this area, people get worried about the amount of regulation we put on things they consider to be very important to them and can do no harm.

The right way to address this important issue is for the HELP Committee to have hearings and work together, as we have done on this bill, to find common ground on the policy. When we find common ground, as we have on this FDA bill, then we can get something done. But I think this is a little premature. So I hope people will not support this amendment at this time.

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

Mr. HARKIN. Mr. President, how much time remains on this amendment?

The PRESIDING OFFICER. Seven minutes in favor of the amendment.

Mr. HARKIN. Mr. President, I just want to say, first of all, that I have the greatest respect, as he knows, for the Senator from Illinois. He is one of the true consumer champions in the entire Congress and has been for all of his time here. So it is kind of hard to argue against the Senator when he is such a champion of consumers. But on this issue I think we part a little company.

I want to make it very clear that under DSHEA, supplement labels must already disclose their ingredients—must disclose their ingredients. Even when a product is reformulated, if the supplement contains new ingredients, then the label must reflect that change. These were all added to the bill. We added that for consumer protection.

Now, again, it is not as though FDA doesn't know what is out there. Under current law, supplement manufacturers have to biannually register their products. There is a biannual registration requirement right now. So the concern is that FDA just doesn't have the resources to do anything. I have tried—and the Senator knows because he is on the Appropriations Committee—to get more funds for the FDA to do this, but we haven't been able to get the funds necessary for the FDA to even do what jobs they are supposed to do now.

I repeat for emphasis sake that every FDA Commissioner—those appointed both by Democratic or Republican Presidents—have said the DSHEA gives them adequate authority to keep dangerous products off the shelves. So the authority is already there. What the FDA needs is the resources. That is money. That means appropriations. Quite frankly, I don't see that happening this year—that we are going to give them any more. We are just going to give them more of a burden, and I think it will give a false sense of security to people because FDA simply won't be able to do that.

Lastly, as the Senator did say, we do have a voluntary program for ingredients and things with the dietary supplements with the National Institutes of Health that is already in place. That is coupled with the biannual reporting requirements plus the fact every dietary supplement has to have the ingredients listed on the label. So there is plenty of consumer protections out there. It is just that we can't protect a consumer who doesn't want to follow directions, who doesn't want to follow the guidelines listed on the labels themselves. I don't know how to protect people from that. Sometimes we just have to continually tell people to follow the directions. If they follow the directions, they will be fine.

That is why I think this amendment is ill-timed. I said to the Senator, and I mean this, that the Senator from Utah and our committee would be more than happy to have hearings again to flesh it out a little more and to see just what might be possible. But I come down to this as the bottom line: The FDA needs more money and they need more personnel to do this job.

I yield the floor.

Mr. DURBIN. Mr. President, how much time remains on my amendment?

The PRESIDING OFFICER. Seven minutes.

Mr. DURBIN. On my side?

The PRESIDING OFFICER. On the Senator's side.

Mr. DURBIN. Any time remaining on the opposite side?

The PRESIDING OFFICER. One minute.

Mr. DURBIN. Mr. President, I respect the Senator from Iowa and the Senator from Wyoming as well. They are two excellent colleagues, good people, and this is a tough bill. The underlying bill is a masterpiece of bipartisan accomplishment they can both be proud of.

What I am saying about dietary supplements is no reflection on Senators HARKIN or ENZI. This is an industry I have been watching for a long time for a variety of reasons.

I would say the argument Senator ENZI made—that merely disclosing the label ingredients and name of the product to the FDA doesn't get to the consumer—argues for a bigger amendment than I am offering. It argues for a Web site and access and so forth. I understood that going in, and I agree with Senator HARKIN that is an overreach in this time of budgetary problems. I wish we could do it. I think we should. I think we have an obligation to. But I didn't put it in here because I knew the first thing that would be said is we can't afford it.

So we went to the FDA and said: Do you want this information?

They said: Not only do we want it, we have already publicly stated we want it in reply to the GAO report.

We said: Can you handle it if we send you the basic information of the products presently being sold?

They said: Yes.

I could go further and say more can be done, but that calls for a bigger role of government than even this amendment suggests. But when the Institute of Medicine tells us that each year there are 1,000 new products—dietary supplements—being placed on shelves all across America in stores and drugstores, where families and children are walking in and buying them, how does anyone argue we shouldn't know they are here; that we don't want that Chinese product that just made it to the shelf in Springfield, IL, to register with the FDA before they do business here? How do you make that argument?

Shouldn't we assume, as a consumer, a family member, that when we walk in the store that somebody somewhere knows this company exists, that this product exists? Right now, they do not. The only disclosure to the government is voluntary. As I said, about 1 out of 10 companies volunteers the information. That, to me, is not the way to protect consumers.

Why do we need this information? Simply put, when an ingredient turns out to be dangerous, we want to know if that ingredient is in more than one product and then go after it to protect American consumers. If we don't know the product is in the United States, and we don't know what the ingredients are, how are we going to find that out? Wouldn't we want that basic information?

God forbid something happens with one of these products and someone loses their life, like this poor young girl in Hagerstown, MD, who drank that Monster Energy Drink. She had two of them, and it killed her, put her in cardiac arrest. God forbid that happens again and we say: You know, we didn't even know that product was in America because they don't have to tell anybody anything.

The argument made by Senator HARKIN is they have to put a label on the product. That is a good thing. We also

found out that sometimes the ingredients listed aren't the actual ingredients. I will not get into that because that is another whole issue the FDA is working on. But that isn't enough. My colleagues should see some of the claims being made on the labels of these dietary supplements. They are preposterous. Not for all of them, some are basic and good, but some go way overboard.

Don't we owe it to consumers across America to give them the basic information, to at least let them know we know the name of the company and the ingredients in the product sold? Some people say they ought to be able to sell whatever they want in America and never tell a soul. I don't believe that. I think we have a responsibility in Congress to protect these families.

I reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Just one minor correction I would make, and that is under the DSHEA law, the FDA must approve any health claims made by any dietary supplement or vitamin. The only health claims they can make are structure function claims, but they have to be approved by the FDA. I just wanted to clear up that point.

I would also say further that I honestly don't know of any vitamin or supplement that is out there in the market that is dangerous if taken as directed—if taken as directed. As I said, anybody can abuse things. But if taken as directed, I, quite frankly, don't know of any supplement out there that is dangerous. Quite frankly, if taken as directed, they help maintain people's health and keep them healthy rather than being injurious to their health.

I yield the floor.

Mr. DURBIN. Mr. President, how much time remains?

The PRESIDING OFFICER. Three minutes.

Mr. DURBIN. I will just close.

I thank the Senator from Iowa. He will acknowledge, I hope, that no one tests dietary supplements. No one tests them. Companies that make these products may test them if they wish, but there is no requirement under the law that they test them. There is certainly no agency of government that tests the dietary supplements. So to say they are perfectly safe as they instruct people to take them on the label, how would we know that? How could we possibly know that? There is no testing involved.

When it comes to prescription drugs and over-the-counter drugs, there is testing involved. At least we can point to the test to say whether it is safe and effective. Dietary supplements is a whole different world. I will just say that we are conscientious enough on behalf of consumers to limit the amount of caffeine that can be put in a cola, but then a company such as this Monster drink company decides to call theirs a dietary supplement rather than a beverage or a food, and it is no holds barred. They can put in as much as they want. That is why that poor girl died. Two Monster Energy Drinks—480 milligrams, I believe, of caffeine—and she died from cardiac arrest. Is it too much to ask that we know the ingredients and know the company?

The next time there is another tragedy, I would like to be sure we can say we at least took this modest, tiny, small step forward to say to the industry: If you are a good actor, don't be threatened. But when it comes to bad actors and things coming in from overseas, we are going to make you show up and identify who you are and what you are selling, period. That is it.

So at this point, I yield the floor and yield back the remainder of my time.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Again, Mr. President, I have to ask, how much time remains on the bill for both sides?

The PRESIDING OFFICER. The majority has 19 minutes and the minority has 29 minutes.

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

AMENDMENT NO. 2109

Mr. SANDERS. Mr. President, I thank the chairman for his hard work on this legislation and for the opportunity to talk about what I consider to be a very important amendment.

I ask unanimous consent to call up my amendment No. 2109.

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

The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Vermont [Mr. SANDERS] proposes an amendment numbered 2109.

Mr. SANDERS. I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To revoke the exclusivity of certain entities that are responsible for violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other certain laws)

At the end of title XI, add the following:

SEC. 11___. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by inserting after section 569C, as added by this Act, the following:

"SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

"(a) TERMINATION OF EXCLUSIVITY.—Notwithstanding any other provision of this Act, any period of exclusivity described in subsection (b) granted to a person or assigned to a person on or after the date of enactment of this section with respect to a drug shall be terminated if the person to which such exclusivity was granted or any person to which such exclusivity is assigned—

"(1) commits a violation described in subsection (c)(1) with respect to such drug; or

"(2) fails to report such a violation as required by subsection (e).

"(b) EXCLUSIVITIES AFFECTED.—The periods of exclusivity described in this subsection are those periods of exclusivity granted under any of the following sections:

"(1) Clause (ii), (iii), or (iv) of section 505(c)(3)(E).

"(2) Clause (iv) of section 505(j)(5)(B).

"(3) Clause (ii), (iii), or (iv) of section 505(j)(5)(F).

"(4) Section 505A.

"(5) Section 505E.

"(6) Section 527.

"(7) Section 351(k)(7) of the Public Health Service Act.

"(8) Any other provision of this Act that provides for market exclusivity (or extension of market exclusivity) with respect to a drug.

"(c) VIOLATIONS.—

"(1) IN GENERAL.—A violation described in this subsection is a violation of a law described in paragraph (2) that results in—

"(A) a criminal conviction of a person described in subsection (a);

"(B) a civil judgment against a person described in subsection (a); or

"(C) a settlement agreement in which a person described in subsection (a) admits to fault.

"(2) LAWS DESCRIBED.—The laws described in this paragraph are the following:

"(A) The provisions of this Act that prohibit—

"(i) the adulteration or misbranding of a drug;

"(ii) the making of false statements to the Secretary or committing fraud; or

"(iii) the illegal marketing of a drug.

"(B) The provisions of subchapter III of chapter 37 of title 31, United States Code (commonly known as the 'False Claims Act').

"(C) Section 287 of title 18, United States Code.

"(D) The Medicare and Medicaid Patient Protection and Program Act of 1987 (commonly known as the 'Antikickback Statute').

"(E) Section 1927 of the Social Security Act.

"(F) A State law against fraud comparable to a law described in subparagraphs (A) through (E).

"(d) DATE OF EXCLUSIVITY TERMINATION.—The date on which the exclusivity shall be terminated as described in subsection (a) is the date on which, as applicable—

"(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

"(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

"(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.

"(e) REPORTING OF INFORMATION.—A person described in subsection (a) that commits a violation described in subsection (c)(1) shall report such violation to the Secretary no later than 30 days after the date that—

"(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

"(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and non-appealable.''.

Mr. SANDERS. Mr. President, this amendment, to my mind, is an extremely important amendment and it has the support of some of the major consumer organizations in our country, including Public Citizen, U.S. PIRG, the Consumer Federation of America, Consumers Union, the National Committee to Preserve Social Security and Medicare, and the National Women's Health Network. These are some of the large consumer organizations in America representing tens of millions of our people.

When we talk about prescription drugs, it is important to understand that in our country we pay by far the highest prices in the world for prescription drugs. That is simply the reality. That causes enormous problems because millions of our people go to the doctor, the doctor writes a prescription, and then the person can't afford to fill that prescription. That is pretty crazy, because doctors are doing the diagnosis, telling the patients what they need; patients can't afford to pay for the drugs because they are the highest prices in the world in this country. This is an issue we have to deal with.

There are a number of reasons why prices in this country are higher than in Canada, Europe, and Scandinavia. Certainly one of them is that we are the only major country on Earth that doesn't have a national health care program so that the government can negotiate prices with the drug companies. So what happens in this country is the drug companies simply charge us what the market will bear—any price they can come up with by which they can make money. The end result is that in 2009, prices in this country were 85 percent higher than Canada, 150 percent higher than France, Italy, Sweden, Switzerland, and so forth and so on.

But the reason drug prices are high in this country is not just that we don't have a national health care program, it is because of the enormous amount of fraud that takes place within the pharmaceutical industry. In fact, every single year the major drug companies are ripping off the American people to the tune of billions of dollars a year because of fraudulent practices.

While I do not have enough time here today to recite every example of fraud that has been caught and prosecuted in the last 10 years. But here is the bottom line—and I am going to list some of the cases of fraud. Virtually every major pharmaceutical company in this country has either been convicted of fraud—i.e., ripping off the Federal Government, State government, or individuals—or else has reached a settlement. We have got to get a handle on this crisis. I am going to bore some people because it is a long list. Sadly, it is a long list. But it is a list that has to get out, and it is an issue we have got to deal with.

Abbott Labs is one of the top 10 pharmaceutical companies in the world. It had $38.8 billion in revenues and $4.7 billion in profits in 2011. Last month, Abbott reached an agreement with the U.S. Department of Justice to pay $1.6 billion for illegally marketing the antiseizure drug Depakote. According to the New York Times:

As part of the agreement, Abbott said that it would pay $800 million to resolve civil cases brought by federal and state authorities, $700 million in criminal penalties and $100 million to states in connection with consumer protection matters.

That was just last month, they are going to pay $1.6 billion.

In 2010, 2 years ago, Abbott and two smaller companies collectively agreed to pay $429 million to settle charges that they deliberately misreported drug pricing in order to hike reimbursements from Medicare and Medicaid. That is Abbott in recent years.

Pfizer is the largest pharmaceutical company in the world, $67.9 billion in revenues and $10 billion in profits in 2011. Pfizer in 2012, this year, allegedly avoided paying hundreds of millions in rebates due to State Medicaid Programs for Prontonix. Pfizer holds four different exclusives for Prontonix. Talks are under way with the U.S. Department of Justice to settle the charges for up to $2 billion for ripping off Medicaid.

In 2009, Pfizer agreed to plead guilty to a felony of ''misbranding Bextra with the intent to defraud or mislead'' and to pay $1 billion to resolve allegations under the civil False Claims Act.

In 2004, a division of Pfizer pled guilty to two felonies and agreed to pay $430 million to settle charges that it fraudulently promoted the drug Neurontin for a string of unapproved uses.

Johnson & Johnson is the second largest pharmaceutical company in the world, which had $65 billion in revenues and almost $10 billion in profits in 2011.

In 2012, this year, Johnson & Johnson illegally marketed Risperdal, an antipsychotic medication, to nursing home patients, and paid over $2 billion in fines, which constituted a mere 6.3 percent of sales revenue from the drugs.

In 2010, two subsidiaries of Johnson & Johnson illegally marketed the epilepsy drug Topamax for off-label psychiatric uses.

Now we go to Merck. Merck is the third largest pharmaceutical company in the world. In 2011, last year, Merck pleaded guilty to a criminal misdemeanor charge for violation of the Food, Drug, and Cosmetic Act, and paid a $950 million settlement for illegally promoting Vioxx for rheumatoid arthritis before that use was approved.

In 2011, Merck will pay the State of Massachusetts $24 million to settle claims that former subsidiary Warrick Pharmaceuticals reported inflated and false prices for asthma medications, causing the State's Medicaid Program to overpay.

In 2008, Merck reached a $670 million settlement for fraud on patients and Medicare/Medicaid, involving a conspiracy with hospitals to give the elderly cheaper drugs but charging them for the more expensive product.

Now we go to GlaxoSmithKline. GlaxoSmithKline is, again, one of the largest pharmaceutical companies in the world. It made profits of almost $44 billion in 2011.

GlaxoSmithKline in 2011 announced that it had reached an ''agreement in principle'' with the U.S. government to pay $3 billion to conclude the company's most significant ongoing Federal Government investigations, specifically illegal sales and marketing practices in Colorado and Massachusetts; overcharging the Medicaid rebate program; and illegal development and marketing of Avandia, a diabetes drug.

In 2006, GlaxoSmithKline agreed to pay $14 million to settle allegations that it engaged in patient fraud.

In 2005, GlaxoSmithKline paid $150 million to settle claims it overcharged the government for two antinausea drugs.

In 2003, GlaxoSmithKline signed a corporate integrity agreement and paid $88 million in a civil fine for overcharging Medicaid.

And on and on and on it goes.

When we talk about the high cost of health care, when we talk about the fact that the United States has the highest prices in the world for prescription drugs, it is important for us to address the crisis in terms of fraud within the pharmaceutical industry and the fact that virtually every major drug company has been found guilty of fraud or reached a settlement in terms of fraud charges.

In 2010, the pharmaceutical industry achieved a dubious distinction. It surpassed the notoriously corrupt defense contracting industry in defrauding the government. The pharmaceutical industry accounted for nearly half—$1.8 billion of a total of $4.1 billion—of the penalties collected in 2011 by the Department of Justice/Health and Human Services Health Care Fraud and Abuse Control Program.

In 2012—and this is quite amazing—the pharmaceutical industry is expected to pay out up to four times the amount of last year's penalty, between $8 billion to $9 billion in penalties due to pending fraud settlements with the Department of Justice. And those are the penalties for fraud that has been discovered. Who knows what type of fraud is taking place on behalf of the drug companies that has not been discovered.

Let me recapitulate. Virtually every major drug company has either been found guilty of, or settled charges of, significant fraud over the last 10 years.

The question arises—and this is an important question—is fraud within

the pharmaceutical industry the exception or, is it, simply put, their business model? Is fraud the business model of the pharmaceutical industry, which thinks that in most cases they can get away with the fraud, make huge profits and, in some cases when they get caught, they will in fact pay a penalty but the penalty will in no way match the kinds of huge profits they are making from their fraudulent activity?

The question the Senate has got to address is, Do we look away from this issue, do we ignore this issue, or do we finally address the very important issue of fraud within the pharmaceutical industry, fraud being practiced by virtually every drug company in our country?

It is obvious to anyone paying attention to the prevalence of pharmaceutical industry fraud that our punishments are not enough to address this problem, because apparently the drug companies are not too intimidated by the laws on the books. They think it makes business sense for them to continue going forward on their fraudulent activities.

The amendment I am offering would send a strong and clear message to the drug industry: Illegal behavior will not be rewarded with continued government-granted monopolies. There are some things—patients' safety, the devotion of scarce public resources to provide health care to needy patients—that are more important than drug company profits.

This amendment is designed to effectively deter pharmaceutical fraud by making government-granted monopolies contingent on good corporate behavior. I think that is the least we can do.

This amendment would penalize any instance of pharmaceutical fraud resulting in a civil or criminal judgment or a settlement with an acknowledgement of fault by revoking any applicable data or marketing exclusivity for the particular drug or product involved in the fraud. giving pharmaceutical companies another factor to consider, when weighing whether to violate the law in their sales or billing practices.

If a company violated Federal or State law by inflating the price of a drug in Medicare or Medicaid billing or illegally marketing a medication, under my amendment that company would lose the remainder of any exclusivity period for that medication. Companies would be required to self-report qualifying violations to the FDA within 30 days.

Let me conclude by saying this: Our people are paying the highest prices——

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

Mr. SANDERS. I ask unanimous consent for 1 additional minute.

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

Mr. SANDERS. Our people are paying the highest prices in the world for prescription drugs. One of the reasons is widespread fraudulent activity on the part of virtually every major drug company in our country. It is no longer acceptable to turn a blind eye to that crisis. The time to act is now. This amendment would go a long way forward to ending that outrageous fraud. I ask the support of my colleagues for this amendment.

I yield the floor.

The PRESIDING OFFICER (Mr. MERKLEY). The Senator from Wyoming.

Mr. ENZI. Mr. President, I appreciate the concern by the Senator from Vermont, but I have to oppose the amendment, No. 2109, because of some of the unintended consequences it will have.

This amendment would require drug companies to forfeit exclusivity for certain violations of the Federal Food, Drug, and Cosmetic Act and other laws.

''Exclusivity'' means exclusive market rights granted by the Food and Drug Administration upon approval of a drug. It may or may not run concurrently with a patent. Exclusivity is a very important type of intellectual property protection. Without it, innovators cannot predictably obtain returns on their drug development investments.

The stated purpose of the amendment is to combat healthcare related fraud. The premise is, if companies know their profits are at risk, they will be strongly discouraged from engaging in fraudulent activity. But this amendment is counterproductive: It will make it more costly for law enforcement to fight fraud and could hurt patients.

Congress is also thinking of ways to improve healthcare antifraud programs. For example, in a recent open letter to the health care community, six members of the Senate Finance Committee, led by Chairman BAUCUS and Ranking Member HATCH, announced a bipartisan effort to solicit ideas from the healthcare community on ways to reduce healthcare waste, fraud and abuse.

Estimates of the amount of fraud and misspending in Medicare and Medicaid vary widely, from $20 billion to as much as $100 billion. To address this problem, the six Senators solicited ideas on program integrity and fraud and abuse enforcement reforms.

This sort of constructive search for real solutions is long overdue. Healthcare fraud is a serious problem, and I strongly agree that the Congress should develop substantive solutions to it.

The problem here is, the pending amendment does not really tackle the problem of fraud.

Instead, the amendment uses a blunt instrument—revocation of exclusivity—to punish an incredibly broad range of legal violations.

This amendment would discourage settlements in fraud cases. A settlement agreement concerning a listed violation would trigger forfeiture.

If a company knows that settlement would trigger a result that could cost it hundreds of millions of dollars, it will be less likely to settle. This will make it harder for the government to settle cases, and increase the backlog of cases waiting for trial. It also creates the risk that a fraudster could prevail or appeal, and prevent the prosecutor from pursuing other cases.

Settlement is an important tool in a prosecutor's toolkit. It enables them to pursue a higher volume of cases, while still obtaining sizable judgments to deter future fraud.

In fiscal year 2011, the Departments of Justice and Health and Human Services together recovered nearly $4.1 billion in taxpayer dollars through healthcare anti-fraud prevention and enforcement efforts. The ability to settle claims contributed substantially to this achievement by allowing the government to pursue a higher volume of cases.

Within the Federal Food, Drug, and Cosmetic Act itself, there are already robust standards and enforcement tools concerning industry marketing and communications, and interactions with healthcare providers and professionals.

The False Claims Act and strong anti-kickback laws are also on the books already.

This amendment will also discourage manufacturers from developing new cures. It creates tremendous uncertainty about whether investors can obtain returns on their drug development investments. If a trivial violation of FDA's detailed, elaborate regulations could put the entire investment in a drug at risk, it will discourage investment in new treatments.

This would severely threaten biomedical investment and jobs. More importantly, it would lead to fewer lifesaving therapies for patients.

This amendment could produce absurd results. For example, the amendment would revoke exclusivity for a civil judgment concerning adulteration of a drug. A drug is considered adulterated if a manufacturer violates FDA's current Good Manufacturing Practices, known as cGMPs. There is no intent requirement, and no minimum number of inspection requirements to trigger liability. Some examples of cGMP violations include: Washing and toilet facilities are not easily accessible to working areas; adequate lighting is not provided in all areas; laboratory records do not include complete records of the periodic calibration of laboratory instruments.

It obviously does not make sense to strip drug companies of exclusivity for violations like this, which do not reflect fraudulent intent. It is disproportionate and counterproductive.

Again, I strongly agree that healthcare fraud is a significant problem. The best way to solve it is through robust enforcement of the many current laws on point, and continuing to work with the health care community to find effective solutions.

That would be going through committee hearings as well. The pending amendment would not reduce fraud. On the contrary, it would frustrate the government's current anti-fraud efforts, and ultimately harm patients and taxpayers alike.

I encourage a ''no'' vote on this amendment.

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

Mr. COBURN. I ask unanimous consent that the pending amendment be set aside and that Coburn amendment No. 2131 be called up.

Mr. HARKIN. Mr. President, I object. How much time is left on the Sanders amendment?

The PRESIDING OFFICER. The Senator from Vermont has no time left. The Senator from Wyoming controls 10 minutes.

Mr. HARKIN. Will the Senator from Oklahoma withhold? We have some people who want to speak. Once the time has run, then we automatically move on to another amendment and could bring up the Senator's amendment at that point.

Mr. COBURN. It is my understanding that the time is under our control. At present, there is 10 minutes left.

Mr. HARKIN. There is 10 minutes in opposition to the amendment.

Mr. COBURN. I will be happy to yield to the ranking member. If he has people who wish to speak in opposition, that is fine.

Mr. HARKIN. Senator MIKULSKI was here earlier. She wants to speak on this amendment. If we just wait 5 minutes?

The PRESIDING OFFICER. The Senator from Maryland.

Ms. MIKULSKI. Mr. President, first I thank my colleague from Oklahoma. I just want to take a few minutes, if I could, to talk about an important issue.

Mr. HARKIN. I am sorry, I was wrong. I thought the Senator wanted to speak on the Sanders amendment. She wanted to speak on the underlying bill itself?

Ms. MIKULSKI. Yes.

Mr. HARKIN. The Senator just seeks 5 minutes?

Ms. MIKULSKI. Or less.

Mr. HARKIN. Since it is my time, I yield the Senator from Maryland 5 minutes on the underlying bill.

Ms. MIKULSKI. I will be very brief.

The PRESIDING OFFICER. The Senator from Maryland.

Ms. MIKULSKI. Mr. President, I say to our colleague from Oklahoma, himself a physician, that he will be very keenly interested in this issue of prescription drug shortages. This is a problem that has been brought to my attention by Marylanders, leaders of great institutions such as the University of Maryland and Hopkins, as well as family members who care for someone and find that, although there has been the right diagnosis and there is even the right drug to care for that problem—like the dread ''cancer'' word—the drug is not available. So you can imagine the last thing you want to hear is that your child has cancer, and then the worst thing you want to hear is that there is a shortage of that drug to take care of that child. That is not because it has not been developed, not because there has not been a scientific breakthrough, but because there has been a manufacturing problem or because the company stopped making the drug when it was no longer profitable. That is inexcusable. The bill before us does something about it.

In 2011 we had more than 250 drug shortages. That is not incidents, that is 250 drugs that were in shortage. Half of the drugs that experience a shortage go into shortage multiple times.

This drug shortage threatens public health by preventing patients and physicians from accessing needed medications. It forces doctors to often delay medical procedures, use alternative products that may carry unwanted side effects or to rely on foreign versions of drugs that might not have been reviewed by FDA or it sends their very able pharmacists in their institutions to spend endless hours on the phone to be able to come up with the needed drug.

As I said, this was brought to my attention by letters from some famous constituents—meaning well-known in our community—with great health insurance who had a child who had leukemia and then found the drug was in short supply. We heard from doctors who were forced to delay or turn to alternative treatments, hospitals scrambling to manage these shortages, and pharmacists trying to track down needed treatments. Even then, we heard about gouging and we heard about a gray market. The gouging was pumping up the price when there was a shortage, and then there is a gray market where you can go to buy these drugs, but they might not be the drug you wanted or they might have been on somebody's shelf a long time and were flawed and even dangerous or they had not been refrigerated.

I could go through one horror story after another. I wanted to bring this to the attention of the full Senate because as we work on this excellent, bipartisan bill on user fees, what we also have is a very commonsense way of dealing with the drug shortage issue.

It has the support of the private sector and certainly those who care for patients, as well as patients themselves. I hope we pass this underlying bill, and I hope we do not tie up this legislation with amendments that could either derail or deter it.

I yield the floor.

Mr. HARKIN. Mr. President, how much time is remaining on the Sanders amendment?

The PRESIDING OFFICER. There is 7 minutes in opposition that remains on the Sanders amendment.

Mr. HARKIN. I will yield myself a couple of minutes.

I join with my colleague Senator ENZI in opposition to the Sanders amendment. We are all disturbed by a lot of what we are reading and these big settlements. I know the recent one a couple of weeks ago on Abbott Labs where part of the prosecution case was actually that this was part of their business model. Then they had to settle it. So this is all very disturbing.

However, that cries out more for, perhaps, looking at the criminal charges and perhaps strengthening some of those things but not taking away exclusivity. If you do that, a lot of times you could take away exclusivity from someone who just committed a misdemeanor. A lot of these settlements were misdemeanor charges where no intent was shown.

A lot of times, if you did this, you might penalize someone who maybe had done something wrong in the past, and now maybe they have new leadership, a new company, and reformed themselves, and now they have to lose their exclusivity? You would not want to do that.

Third, if you do this—I think Senator ENZI pointed this out correctly—if there is no reason to settle, then people are going to go to the wall in terms of defending themselves, and DOJ doesn't have all that kind of personnel and the time to do that. I think we would then have an even worse situation of people committing fraud because then they would know they would not have any reason to settle it whatsoever. Settlement is a good tool to be used by prosecutors to get cases to justice, to make sure consumers are made whole, and to let people know they are being watched. That is what they do.

I think the Sanders amendment, while maybe well-intentioned—I know it is well-intentioned. I know the Senator has all good intentions of what he wants to do. But I think it goes too far and is not the right solution to that problem. So I would oppose Senator SANDERS amendment also.

I yield the floor.

The PRESIDING OFFICER. The Senator from Oklahoma.

AMENDMENT NO. 2131

Mr. COBURN. I ask unanimous consent that the pending amendment be set aside, and I call up amendment No. 2131, which is at the desk, and ask that it be reported.

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

The assistant legislative clerk read as follows:

The Senator from Oklahoma [Mr. COBURN], for himself, and Mr. BURR, proposes an amendment numbered 2131.

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

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

The amendment is as follows:

(Purpose: To require an independent assessment of the Food and Drug Administration's review of drug applications)

At the end of title VII, add the following:

SEC. 7___. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting

firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

Mr. COBURN. Mr. President, let me say how proud I am of all of the members of the HELP Committee on this difficult and complicated issue they are bringing before us. Having been in business and under the control of the FDA as a medical device manufacturer, this is a very complicated area of law that, if done right, will have tremendous positive effects, and I think the Senators have put out a very good bill. I congratulate my colleagues and all the members on doing that.

I have two amendments, and I am going to speak for a very short period of time on both of them. I will work with the ranking member and the chairman to see if we can't get to where we don't have to vote on them.

I would like to give just a little history on PDUFA and MDUFA. The reason they were set up in the first place was to help fund the FDA, and the reason the manufacturers agreed to do that was to get more timeliness in terms of response to their applications. That was the whole basis for it. And what we have before us today is some improvement in terms of the FDA's response but really not everything we should have gotten.

I, along with Senator BURR, asked for a GAO study to the FDA in terms of meeting stated performance goals, and we found out a whole lot about that, and that is my next amendment, but I say that to preface why I have this amendment.

In this bill is a wonderful requirement that causes the FDA to contract with an independent management company to assess the management of the missions and resources of the device regulation component of the FDA. What is missing is that same independent review in terms of drugs. It is one of those situations where we invest in something that would pay us additional big dividends. I know it will pay big dividends in the device area. It will also pay big dividends in the drug area. I don't know what the workings of the committee are and why they decided not to put this in as far as the drug review process, but having a second look at a very complicated regulatory and approval structure could be very beneficial in terms of improving both the quality of the outcome as well as the timeliness.

So this amendment simply says that what we are going to do for the device, which is in the bill already, we are also going to do for the drug side of the FDA. It is about gathering knowledge for both the FDA and for us as we help this agency perform very needed things.

As a physician, I read a lot about new science on new drugs. The things that are coming in this country are going to be phenomenal in terms of new treatments and new drugs and new capabilities. In terms of our competitiveness worldwide but also in terms of how we address these diseases, we need to have the most efficient regulatory agency we can.

All I am asking is that we treat all of the FDA the same in terms of taking a look at how well they are doing, what could they do better, and how they could do it better. That report comes to us and the FDA, and so we can see the weaknesses. We have not been through every area of the FDA as Members of the Senate, and to have an independent assessment of the drug side as well as the device side will pay huge benefits to the FDA, but mostly it will pay huge benefits to people of this country in terms of the timeliness of drug presentation.

I won't speak any more to that. It is a commonsense, good-government amendment. Part of it is in the bill, and part of it is not in the bill. It is something that will pay us big dividends not only in terms of health care and improving the operation of the FDA but also in terms of improving our competitiveness worldwide.

AMENDMENT NO. 2132

Mr. COBURN. Mr. President, I ask that that amendment be set aside, and I call up amendment No. 2132, which is at the desk, and ask that it be reported.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Oklahoma [Mr. COBURN], for himself, and Mr. BURR, proposes an amendment numbered 2132.

Mr. COBURN. Mr. President, I ask unanimous consent that the reading of the amendment be waived.

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

The amendment is as follows:

(Purpose: To provide that a portion of the performance awards of each employee of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research be connected to an evaluation of the employee's contribution to goals under the user fee agreements)

At the end of title XI, add the following:

SEC. 11___. PERFORMANCE AWARDS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a system by which a portion of the performance awards of each employee described in subsection (b) shall be connected to the evaluation of the employee's contribution, in the discretion of the Secretary, to the goals under the user fee agreements described in section 101(b), 201(b), 301(b), or 401(b), as appropriate.

(b) EMPLOYEES DESCRIBED.—

(1) IN GENERAL.—Subsection (a) shall apply only to employees who—

(A) are employed by the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Biologics Evaluation and Research; and

(B) are involved in the review of drugs, devices, or biological products.

(2) COMMISSIONED CORPS.—For purposes of this section, the term ''employee'' includes members of the Public Health Service Commissioned Corps.

(c) EFFECT ON AWARD.—The degree to which the performance award of an employee is affected by the evaluation of the employee's contribution to the goals under the user fee agreements, as described in subsection (a), shall be proportional to the extent to which the employee is involved in the review of drugs, devices, or biological products.

(d) REPORT.—The Secretary shall issue an annual report detailing how many employees were involved in meeting the goals under the user fee agreements described in section 101(b), 201(b), 301(b), and 401(b), and the manner of the involvement of such employees.

Mr. COBURN. Mr. President, this is an amendment that comes out of a study of GAO's findings, and GAO did a wonderful job looking at the FDA. What we found out—part of it will be covered if, in fact, we do this other study on the management, but what GAO is telling us is that there is an irregular pattern of performance review at the FDA. Part of the evaluation of about 40 percent of the people who are involved in the drug and device approval process, in terms of their performance review, has to do with the timeliness of their work product. And it is only a small component, but it is still a component of it.

What this amendment does is it says: FDA, make this part of your component on the people who are actually reviewed in the review process—not to try to push them to do it better but to have a management tool with which to evaluate individual employees doing this.

The fact that they are already doing this on some—and what GAO really said is that it is just a lack of management effectiveness that they have not installed it everywhere else. All this amendment says is that this should be one component as they evaluate their employees on their performance reviews and ask: How did you do on timeliness? Was your work product timely?

The idea behind this is not to push drugs out that should not be approved. It is not to push out devices that should not be approved. But remember that the purpose for PDUFA and MDUFA in the first place was to fund FDA with additional money so they would be more timely.

The opposition I hear to this amendment that we are afraid that if this is a component of review, they might review a product and let it go when they shouldn't does not make sense since already 40 percent of the employees doing this are being evaluated on this performance standard anyway. So I would raise the question: If we are in opposition to this amendment, why in the world haven't we eliminated this as a part of all the review process already if, in fact, there is a concern? There is not a concern with it. It is a good management tool. It is used in all sorts of government agencies. And I commend to the attention of my colleagues the GAO report that backs up exactly what I am saying and their recommendation. These are not TOM COBURN's recommendations, these are the GAO recommendations for FDA. They address the concerns of inappropriate pressure for early approval or inappropriate approval for drugs or devices.

Again, it is good government and common sense. It is how one would manage a private organization. You would put every component that the employee is involved with as a component as part of the review process.

My hope is that we do not have to vote on this. When my colleagues actually thoroughly study the GAO report, they will embrace what they are saying. It is common sense with sound judgment that deals with the FDA.

I yield the floor.

Mr. HARKIN. Would the Senator yield for a question?

Mr. COBURN. I would be happy to.

Mr. HARKIN. I think the Senator is making a lot of common sense. The only question I would ask is—and I don't know a lot about this. I haven't read the GAO report. But if, in fact, every employee says, I know they are going to get me on this timeliness. So it is the balance of safety and quickness, safety and expediency. In other words, we try to get a balance. We want devices and drugs approved as quickly as possible, but we don't want to jeopardize safety. Those are the two things we always try to balance here, safety being the foremost. We want things to be safe.

My question is, by enshrining this into law rather than in the administration, would this somehow put more undue pressure on reviewers and others to do something quickly and jeopardize the safety aspect?

Mr. COBURN. My answer to the chairman through the Chair is that the FDA does nothing quickly now, and he knows that because he has been sitting in oversight over them for years. That is No. 1. The answer to No. 2 is, if the Senator reads the GAO report, they have no explanation on why they do it on some employees and not others. The fact is, if this is a bad thing, why are they doing it on 40 percent of the employees now? The No. 1 and No. 2 things the FDA is charged with are safety and efficacy. Safety comes first. They get graded on how well they do on that. So we have this counterbalance.

Well, what we have is a lack of responsiveness even though billions of dollars are going to the FDA from the device companies and the drug companies. Part of the deal was to make them more timely. That means in no way do you ignore safety and in no way do you ignore efficacy. The fact is they do deserve answers, and what is happening a lot of times is they are not.

I fully support the bureaucracy of the FDA in terms of them doing their job. I think they do an awfully good job. They are just awfully slow at it, and when you ask why, there is not a good answer.

The point is, if there are a large number of employees who are already reviewed as a small component, it doesn't have to be a major one, but it ought to be something you think about. Do I push this off my desk because I am bored with it? Does the timeframe mean anything?

We are not going after eliminating safety and efficacy, we are going after smart management, and those two things, safety and efficacy, reign supreme at the FDA. That is why we spend so much in this country. That is why most of the drugs are approved outside of this country way ahead of when they get approved here, because our drugs and devices are safer and we are slow to approve, and rightly so, but we should not be like frozen ice slowly slipping down a hill. All this says is, let's make it one component of many in terms of review. Again, I tell the chairman, this is not my recommendation, this is the GAO's recommendation.

So I would appreciate consideration by the chairman and ranking member for these amendments. I think they are common sense. We could look at them again. If the Senator thinks there is a problem, we can put in a caveat. Let's look at it in a year and say: Have there been problems because we have done this? But it is good management, it does make sense, and they are already doing it on 40 percent of their employees who are involved in the approval of both drugs and devices.

I thank the chair for his question.

I yield the floor, and I will be back.

The PRESIDING OFFICER. The Senator from Iowa.

AMENDMENT NO. 2129

Mr. GRASSLEY. Mr. President, I rise for the purpose of calling up amendment No. 2129.

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

The assistant legislative clerk read as follows:

The Senator from Iowa [Mr. GRASSLEY], proposes an amendment numbered 2129.

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

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

The amendment is as follows:

(Purpose: To provide deadlines for the issuance of certain regulations and to require a GAO report on the implementation of the clinical trial registration and reporting requirements under the Public Health Service Act)

At the end of title XI, add the following:

SEC. 11___. REGULATIONS ON CLINICAL TRIAL REGISTRATION; GAO STUDY OF CLINICAL TRIAL REGISTRATION AND REPORTING REQUIREMENTS.

(a) DEFINITIONS.—In this section—

(1) the term ''applicable clinical trial'' has the meaning given such term under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(2) the term ''Director'' means the Director of the National Institutes of Health;

(3) the term ''responsible party'' has the meaning given such term under such section 402(j); and

(4) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) REQUIRED REGULATIONS.—

(1) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) FINAL RULE.—Not later than 180 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue the final rule on the registration of applicable clinical trials by responsible parties under such section 402(j).

(3) LETTER TO CONGRESS.—If the final rule described in paragraph (2) is not issued by the date required under such paragraph, the Secretary shall submit to Congress a letter that describes the reasons why such final rule has not been issued.

(c) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 2 years after the issuance of the final rule under subsection (b), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the registration and reporting requirements for applicable drug and device clinical trials under section 402(j) the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

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

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of trial (phase II, III, or IV), whether the applicable clinical trial is conducted domestically, in foreign sites, or a combination of sites, and such other categories as the Comptroller General determines useful) with the requirements of—

(i) registering applicable clinical trials under such section 402(j);

(ii) reporting the results of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) information on the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Comptroller General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the implementation of registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Comptroller General shall, after consulting with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative or legislative actions to increase the compliance with the requirements of such section 402(j).

Mr. GRASSLEY. Mr. President, first of all, I congratulate my colleague from Iowa and my colleague from Wyoming for the bipartisanship of this legislation.

The FDA amendments of 2007 mandated basic public results reporting for all clinical trials supporting FDA-approved drugs and devices. Clinical trials results help both patients and doctors understand the benefits and efficacy of a particular medical product.

Moreover, a July 2011 FDA report stated:

Understanding variable characteristics in clinical trial sites is becoming increasingly important because of the international nature of current clinical trials. The sources of differences in efficacy results between the U.S. and foreign clinical trials sites have yet to be determined, but differences rooted in the conduct of the clinical trial should be evaluated.

It has been 5 years since the passage of the FDA Amendments Act, and the National Institutes of Health is still in the process of writing proposed regulations. The clinicaltrials.gov program and title VIII of the FDA Amendments Act were considered major reforms and helped science information advances. If they are not being implemented well or adequately enforced, society will fail to reap the full benefits of the billions of dollars in good medical science research.

This amendment before the Senate will impose a deadline by which the NIH will finalize both the proposed and final regulations. Further, 2 years after the regulation has been in place, the Government Accountability Office will conduct a study on compliance with regulations and will look at, among other things, whether the applicable clinical trial is conducted domestically, in foreign sites, or in a combination of sites. The rapid increase in trials being run overseas makes it imperative that the Government Accountability Office investigate this matter.

Currently, ''80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials.'' The ''FDA inspected 1.9 percent of domestic clinical trial sites and 0.7 percent of foreign clinical trial sites.'' We need stronger reporting requirements to ensure we understand what the implications are of this move to having so many trials conducted overseas. I encourage my colleagues to support this important amendment.

Before I move on, I wish to talk about another amendment I am a cosponsor of, which is an amendment offered by Senator PORTMAN that will make dangerous synthetic drugs such as K2 and bath salts schedule I narcotics. I have worked for over a year now to get this legislation passed through the Senate after a constituent of mine named David Rozga committed suicide shortly after smoking K2 with some friends nearly 2 years ago.

I introduced the David Mitchell Rozga Act in March of 2011, and the Senate Judiciary Committee unanimously passed it out of committee along with two other related bills sponsored by Senator SCHUMER and Senator KLOBUCHAR last July. Since that time, the use of synthetic drugs has grown very rapidly, with the number of calls into poison control centers going from as few as 19 in the year 2009 to over 6,000 in the year 2011.

The House passed their version of this bill last December on a strong bipartisan vote, but one Senator has blocked consideration of this legislation in this Chamber up to now.

So I am grateful we are finally able to have a vote on this issue, and I urge passage of the Portman amendment as well.

Madam President, I wish to go to another amendment, if that would be appropriate at this time.

The PRESIDING OFFICER (Ms. KLOBUCHAR). Without objection, it is so ordered.

AMENDMENT NO. 2121

Mr. GRASSLEY. I call up amendment No. 2121.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

The Senator from Iowa [Mr. GRASSLEY] proposes an amendment numbered 2121.

Mr. GRASSLEY. I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To provide employee protections for the Commissioned Corps of the Public Health Service Act)

At the end of title XI, add the following:

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

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

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

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

Mr. GRASSLEY. Madam President, the bill before us, S. 3187, did not address a top priority of mine, and that is ensuring whistleblowers have adequate protections.

Four months ago my office learned of a very abusive treatment by the FDA on certain whistleblowers due to those whistleblowers' protected communications with Congress and, more specifically, with this Senator's office. Once the agency learned of the communication, even though they were on personal e-mail, it began actively monitoring and observing employees' personal e-mail, as one might expect, and they observed those e-mail accounts for 2 years—for a whole 2 years—until the agency was able to have the employee fired.

Whistleblowers shouldn't be fired for doing what is patriotic; that is, reporting wrongdoing to Congress. Regrettably, I was not shocked to learn that the FDA was mistreating whistleblowers within its agency, as it has done on more than one occasion, and as I have pointed out to my colleagues. I have been reporting those things ever since the Vioxx situation of 2004, I believe.

What makes this example different, though—and even worse—is the FDA intentionally went after an employee because it knew this employee was not covered by the Whistleblower Protection Act. Now, it might surprise some of my colleagues that all employees aren't covered by the Whistleblower Protection Act. This employee in question was a member of the Public Health Service Commissioned Corps, and because of a decision from the Court of Federal Claims these employees—meaning the Public Health Service along with other members of the uniformed services—are not covered by the Federal employee whistleblower protections.

I think the court case was wrong, but anyway, that is the way the Court of Federal Claims ruled. That ruling came as a result of the Verbeck v. United States case, and the Court of Federal Claims held that an officer in the Public Health Service Commissioned Corps is a member of the uniformed service and as such is not covered by the civilian Whistleblower Protection Act, nor even the Military Whistleblower Protection Act. This same logic extends to the commissioned corps of the National Oceanic and Atmospheric Administration as well. So under the precedent of this Verbeck case, the officers of both the Public Health Service and NOAA currently have no whistleblower protection under Federal law.

This is particularly problematic when we consider that the Public Health Service and NOAA officers can be detailed to agencies such as the FDC or the Centers for Disease Control. There, these officers, working in another agency, happen to work side-by-side with civilian employees of that agency doing very critical work to review and approve drugs, oversee medical devices, and even work on infectious diseases. However, unlike their civilian colleagues who are employees of that agency and who are sitting right next to them, if these employees uncover wrongdoing, waste, fraud, and abuse, they can be retaliated against by the agency and have no recourse for it. That is exactly what happened to this Public Health Service employee working in the Food and Drug Administration when they reported wrongdoing at that agency to Congress. They did it by personal e-mail, and the FDA got on to it and then fired the one employee who was reporting to Congress but did not fire the employees who were protected by the Whistleblower Protection Act. So that is why I say this is wrong, and it needs to be fixed. This amendment will fix it.

Whistleblowers point out fraud, waste, and abuse when no one else will, and they do so while risking their professional careers. Whistleblowers have played a critical role in exposing government failures, and retaliation against whistleblowers should never be tolerated.

For this reason, I offered an amendment that expands whistleblower protection for uniformed employees of the Public Health Service. It corrects the anomaly pointed out by the Court of Federal Claims and ensures that officers in the Public Health Service have some baseline whistleblower protection. It expressly includes the commissioned corps of the Public Health Service within the protections of the Military Whistleblower Protection Act. This is consistent with the structure of the commissioned corps functioning like a military organization and matches the fact that these officers receive military-like benefits in retirement.

Unfortunately, this amendment, which I was able to get into this legislation, only covers employees of the Public Health Service. It does not address the commissioned corps of NOAA because of other Senators' concern that is not related to the underlying bill. So I hope to be able to address that remaining gap in whistleblower protections in the near future so that all employees of the Federal Government are covered.

All Federal employees should feel comfortable expressing their opinions both inside the agency they work for as well as to Congress. The inclusion of this language will ensure those opinions receive appropriate protections.

I wish to take this opportunity, as I did in my opening comments on these two amendments, to express my appreciation to Senators HARKIN and ENZI and their commitment and efforts over the years to reform and improve the FDA.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. What is the pending business on the Senate floor?

The PRESIDING OFFICER. The pending business is Grassley amendment No. 2121.

AMENDMENT NO. 2130

Mr. BURR. I ask unanimous consent to set aside the pending amendment and to call up amendment No. 2130.

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

The clerk will report.

The bill clerk read as follows:

The Senator from North Carolina [Mr. BURR], for himself and Mr. COBURN, proposes an amendment numbered 2130.

The PRESIDING OFFICER. I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To ensure transparency in Food and Drug Administration user fee agreement negotiations)

At the end of title XI, add the following:

SEC. 11____. TRANSPARENCY IN FDA USER FEE AGREEMENT NEGOTIATIONS.

(a) PDUFA.—Section 736B(d) (21 U.S.C. 379h–2(d)), as amended by section 104, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(b) MDUFA.—Section 738A(b) (21 U.S.C. 379j–1(b)), as amended by section 204, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(c) GDUFA.—Section 744C(d), as added by section 303 of this Act, is amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(d) BSUFA.—Section 744I(e), as added by section 403 of this Act, is amended by adding at the end the following:

''(4) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

Mr. BURR. Madam President, let me reiterate what my colleague just said, which is that Chairman HARKIN and Ranking Member ENZI have done a wonderful job with a very complicated bill in navigating what was a negotiation that Members of Congress never played a part in—negotiations that happened between the Food and Drug Administration and the pharmaceutical industry for one piece, the device industry for another piece, and the generic drug industry for a third piece; and, I might say, the third piece is the first time Congress will consider this.

I think it is important that Members of the Senate, Members of Congress, and the American people understand that, typically, all legislation is crafted in the Congress of the United States. It is not negotiated in the back room of the Food and Drug Administration or in the back rooms of the device, pharmaceutical, and generic drug

manufacturers—except for this. In fact, my amendment gets at the heart of that issue. It is called the amendment ''to ensure transparency in the Food and Drug Administration user fee agreement negotiations.''

The amendment is straightforward. It would ensure transparency in FDA's drug and device user agreement negotiations by allowing Members of Congress or their designated staff to attend the negotiations between the FDA and the industry. What a novel thing to say, that those who are responsible to actually implement the policy could sit in the room and listen. I am not talking about playing a role in negotiating.

Why is this amendment necessary? The bottom line is while the FDA may consult with many of the stakeholders at various points in the process, the drug and device user fee agreements are not negotiated so Members of Congress and the general public know exactly what is in them. Congress is effectively shut out of the process until the negotiated deal behind closed doors is announced. In other words, we are presented with what they have negotiated, and we are basically told: Here is what we want you to pass. At no other point in the legislative process does it happen like this in the Congress of the United States.

The drug and device user fee agreements have significant implications for the American people as well as Congress's ability to do oversight. The No. 1 role of the Congress of the United States is to serve on behalf of the American people as an oversight tool over Federal agencies. Congress should not have to read between the lines of the minutes of a negotiation to try to figure out, in fact, the spirit of those negotiations. The ability for Congress and the American people to fully understand and weigh the negotiated agreements and the implications they present for patients, taxpayers, the FDA, and for Congress would greatly be improved by ensuring that Congress might attend the negotiations.

Some of my colleagues will probably come down and suggest this amendment would put Congress at the negotiating table and potentially would jeopardize negotiations. It is not true. It is not what I am attempting to do with this amendment. The amendment merely states if a Member of Congress wants to attend or if they want to have their designated to attend in their place, they may. This amendment does not call for Members of Congress to participate in the negotiation, or certainly staff. The negotiations would still be between the FDA and the industry, but it does ensure that Members of Congress or their staff may be in the room and be informed of the negotiations in real time. Congressional staff may be required to comply with all applicable confidentiality agreements. The FDA's negotiations with the industry would not be jeopardized. Let me say that again to my colleagues: would not be jeopardized because the Members of Congress or the staff would be there just for observation purposes.

Let me suggest that if our being in the room jeopardizes the outcome, then we would not be allowed to attend the Supreme Court when some of the most important cases are tried across the street. But Members of Congress and their staff regularly sit in and listen to the arguments that are made.

The fact is, Congress should not have to wait to be informed of how FDA's public health mission could be strengthened and improved on behalf of patients. By having the option to attend the negotiations, Congress and its staff would gain invaluable insight into how Congress can work with the FDA to ensure the agency is fulfilling its public health mission on behalf of patients.

Congress has a critical role to play in the process. When the negotiated user fee agreements arrive on our doorstep, we are expected to take them up, and we are expected to pass them quickly without change. Let me say that again. We are expected to take them up, we are expected to take them up quickly because we do not want to break the continuity of the user fee agreements, and we are expected to do it without change, because to change those agreements would be to break what was negotiated.

Let me suggest to my colleagues: This is the only time in the legislative process where Congress is asked to take somebody else's negotiated product and not to provide the input of two Senators from every State or every Member of the House of Representatives. It completely goes around the structure, the legislative structure, of the Congress of the United States—something that has been tested and tested for hundreds of years.

So Congress is told to tiptoe around the agreements, and we focus our efforts on belt-and-suspender policies to complement the agreements. This does not make for the most deliberative process in considering how Congress can work with the FDA and industry to strengthen and improve FDA's drug and device work.

As a matter of fact, I would say to my colleagues, as we talk about health care policy in this institution, where our goal today is how we reduce the overall cost of health care, remember, as we sign off on this user fee agreement, every dime that is transferred from the industry to an agency means industry is going to have to raise the price of its products to accommodate what they are paying.

What are we here doing? We are raising the cost of pharmaceutical products, devices, and for the first time we are raising the cost of generics because an industry has negotiated something outside of the walls of the Congress of the United States.

FDA faces unprecedented challenges today—challenges we could not have envisioned a generation ago. The agreements and many of the provisions in the Senate bill are intended to help address these real challenges the agency is facing.

But I ask my colleagues this, in closing: What if they do not? What if they do not address the challenges? What if now generic drugs become more expensive than some people can pay because of this agreement? That is why it is absolutely crucial that Congress play a part in this role to balance this policy.

Where will we be in 5 years when it is time to renegotiate this agreement? Well, I hope we are in a much better situation than we are today, that we actually have the right matrix in place through this legislation—not something that was negotiated between the FDA and the industry but something that the Senate of the United States put into this language that gives people on both sides of the aisle the ability to have a yardstick of measurement of success. Did the agency live up to what they promised the industry and, more importantly, does that compute to a beneficial product for patients across this country? I hope that is what we will find 5 years from now. It is what we have tried to construct in a very difficult and challenging piece of legislation.

I will tell my colleagues, this is not an amendment I will ask for a vote on. At the end of the day, the reality is this probably upsets the apple cart a little too much. But I think it is absolutely crucial that somebody ask the questions of how can Congress legitimately stand here and allow something this complex and this important to be negotiated without the input, the full input of the Congress of the United States.

Again, I conclude the same way I started: I think Chairman HARKIN and Ranking Member ENZI have done a magnificent job of navigating a very difficult issue, and they deserve a tremendous amount of credit for taking a negotiated product and incorporating what I think are some very positive changes that make this a better product than was negotiated by the private sector and the agency.

My only wish is that the next time we do this, we will not have to try to figure out why certain things happened in the negotiations, we will be privy to those negotiations, and we will better understand collectively how we can take an agency and an industry and public policy and move it in a situation where the American patients are the beneficiaries of it in a much more effective way than I think we have today.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I thank the Senator for his comments and his insight and his idea. I appreciate that we are not going to be voting on this one right away because I think this needs a little time to germinate. I

think it is something that, as people look at it and think about it, they will recognize the value there would be if we had more insight into what the negotiations were—not just on this but perhaps on regulations that are being done as well.

I want to thank the Senator, though, for the way he has dug into the entire user fee bill and made some very substantial changes in a number of other places. I do not know of anybody who works as hard on the medical issues as does Senator BURR, and understands it, and gets into some of the details. And, of course, he worked all of these when he was in the House and now works them in the Senate, and is our foremost expert on any of the pandemic issues and was very successful earlier in the year in getting that bill through the Senate. He has been very cooperative on the other amendments which are now a part of the bill that we will not be voting on because they are already in there. I appreciate this one more suggestion and suggest that is something we should take a look at.

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

The PRESIDING OFFICER. The Senator from Iowa is recognized.

Mr. HARKIN. Madam President, I join Senator ENZI in thanking Senator BURR for being not only a very valuable member of our committee but I would say the Senator's fingerprints are a lot on this bill we have before us. He has worked very hard on this bill and I think helped to improve it every step of the way over the last year.

I was looking through the list of different things here. Senator BURR was one of the leaders in our working group on the supply chain, which we have in this bill to make sure those things coming from other countries have good manufacturing practices on them and we can keep track of them.

The provision of clarifying the ''least burdensome'' standard on clinical data for device approval was also the result of the Senator's hard work. The Senator was also in the working group on the GAIN bill regarding antibiotic incentives for getting more incentives for new antibiotics. And there was a Burr-Coburn bill regarding enhanced reporting requirements for FDA, and that basically is also included in the bill we have in front of us.

So in every respect, the Senator from North Carolina is a great member of our committee, a very valuable member of our committee. As I said, we are looking at the amendment he has now brought up, and I am sure, as Senator ENZI said, we will be talking about this in the next few hours and going into tomorrow. But I again want to pay my respect to the Senator from North Carolina and thank him for all the hard work he has done on this bill.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Minnesota is recognized.

Mr. FRANKEN. Thank you, Madam President.

Madam President, I wish to thank my friends on both sides of——

The PRESIDING OFFICER. Who yields time?

Mr. HARKIN. Madam President, an inquiry: Is the Senator bringing up——no, the Senator does not have an amendment pending.

Mr. FRANKEN. I wish to speak on the FDA bill.

Mr. HARKIN. The Senator wishes to speak on which amendment?

Mr. FRANKEN. Not on an amendment, just on the bill overall.

Mr. HARKIN. Madam President, how much time is remaining on the Grassley amendments, the amendments offered by the Senator from Iowa?

The PRESIDING OFFICER. The Senator from Iowa has 9 minutes and the time in opposition is 15 minutes.

Mr. HARKIN. How much time does the Senator wish to take?

Mr. FRANKEN. Well, about 10 minutes.

Mr. HARKIN. I would ask that 10 minutes of the time in opposition to the Grassley amendment be allocated to the Senator from Minnesota.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. FRANKEN. I object to the Grassley amendment.

I am joking.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. FRANKEN. Thank you. I thank the Senator from Iowa for the time.

Madam President, I thank my friends on both sides of the aisle for their work on the legislation we are considering today. The Food and Drug Administration Safety and Improvement Act is not only among the most important piece of legislation we will consider this year, it is also the product of more than a year's hard work and negotiation.

This legislation will help support a culture of innovation in this country. It will help millions of Americans access the lifesaving medications and devices they need, when they need them. As a member of the HELP Committee, I am proud of the bipartisan bill before us today and look forward to passing it into law.

Let me tell you why. Of course, the Presiding Officer spoke so eloquently about this bill earlier. The Presiding Officer does not have to know why, but let me tell you a story about a little girl in Minnesota—from our State—named Josie.

Josie seemed perfectly healthy when she was born, but at 9 months of age Josie's parents found out she had a rare congenital heart disorder, a condition with the scary name of ''atrial septal defect,'' which means she had a hole in the wall between the upper two chambers of her heart.

When the doctors tested her, they found Josie had not one, not two, but three holes in her heart. It became clear that what was originally a fairly simple surgery to repair the hole was actually a lot more complicated.

But Josie was lucky. Josie's parents live in Minnesota, and Josie's doctor, Dr. Daniel Gruenstein, works at the University of Minnesota. Dr. Gruenstein was able to operate on Josie's heart because he had a brandnew device the FDA had approved only months before. The device, which was also developed in Minnesota, saved Josie's life. Because of this procedure, Josie was acting like her same old silly self the very night of her operation, and she walked out of the hospital the next day.

A few years later when Josie's little sister Jenna was born with the same congenital heart defect, Dr. Gruenstein repaired her heart using the very same device. But too many children like Josie and Jenna are not so lucky. Too many children do not have access to the medical technology they needed to save their lives or to prevent their illness or to help them recover from their rare condition. That is because too many medical devices get stuck or delayed in the agency that regulates our medical technologies. It is because we do not do enough to support a culture of innovation in this country.

The Food and Drug Administration has a tough job. The technologies they regulate are moving at the speed of light, and they do not have the workforce or the expertise to know everything about every new treatment.

In fact, the number of annual 510(k) submissions—that is the most common kind of new device application the FDA receives—has quadrupled since 1976. That is why when the HELP Committee sat down to develop this legislation, we agreed we had to streamline the FDA's processes and make them more efficient. We agreed we had to do more to support a culture of innovation which will help manufacturers get safe technologies and treatments to patients. That is exactly what the bill does. I thank both the chairman and the ranking member.

It requires the FDA to stop using ''FDA days'' and start using regular calendar days like everyone else. It lifts restrictive constraints on the FDA's consultation with outside experts, something the Presiding Officer knows well—outside experts such as are at the University of Minnesota. It creates new incentives for manufacturers that develop treatments for people with rare diseases and conditions like Josie's and Jenna's. These provisions will support innovation and will remove redtape from the process.

The three provisions I championed are included in this legislation in addition to the base bill which we negotiated as a committee. The first provision will strengthen the Food and Drug Administration's workforce by removing overly restrictive requirements that keep the FDA from consulting with outside experts, again something the Presiding Officer has been a leader

on as well. This provision will change the rules that keep the FDA from talking with many outside experts. It will make these rules consistent with those of all other agencies, including the National Institutes of Health, so as the FDA's experienced workforce retires, the FDA will be able to consult with leading experts when they are reviewing a new technology or a new treatment for a rare disease.

This provision will give the FDA the flexibility it needs to consult with experts and keep patients safe, and at the end of the day that means more patients will get the health care they need.

The second provision will require the FDA to remove new and burdensome guidance on the industry that could triple the number of required new submissions for existing devices. This provision, which Senator BURR from North Carolina also championed, will prevent this guidance from overburdening both the industry and the FDA, which could have caused innovation to come to a screeching halt.

My third provision will help companies develop innovative new products for patients across the country with rare conditions. According to the National Institutes of Health, 25 million Americans struggle with a rare disease, and these patients have to jump hurdle after hurdle to get the care they need. Many of them will go from doctor to doctor for years before they find a specialist who understands their condition.

If you live in rural Minnesota, you may have to drive hundreds of miles to find a doctor who can help you. Even for patients who find the right doctor, too often the treatment for their condition does not exist, or has not been approved. So my provision will reward companies that choose to develop treatments for patients with rare diseases.

We did this in 2007 to help companies develop devices for children with rare conditions, and we saw the number of devices that companies developed quadruple in a few years. This provision will help get treatments to adult patients with rare conditions in Minnesota and around the country and around the world.

Minnesotans know what it means to foster a culture of innovation. Our manufacturers have developed new treatments for everything from skin lacerations to brain aneurysms. This bill will go farther to support this kind of innovation by streamlining the processes that are currently impeding investment in new technologies and making the FDA more efficient and predictable.

This legislation will help patients in Minnesota access the medical technologies they need, just like Josie and Jenna. And in a time of economic hardship, it is an investment in one of our country's strongest industries, one of our State's strongest industries. This bill is a step toward a healthier future for our country. I look forward to making sure it becomes part of our law.

I yield the floor.

The PRESIDING OFFICER. The Senator from Alaska is recognized.

AMENDMENT NO. 2108

Ms. MURKOWSKI. Madam President, I ask unanimous consent to call up amendment No. 2108.

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

The clerk will report.

The bill clerk read as follows:

The Senator from Alaska [Ms. MURKOWSKI], for herself, Mr. BEGICH, Mr. MERKLEY, Mr. SANDERS, Mr. LEAHY, and Ms. CANTWELL, proposes an amendment numbered 2108.

Ms. MURKOWSKI. Madam President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To prohibit approval by the Food and Drug Administration of genetically engineered fish unless the National Oceanic and Atmospheric Administration concurs with such approval)

At the end of title XI, add the following:

SEC. 11___. ANALYSES OF APPLICATION FOR APPROVAL OF GENETICALLY-ENGINEERED FISH.

Notwithstanding any other provision of law, approval by the Secretary of Health and Human Services of an application submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for approval of any genetically modified marine or anadromous organism shall not take effect until the date that the Secretary of Commerce, acting through the Under Secretary for Oceans and Atmosphere, approves such application using standards applied by the Under Secretary under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), which shall include a Regulatory Impact Review required by Executive Order 12866 (58 Fed. Reg. 51735) and Initial Regulatory Flexibility Analyses required under chapter 6 of title 5, United States Code (commonly referred to as the ''Regulatory Flexibility Act'').

Ms. MURKOWSKI. Madam President, I rise today to speak to an amendment we will have on the floor tomorrow afternoon. This is an amendment that certainly has generated a fair amount of interest within my State, in fact, most of our coastal States, anywhere where we have an interest in seafood and the seafood industry. It has been kind of unceremoniously dubbed the frankenfish amendment, so my apologies to my colleague who just yielded the floor to me. Certainly no affront to him.

But what we are speaking about today is genetically engineered salmon. It has been somewhat affectionately dubbed frankenfish because of the images this genetically engineered fish conjures up, a fish that would literally be growing in size, doubling in size, unlike the fish we see in our streams and in our waters.

What is happening today is the FDA is on a path to approve an application for this genetically engineered fish. I want to discuss the amendment I have filed which would require NOAA to conduct a full environmental assessment and analysis of economic impact to affected fisheries before the FDA approves any of these genetically engineered fish.

I start my comments by saying I am not looking to pull the plug on the FDA. I am not looking to insert Congress's judgment into the FDA process. I am asking that when we are talking about basically a new fishery for a modified salmon, I am asking the agency that is tasked with our fisheries have some role in what is moving forward. So let me give you a little background in terms of what we are talking about with this genetically engineered fish, this frankenfish. This would be a fish, an Atlantic salmon, that has DNA spliced from a Chinook salmon with that of what they call an ocean pout, which is some kind of an eel type of a fish that apparently is in colder waters. But the technology the FDA is looking at that would allow for this genetic engineering would essentially provide for a fish that would grow to market size in about half the time of a conventional salmon. In other words, a salmon out in the wild takes about 30 months to gain full maturity. With this frankenfish, this genetically modified salmon, they could be of good market size, basically good eating size, within about 15 to 18 months.

You are thinking, okay, well, how can this be bad? We get a salmon that looks like a salmon, and it comes to us in half the time. So how can this be a bad thing? I wish to share with you why I feel this is a bad thing. When I am talking, you will hear me talking about salmon, because that is what the FDA process is engaged with right now. But I will tell you we understand that similar efforts are underway to develop a genetically modified trout, as well as a genetically modified tilapia, again, designed to grow faster than occurs in nature and out in the wild.

The pending application for the salmon would be the very first food from a transgenic animal that has been approved by the FDA, so this is precedent setting. People have suggested that, well, we see this in other forms of agriculture. But the fact is this would be the first food from a transgenic animal application that has been approved by the FDA, so this is quite precedent setting.

What is happening is this approval process for the genetically engineered fish continues to move forward as a new animal drug, rather than what it is, what I mentioned before, which is a new fishery for this modified salmon, this salmon that has been tinkered with, basically a test-tube salmon.

Here are the reasons why I think this is a bad thing, to be messing with Mother Nature, to encourage this unnatural growth. We heard on the floor this morning—the Senator from New Jersey and the Senator from New York both stood and talked about a measure

that is out there, the march that was out on the Capitol yesterday, mothers concerned about toxins in the food supply, toxins in the world around us, and knowing what is out there, knowing what we are exposed to.

Well, I, along with many consumers out there, am concerned about genetically engineered animal products that are intended for human consumption, including those that are in our marine resources. I am not the best cook in the family; my husband is. But I want to know, he wants to know, our kids want to know, that what we are eating is good and safe and sound.

At home, we eat a lot of salmon. I can stand there and tell my kids: Eat this. This is brain food. This is good for you. It is loaded with omega-3 fatty acids. It is as good as you can possibly get. I can say that with certainty.

We cannot say that, we will not be able to say that with this genetically engineered fish. As a mom, I am not going to say to my kids: Eat this frankenfish. Not quite sure what an eel pout is or an ocean pout; not quite sure how they splice this DNA together; not quite sure whether they have made it sterile.

We are not quite sure what it is, but it came to market quickly, and we are going to be able to get a cheaper price on it. I think we want to know.

The scary thing with the FDA right now is that they are reluctant to label genetically engineered products, even though it allows the public to know what they are eating. The data out there is pretty clear that there are higher human allergen effects with genetically engineered fish. If you are a mom and your kids have allergies, are you going to look at this fish and say: I wonder if this is going to set allergies off. No. You are going to stay away from it. You will not serve that to your kids or your family even though you know the wild stuff is good and healthy. But how do you know which is which if the FDA isn't moving forward to label and you are not quite sure that what you are buying in the grocery store is as advertised? How are we helping the consumer here?

The first problem I have is that this is, again, a product that is intended for human consumption, and we have some real concerns about the safety of the food in the first place. Second—and this is one that, as an Alaskan, where we have very strong fisheries, very healthy fisheries, I worry about what will happen if, in fact, there was escapement into the wild by these genetically engineered fish. You have a frankenfish that gets loose. They will tell you: They are going to be in pens, and we will make sure there is no escape. How can they make sure we are not going to see escapement? We have seen that, clearly, from the farm fish that mingle with the wild stock. We see the disease that can be transmitted. How is any of this good? Even though the genetically engineered fish supposedly is going to be kept in onshore pens, the possibility of escape is recognized, it is out there, and it exists.

Then you are going to have these genetically engineered fish that will breed year-round. They are also going to be eating year-round. They are going to be feeding year-round. What you can very possibly see is this competition with the wild stock. They will compete with one another for the food the species feeds on, and they will wreak havoc with the ecosystem. So you can introduce—granted, not intentionally—into the ecosystem that fish that just doesn't work with our wild stock. Unlike hatchery produced fish, genetically produced fish would reportedly be sterilized and their hormones altered. But many scientists believe that the FDA testing to confirm the agricultural safety and sterilization of these fish is deficient. We see this in the CRS report that has looked specifically to this issue.

Unlike other agricultural products, if you have an escape of frankenfish, it would be to an uncontrolled marine environment, exposing valued ecosystems to associated risks. If you have a cow that has been genetically modified and that cow is on land and gets out of the pen, you have more ability to control that. You don't have the ability to control in a marine environment. It is just not possible. So what is happening is that we are putting at risk the health and safety of our wild stock. Unacceptable.

Third, many find the FDA process for approving an animal product intended for human consumption as it would a veterinary drug to be insufficient. It lacks the robustness and transparency one would expect for a product that would be treated as a substitute for fish that is currently on our dinner plates in this country today.

The CRS report which I just mentioned will be introduced for the RECORD. It is a report by CRS, dated June 7 of last year, titled ''Genetically Engineered Fish and Seafood: Environmental Concerns.''

One of the concerns raised in this report is this:

> A National Research Council report stated that transgenic fish pose the ''greatest science-based concerns associated with animal biotechnology, in large part due to the uncertainty inherent in identifying environmental problems early on and the difficulty of remediation once a problem has been identified.

Our fishermen are very highly regulated, and any change to a Federal fishery, including a new GE fishery, should be analyzed for environmental effects and economic impacts to affected businesses and fishing communities. We are bringing NOAA in to be part of this process in this amendment.

The last point I will make on this is that there could be very significant economic consequences of approving genetically engineered fish. Historically, the entrance and growth of farmed salmon in the marketplace has had negative impacts on our salmon industry. We have an incredible abundance in the wild stocks, and we are very proud of it. The seafood industry in Alaska is our second largest employer, valued at $500 million with salmon alone. But the concern is that, although we have very strong wild stocks, we could see the market respond with unreasonable fear and confusion to the introduction and growth of engineered fish, particularly if it is not labeled. This, in my opinion, could have a devastating economic impact on our fish industry and the jobs it supports, clearly at a time that our Nation can't afford it.

Some will come back and say: Hey, this is a new industry, it is going to create new jobs.

I will take you back to that CRS report. One of the things I find interesting is that it says:

> To address these concerns, AquaBounty has proposed producing salmon eggs in Canada, shipping these eggs to Panama, growing and processing fish in Panama, and shipping table-ready, processed fish to the United States for retail sale.

They would ship these frankenfish to the United States for resale. So basically we get all the harm, but we don't get any jobs. But what we are doing is putting at risk the existing jobs within the seafood industry in this country—priority No. 1.

I see that my time has expired.

I commend to my colleagues this CRS Report dated June 7, 2011.

I ask unanimous consent that two letters of support for my amendment be printed in the RECORD.

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

CONSUMERS UNION,
Washington, DC, May 23, 2012.

Hon. LISA A. MURKOWSKI,
U.S. Senate,
Washington, DC.

DEAR SENATOR MURKOWSKI: Consumers Union, (CU) the advocacy and public policy arm of Consumer Reports®, urges you to support Senator Murkowski's amendment to the Food and Drug Administration Safety and Innovation Act (S. 3187), which would require additional approval by the Secretary of Commerce of GE fish applications using standards applied by the Under Secretary under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

Consumers Union has frequently spoken out on the issues and concerns surrounding the approval of genetically-engineered salmon for human consumption. Among our many concerns is that not enough research has been carried out to determine the increased potential of Aquabounty GE salmon to cause allergic reactions in humans. CU's Dr. Michael Hansen, a Ph.D. biologist, testified at the FDA hearing on this matter that Aquabounty's assessment of the potential for allergic reactions was based on just six (6) engineered fish. We believe that a much larger assessment involving hundreds to thousands of fish should be conducted. FDA has also indicated that once GE salmon are approved for human consumption, it does not intend to require labeling—a position CU strongly opposes.

We are also concerned about the potential environmental impacts of genetically-engineered fish, and particularly in regards to the impact that GE salmon would have on

the wild Alaska salmon population. Alaska wild salmon is a tasty, healthful, low-cost, and low mercury canned fish alternative. Consumers Union recommends it for pregnant women and young children who should limit mercury intake. However, some studies have shown that if GE salmon were to escape into the wild, they could potentially have serious effects upon the wild salmon population.

Consumers Union urges you to support the Murkowski amendment, in order to ensure that GE fish applications undergo an additional environmental impact review. Should you have any questions, please do not hesitate to contact me at (202) 462–6262.

Sincerely,

IOANA RUSU,
Regulatory Counsel.

TROUT UNLIMITED,
Arlington, VA, May 22, 2012.

Re Support for Murkowski genetically engineered fish amendment to S. 3187

To: U.S. SENATE

On behalf of Trout Unlimited and its 140,000 members nationwide I write to urge you to support the Murkowski amendment to ensure adequate study of genetically engineered fish prior to FDA approval. The amendment to S. 3187 prohibits approval by the FDA of genetically engineered fish unless NOAA concurs with such approval.

The acute need for this amendment is illustrated by the flawed process currently being used to review an application for commercial production of genetically modified salmon. AquaBounty Technologies has requested FDA approval for the production and marketing of genetically modified Atlantic salmon as a new animal drug. Asking the FDA to consider impacts to wild salmon is like going to a chiropractor to get your eyes checked. The FDA's pending decision has extraordinary implications for wild salmon, yet the agency with a mission to conserve and manage wild salmon—NOAA—has not been asked to analyze potential impacts, and does not have a say in the final decision. The Murkowski amendment simply states that the agency with expertise in the affected resource, NOAA, must be involved in a decision that could profoundly impact anadromous fish.

Trout Unlimited's mission is to conserve, protect and restore North America's trout and salmon fisheries and their watersheds. We work to protect healthy runs of wild salmon in places like Alaska's Bristol Bay, and restore depleted runs through habitat restoration projects on the Atlantic and Pacific coasts. Wild salmon and other anadromous fish are too important commercially, recreationally, and culturally to be put at risk by decisions that failed to adequately consider the potential impacts.

Trout Unlimited strongly supports the Murkowski amendment, and encourages you to vote Yes when the amendment is offered.

Sincerely,

KEITH CURLEY,
Director of Government Affairs.

The PRESIDING OFFICER. The Senator from Maryland.

AMENDMENT NO. 2125

Mr. CARDIN. Madam President, I ask unanimous consent that the pending amended be set aside so that I may call up amendment No. 2125.

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

The legislative clerk read as follows:

The Senator from Maryland [Mr. CARDIN] proposes an amendment numbered 2125.

The amendment is as follows:

(Purpose: To ensure that adequate information is disseminated to health care providers and payors about the potential benefits and risks of medical products on all patient populations, particularly underrepresented subpopulateds, including racial subgroups)

At the end of title XI, add the following:

SEC. 11___. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

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

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

AMENDMENT NO. 2141

Mr. CARDIN. Madam President, I ask unanimous consent that that amendment be set aside so I may call up my amendment No. 2141.

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

The clerk will report.

The legislative clerk read as follows:

The Senator from Maryland [Mr. CARDIN] for himself, and Ms. LANDRIEU, proposes an amendment numbered 2141.

The amendment is as follows:

(Purpose: To require the Commissioner of Food and Drugs to report to Congress on issues with respect to small businesses)

At the end of title XI, add the following:

SEC. 11___. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants, the amount of tax credits issued for clinical research, and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) with respect to waivers and reductions for small business under the Prescription Drug User Fee Act, the number of small businesses applying for and receiving waivers and reductions from drug user fees under subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

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

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

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

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

Mr. CARDIN. Madam President, I rise to discuss the FDA Safety and Innovation Act, the bill now under consideration here in the Senate.

I applaud Chairman HARKIN and Ranking Member ENZI for their leadership in moving this critical legislation through the HELP committee, and now to the Senate floor.

As an agency of the Department of Health and Human Services, the FDA has as part of its broad mission to protect Americans' health by assuring the safety of drugs, biologics, medical devices, our Nation's food supply, vaccines, tobacco, cosmetics, and animal food and drugs. Every single day, every single American depends on the vital work of FDA's employees.

There is a second key element to the FDA's work—helping to speed innovations to the marketplace through the drug, biologic, and medical device approval process. It's that component of the FDA's mission that we are addressing this week—reauthorizing the user fees that help fund the approval process.

I'm proud of the FDA's workers—the majority of the agency's more than 11,000 employees are based at its headquarters in Silver Spring, MD. It's

there that the process of medical innovation, which begins at NIH with basic research, is completed as lifesaving drugs and medical devices are approved for use.

A recent report from the IMS Institute for Healthcare Informatics found that in 2011 ''medicines with new mechanisms of action were launched in greater numbers than in prior years, with many representing significant breakthroughs and first-time therapies became available to treat several types of cancer, multiple sclerosis, hepatitis C, and cardiovascular conditions.''

At the same time, we know that greater resources are needed for the agency to be able to fulfill its mission in a timely and effective manner. For all of our Nation's investment in health care research, additional new medicines will not reach patients promptly unless the FDA has the necessary funds to perform its regulatory duties.

That's why the user fee amendments are so important. This 5-year reauthorization bill is Congress' opportunity to improve and update the regulatory process, and augment appropriations so that the agency can achieve its goals.

The purpose of the user fee program is to reduce the time in which FDA can review and make decisions on marketing applications. Lengthy review times affect drug and medical device manufacturers, who face delays in bringing their products to market, and more importantly they affect patients, who face delays in receiving needed treatments and cures.

The bill reported out of committee will move us forward. It will reauthorize the prescription drug user fee program, PDUFA, through October 1, 2017.

This is necessary so that the Federal Goverment can continue to collect application, establishment, and product fees from drug companies to support the review process for the next five years.

It will also reauthorize the medical device user fee program, MDUFA, through 2017 as well, and in an effort to ensure that the FDA's personnel needs are met, it would authorize a streamlined hiring of employees. Additionally, the Critical Path Public-Private partnerships, which are so important in encouraging medical product innovation, are reauthorized through 2017.

Two new user fee programs are established in the bill for generics and one for biosimilars. It's estimated that the monies generated from the generic user fee program will enable the FDA approval time for generics to be shortened from the current time frame of 30 months to 10, speeding savings to patients and to all taxpayers, as Medicare, Medicaid, and CHIP programs will reap considerable cost savings.

The base bill takes key first steps toward resolving the vexing issue of drug shortages. I want to acknowledge Senator KLOBUCHAR's work in this area.

All of us have heard from our community hospitals and physicians about the anguish they feel when they cannot secure medicines necessary to treat the patients in their care. I certainly have, and I have also heard from patients themselves who cannot fathom how such shortages could occur.

Carey Fitzmaurice of Bethesda, who is undergoing treatment for ovarian cancer, wrote to me:

> My doctor put me on Doxil and carboplatin to try to get rid of some tumors. Doxil was chosen because of recent research showing that it works especially well in those patients with the BRCA gene, like me.
>
> I had four treatments with both drugs and was responding very, very well. I have now missed three doses of Doxil due to the shortage. I am ''treading water'' with the Carbo but am frustrated that I am no longer making progress towards remission. Then there is all of the stress involved with the shortage—not knowing if there is anything I can do, or what will happen next or how long I will be in treatment.
>
> I am trying to continue to be a wife and mother and to hold down a job. This shortage is adding insult to injury. I wonder why we are being asked to raise money to find cures when we can't even get access to the cures that exist now.

Carey is one reason why I am a cosponsor of Senator KLOBUCHAR's bipartisan bill, the Preserving Access to Life Saving Medications Act, and I am pleased that the bill's early notification requirement provisions are included in the PDUFA bill we are considering today. It also requires the Secretary to establish a task force and create a strategic plan to address shortages.

This is also an urgent matter because shortages affect the ability to conduct clinical trials. Senator ROCKEFELLER and I worked together some years ago to get Medicare beneficiaries coverage for the routine costs associated with clinical trials.

As a result of Senator BROWN's work on the Affordable Care Act, insurance companies now must also cover the routine costs of trials. Access to trials often means the difference between life and death for cancer patients, and the availability of trials has enormous implications for the effectiveness of treatments for all patients going forward. There are more than 150 cancer clinical trials being conducted now at the NIH Clinical Center in Bethesda.

But the impact of shortages on clinical trials has not received a great deal of attention outside the research world. It is an extremely important issue for Medicare beneficiaries, who have the highest rates of cancer incidence. Cancer trials do not usually use placebos.

Rather, they compare standard of care drugs, versus, or in combination with, the experimental drug.

Doctors face difficult choices when the standard of care drug is in short supply. They must decide whether to use the limited supply of an existing drug to treat new patients, or use it in clinical trials to help find a cure for those who are seeking new therapies. Cancer trials have been delayed, limited the number of patients enrolled in the trial or stopped the trial entirely because there is simply not enough of the standard of care drug.

So I am pleased that the bill contains language requiring the Secretary's strategic plan to considering the impact of drug shortages on research and clinical trials.

The Finance Committee held hearings on drug shortages earlier this year as well, and we learned that the majority of shortages are found in the generic drug market. Some are due to a lack of raw materials, while others occur because the drugs yield lower profits than newer generics, and the interest in continuing to market those drugs is no longer there.

The notification language in this bill is a good start, but I believe it should be strengthened to better ensure compliance, and so I have cosponsored Senator BLUMENTHAL's amendment establishing civil monetary penalties for manufacturers who knowingly fail to notify the FDA of shortages for essential medicines.

I express my appreciation to Senator PRYOR for his leadership on nanotechnology. I am pleased to join him in this effort and am hopeful that the language we have sponsored can be included in this bill.

Nanotechnology has become increasingly indispensible in our daily lives—everything from cellphones and MP3 players, to packaging of our snack foods, to cancer treatments in development employ the use of nanotechnology.

As this burgeoning technology continues to power more of our consumer products and drive job creation in America, it is essential that we fully assess, understand, and address any risks that it may pose to safety, public health and our environment.

By soundly assessing the safety of nanotechnology and developing best practices, the Nanotechnology Regulatory Science Act of 2011 will further job creation, public safety and growth in the industry.

Our bill would establish a program within the FDA to assess the health and safety implications of using nanotechnology in everyday products, and develop best practices for companies using nanotechnology. This new program would bring more highly-skilled research jobs to Maryland.

FDA's laboratories and research facilities at its consolidated headquarters are ideally suited to conduct the scientific studies required under the bill.

The USDA's Beltsville Agricultural Research Center, BARC, is similarly equipped to provide innovative scientific technology, training, methods development, and technical expertise to improve public health.

Lastly, I urge my colleagues to support language addressing the lack of available information on the benefits and adverse effects of drugs and medical devices for minority populations.

Today, warnings and safety precautions are included as part of the initial approval by the FDA. The Agency

may also require them post approval—after the drug has been approved and sold for months or years. We know that additional side effects or risks may become known once a product is in the market and a much larger, diverse patient population is using it.

Ideally, a detailed conversation between physician and patient about the risks versus the potential benefit of taking a drug would always take place in a timely and informed manner. However, this is not always the case and is especially true if the warning is added after drug is initially prescribed and been on the market for an appreciable time period.

The randomized controlled trials used by the FDA when reviewing new drug applications, while the gold standard for examining efficacy, do not necessarily reflect the overall population for a variety of reasons.

For example, members of minority groups are generally underrepresented in clinical drug trials even though they are disproportionately affected by diseases such as diabetes, hypertension, colorectal, prostate and cervical cancer, stroke, congestive heart failure, acute coronary disease, and asthma.

We know that there are racial and ethnic differences in responses to pharmaceuticals, and they may not become known until the drug is in wide use, certainly beyond the constraints of a controlled clinical trial.

In today's world, post-approval surveys and studies are becoming more prevalent, and our ability to discern the effect of a drug over time on a variety of patient types is significantly improving. This information should be made available in a variety of ways to ensure that it reaches physicians, payors and patients, and I have filed an amendment that would greatly improve access to this information.

It would build on the current HHS ''Strategic Action Plan to Reduce Racial and Ethnic Health Disparities'' by directing the Secretary to develop a communications plan to ''address the best strategy for communicating safety alerts, changes to the label or labeling of drugs, including black box warnings, biological products or devices, health advisories, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication.''

This amendment has the support of the chairman and the ranking member, as well as the FDA and BIO, and I urge the Senate to adopt it.

Mr. President, PDUFA reauthorization is essential to furthering the Nation's health, bringing the medical innovations conceived by researchers and entrepreneurs into practice, and creating jobs. I look forward to working through the process to improve this bipartisan legislation.

Again, I thank and congratulate Senator HARKIN and Senator ENZI for their incredible work in bringing forward this bill that is so important to the public health of our Nation. We are dealing with the safety of drugs, biologics, medical devices, our Nation's food supply, vaccines, cosmetics, and the list goes on and on. It is critically important that we have the proper authorization so that the FDA has the resources it needs to advance innovation into the marketplace, products that fall within the jurisdiction of the FDA.

We know that the basic research has gone on at NIH. To get products to market, it is important that the FDA have the resources in order to move the process forward. I am proud of the 11,000-member workforce headquartered in Silver Spring, MD, for the FDA. They work very hard. This reauthorization legislation of the user fees will give them the tools in order to get the job done. I am particularly impressed that this is a 5-year reauthorization bill that will give them predictability, which is needed in order to get the job done.

I applaud Senator HARKIN and Senator ENZI. We don't see enough of these bills moving forward with the type of process our leaders have brought forward. They have resolved a lot of the issues, and we thank them for that. They have brought us a bill that enjoys broad bipartisan support and is in the best interest of our Nation. I am proud to support this legislation, and I thank them for the manner in which they have proceeded in committee and now on the floor.

Also, I point out that this bill deals with the drug shortage issues. I applaud the occupant of the chair, Senator KLOBUCHAR, and her efforts in dealing with those issues. We need more effective notification of potential shortages so that we can take appropriate action to make sure the people of this Nation have an adequate supply of medicines.

Let me share with my colleagues a letter I received from Carey Fitzmaurice of Bethesda, MD, who is undergoing treatment for ovarian cancer. She wrote:

> My doctor put me on Doxil and carboplatin to try to get rid of some tumors. Doxil was chosen because of recent research showing that it works especially well in those patients with the BRCA gene, like me.
>
> I had four treatments with both drugs and was responding very, very well. I have now missed three doses of Doxil due to the shortage. I am ''treading water'' with the Carbo but am frustrated that I am no longer making progress towards remission. Then there is all of the stress involved with the shortage—not knowing if there is anything I can do, or what will happen next, or how long I will be in treatment.
>
> I am trying to continue to be a wife and mother and to hold down a job. This shortage is adding insult to injury. I wonder why we are being asked to raise money to find cures when we can't even get access to the cures that exist now.

That is a frustration that is out there on drug shortages. I am very pleased that this legislation will move us in the right direction in answering that question.

It doesn't only affect those under active treatment, it also affects a number of clinical trials. There are currently about 150 clinical trials at NIH involving cancer and trying to find answers and cures for cancer. The problem is that on these clinical trials they don't use placebos, they use the current drug therapy that is known for the treatment against an experimental process. If there are not enough drugs available to treat people for the current protocols, how can those drugs be used in a clinical trial. As a result, we are finding it very challenging to move forward with the clinical trials that are needed. This legislation recognizes that concern and specifically deals with it. I congratulate the committee leadership for addressing that issue.

I also will mention one other issue: nanotechnology. I congratulate Senator PRYOR for his leadership in this area. Programs at FDA to access health safety facts and using nanotechnology in everyday products is something we need to do. This legislation advances that. I point out that I am proud that the lab facilities at the FDA are fully capable of dealing with the challenges presented by nanotechnology. This legislation acknowledges that.

We also, in Maryland, are proud of the Beltsville Agricultural Research Center, which will advance nanotechnology and the impact it has on everyday products and safety. Those issues will be addressed also by the underlying bill. We very much appreciate the leadership of the committee.

Let me talk for a moment about the two amendments I have brought forward. Amendment No. 2125 deals with safety warnings, particularly as they affect the minority community. Clinical trials don't always represent the diversity of our community. We know there is underrepresentation of minorities within clinical trials. Quite frankly, when the FDA gives approval, they give approval to the known risks, as I am sure you are all aware, but it doesn't always represent the impact on all communities. We also know there are racial and ethnic differences in response to pharmaceuticals, and they may not become known until the drug is in wide use, certainly beyond the constraints of a controlled clinical trial. So we do have the initial approval of FDA that includes the known risks, but we also have the capacity under FDA to do postapproval warnings. My amendment deals with that aspect.

Health and Human Services has a strategy to deal with minority health and health disparities. It is called the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities. We also now have an institute at the National Institutes of Health that deals solely with minority health and health disparities. We have a commitment to do a better job as a nation in dealing with minority health disparities. This amendment would help us move forward in that regard.

One particular drug that is used to treat an inflammatory disorder has been determined by several studies to have a mortality risk that is three times higher for African-Americans than the general public. However, it is still widely prescribed, and ads for the product on the Internet and on television prominently feature African-American actors.

This is an area in which the National Medical Association and many other groups concerned about the quality of minority health have focused on for years. Beyond the black box warning, which is the most serious warning that can be issued about the side effects of approved drugs, there are other concerns about products that are marketed for the overall population that may have side effects, but the specific data has not been developed yet to warrant a black box warning.

The amendment I have offered directs the FDA to develop communication plans to address the best strategy for communicating benefits and risks, safety alerts, changes to the label or labeling of drugs, including black box warnings, biological products or devices, health advisories, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including a variety of means of electronic communication.

I might point out this amendment has the support of the FDA and BIO, and it is budget neutral. So I would urge my colleagues to support this amendment to advance the commitment we all have made to deal with reducing and hopefully one day eliminating minority health disparities in our health care system. It is totally consistent with the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities at the Department of Health and Human Services.

The second amendment I have brought forward, amendment No. 2141, deals with small businesses. This is a very appropriate amendment, as it is being considered during Small Business Week. We all acknowledge the importance of small business in the growth of our economy. Two out of every three new jobs are created through small business. We get more innovation through our small businesses on a per-employee basis than we do through larger companies. It is critically important small businesses be energized if our economy is going to rebound, as we know it needs to.

This is particularly true as we deal with innovation in drug development or medical devices. My amendment deals with the issues of coordinating the work between the FDA and small business. It provides a listing of the staffing levels at the small business offices of the FDA so that we know the capacity we have and we can evaluate that. It is our responsibility to do that. It provides an overview of the status of partnership efforts between the FDA and the SBA. We want the two agencies, the Food and Drug Administration and the Small Business Administration, to be working in concert to advance the cause for small businesses as well as the mission of the FDA.

My amendment provides a summary of all outreach efforts to small businesses and small business associations. It details the number of small businesses receiving protocol assistance. It shows the number of unsolicited and solicited grant applications to small businesses, again, so we can evaluate that. Most importantly, it calls for the examination of existing barriers, particularly as it relates to the generic drug shortages.

It is interesting that with regard to the fee schedule, the FDA has the authority to do waivers as it relates to brand names. We know a lot of the generics are where we have our shortages because of the economics of the circumstances. But the SBA has limited ability to waive the fee structure as it relates to the general development of generic drugs. My amendment would ask the SBA to report back to Congress on what impact that has on small businesses being innovative in developing generic drugs to help us generally with less costly drugs that are available for treatment, but also to make sure we deal with the drug shortage issue, which I alluded to earlier.

This amendment is also supported by Senator LANDRIEU, the chairman of the Small Business Committee, on which I have the pleasure of serving. I urge my colleagues to support both amendments I have brought forward. I believe they only enhance the strength of the bill before us and are totally consistent with the work of the chairman and the ranking member of the committee.

With that, Madam President, I would again urge my colleagues to support both amendments and to support the underlying bill.

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

The PRESIDING OFFICER (Mr. WHITEHOUSE). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, how much time remains on the two amendments offered by the Senator from Maryland?

The PRESIDING OFFICER. Six minutes for the majority on amendment No. 2125, and 15 minutes in opposition. For amendment No. 2141, 11 minutes in favor and 15 minutes in opposition.

Mr. HARKIN. Mr. President, I will speak on the time available for the amendments.

AMENDMENT NO. 2125

First of all, amendment No. 2125 will help ensure that health care providers, patients, and payers better understand the benefits and risks associated with drugs, especially with respect to those drugs by underrepresented subpopulations.

I believe this is an important and noncontroversial amendment. I hope we can support this amendment.

AMENDMENT NO. 2141

On the other amendment, No. 2141, which is the small business report, I think it is important FDA give small businesses a helping hand. I understand each FDA center has a small business office and that each of FDA's five regional offices has a small business representative. This report the FDA would have to submit on the basis of the amendment offered by Senator CARDIN would provide Congress with more information about how FDA uses its resources for small businesses to help encourage small companies.

Again, I think this is another valuable addition to our bill and, hopefully, we can support that amendment also. So I thank the Senator from Maryland for his offering these two amendments and for what I consider to be improvements to the underlying bill.

I thank him very much for that.

Mr. President, again, I would say to the Members who may be in their offices that we still have some extra time before we will be adjourning this evening. Again, I would advise Senators that by at least 2 p.m. tomorrow, when the bell rings, we will be moving to voting, if not before then. So any Senator who has an amendment to bring up and who wishes to talk about it, I wish they would come to the floor and do that now.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I would echo the comments of the chairman, and I, too, thank the Senator from Maryland for his amendments. I think everybody appreciates both those amendments and, hopefully, they will become a part of this bill.

I also appreciate all those who have come to speak this afternoon. I know there are still probably a couple of controversial amendments on which Senators should come and speak, and then we might have the possibility of moving some things up a little bit tomorrow so we can get this bill finished expediently.

So I hope if anyone has an amendment, they will come and use their time. I think we have a few minutes in opposition perhaps to two of the amendments that have been debated so far. But that is it, and then I think there are three controversial ones that are left to be debated. One of those has a significant amount of time allocated to it, but the others are limited to 30 minutes equally divided.

So I hope we can take care of some more of those this evening and get started on votes as soon as possible.

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

Mr. HARKIN. Mr. President, I ask unanimous consent that the time during the quorum call be divided equally.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2143

(Purpose: To amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, to prohibit employees of the Food and Drug Administration from carrying firearms and making arrests without warrants, and to adjust the mens rea of certain prohibited acts under the Federal Food, Drug, and Cosmetic Act to knowing and willful)

Mr. PAUL. Mr. President, I ask unanimous consent to call up my amendment No. 2143.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Kentucky [Mr. PAUL] proposes an amendment numbered 2143.

Mr. PAUL. Mr. President, I ask that the reading of the amendment be waived.

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

(The amendment is printed in the RECORD of Tuesday, May 22, 2012, under ''Text of Amendments.'')

Mr. PAUL. Mr. President, today I am offering an amendment to the FDA.

I am troubled by images of armed FDA agents raiding Amish farms and preventing them from selling milk directly from the cow. I think we have bigger problems in our country without sending armed FDA agents onto peaceful farmers' land and telling them they can't sell milk directly from the cow.

My amendment has three parts.

First, it attempts to stop the FDA's overzealous regulation of vitamins, food, and supplements by codifying the first amendment prohibition on prior restraint.

What do I mean by that? The first amendment says we can't prevent speech—even commercial speech—in advance of the speech. We can't tell Cheerios they can't say that there is a health benefit to their Cheerios.

Under our current FDA laws, the FDA says that if someone wants to market prune juice, they can't say it cures constipation. They can't make a health claim about a food supplement or about a vitamin. They can do it about a pharmaceutical, but they are not allowed to do it about a health supplement. I think this should change. There have been several court cases that show this goes against not only the spirit but the letter of the law of the first amendment. So this amendment would change that.

This amendment would stop the FDA from censoring claims about curative, mitigative, or preventive effects of dietary supplements. It would also stop the FDA from prohibiting distribution of scientific articles and publications regarding the role of nutrients in protecting against disease.

Despite four court orders condemning the practice as a violation of the first amendment, the FDA continues to suppress consumers' rights to be informed and to make informed choices by denying them this particular information. It is time for Congress to put an end to FDA censorship.

Second, my amendment would disarm the FDA. Now, some of you might be surprised the FDA is armed. Well, you shouldn't be. We have nearly 40 Federal agencies that are armed.

I am not against having police. I am not against the Army, the military, or the FBI. But I think bureaucrats don't need to be carrying weapons, and I think what we ought to do is if there is a need for an armed policeman to be there, the FBI—who are trained to do this—should do it. But I don't think it is a good idea to be arming bureaucrats to go on the farms, with arms, to stop people from selling milk from a cow.

I think we have too many armed Federal agencies and that we need to put an end to this. Criminal law is increasingly used as a tool of our government bureaucracy to punish and control honest businessmen who are simply attempting to make a living. Historically, the criminal law was intended to punish only the most horrible offenses that everyone agreed were inherently wrong or evil—offenses like murder, rape, theft, arson. But now we have basically federalized thousands of activities and called them crimes.

If bureaucrats need to involve the police, let's have them use the FBI. But I see no reason to have the FDA carrying weapons.

Today, the criminal law is used to punish behavior such as even fishing without a permit, packaging a product incorrectly, or shipping something with an improper label. Simply said, the Federal Government has gone too far.

The plain language of our Constitution specifies a very few Federal crimes. In fact, the Constitution originally only had four Federal crimes, and now we have thousands of Federal crimes. We have moved beyond the original intent of the Constitution. We don't even know or have a complete list of all the Federal crimes. It is estimated there are over 4,000, but no one has an exact number.

Finally, my amendment will require adequate mens rea protection. In other words, when there is a crime, we are supposed to prove the intent. People have to have intended to harm someone. It can't be an honest mistake, where a business man or woman has broken a regulation and didn't intend to harm anyone. If we want to convict someone of a crime and put them in a jail, it should have a mens rea requirement. This is something we have had for hundreds of years that comes out of our common law tradition.

This amendment would fix this problem by strengthening the mens rea component of each of the prohibited acts in the FDA Act by including the words ''knowing'' and ''willful'' before we address and accuse someone of a crime. I think this would give protection to folks who are guilty of inadvertently breaking a regulation and would keep from overflowing our jails. We have plenty of violent criminals without putting people in for honest breaches of regulations.

If Congress is going to criminalize conduct at the Federal level, as it does with the FDA Act, then the least it can do is have an adequate mens rea requirement. My amendment will attempt to do this. It is not that we will not have rules at the Federal level, but the rules ought to be reasonable. We ought to allow people to market vitamins. There is no earthly reason why someone who markets prune juice can't advertise that it helps with constipation. We have gone too far. We have abrogated the first amendment. What we need to do is tell the FDA the courts have ruled that the first amendment does apply to commercial speech, and the FDA has been overstepping their bounds.

I hope this amendment will pass. I will ask for the yeas and nays at the appropriate time.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, I rise in opposition to the amendment offered by the Senator from Kentucky, and I oppose it for several reasons.

I believe I am in the court of equity now: I come with clean hands because I am one of the authors of the Dietary Supplement and Health Education Act, along with Senator HATCH, in 1994. We worked in tandem over a period of a couple of years to get the legislation through. A lot of compromises were made at that time, not only here in the Senate but also with the House when we went to conference. I believe the right balance was struck, and I think it has proven its worth over the years.

We have done some minor modifications to it over the years. As I have often said, when we write laws around here they are not chiseled in stone for all eternity. These aren't the Ten Commandments, they are laws, and sometimes they need to be modified and changed a little bit, usually tweaking. But this amendment basically turns the whole law that we had since 1994 on its head.

We have a process now where the FDA regulates the supplements as foods. These are foods, not drugs. So as

we hammered out this agreement, supplements can make nutrient, structure, function claims without any FDA preapproval. If they want to make a health claim, then it has to be approved by FDA, and FDA has to find that it is supported by appropriate scientific evidence. Under this amendment, substances that today are considered drugs and used to treat diseases as serious as cancer or HIV could be marketed without any rigorous FDA review that we have heard from many speakers here today is the gold standard of drug regulation throughout the world. It would turn our current system of drug regulation on its head. It would be a huge setback for health. It would foster a system rife with potential for health fraud. The big losers would be patients.

Frankly, as someone who is a strong supporter of the Dietary Supplement Health and Education Act, and I would say along with Senator HATCH one of its protectors for all these years, I daresay the amendment offered by the Senator from Kentucky would destroy DSHEA. It would destroy it and I don't want to see it destroyed because I think it is doing a lot of good for a lot of people in this country. It is working well. Consumers have access to a wide range of safe products. There is no reason to upset its success, because this amendment would do that.

To think that somehow you could go out and make any health claim you want? Back to the days of snake oil salesmen: ''This elixir will do everything, it will cure every ailment you have and turn the clock back 20 years on your age.'' People would buy it, and what was it? It was 80-percent alcohol and 20-percent water or something like that. They made all these crazy claims. We are going to move to that kind of system now? And the only recourse would be to take them to Federal court and then have a trial and go through all that and then, OK, then they appeal it and finally you find out, OK, the court says no, there is not enough scientific evidence to warrant it so you have to take that product off the market.

We are going to do that for every one of the thousands and thousands of different products that are out there? What a mess this would be. First of all, the Federal courts would not have the wherewithal to do every one of those. Second, who has the money to take all that to court? And it would literally destroy—bring down an industry that has done well in this country. The dietary supplement industry, the vitamins and minerals industry in this country, has done a great job and I do not want to see it ruined. This would ruin it.

Last, the Senator from Kentucky talked about increasing the mens rea, the mind; you know, in law school, what your mental condition, what your thought processes were—what was your intent. It would increase it. It would need to be shown to enjoin or prosecute serious violations of the Food, Drug, and Cosmetic Act. I find this amazing. This idea that we need to make it harder to enforce a public health protection statute, not easier, is deeply troubling. I see no legitimate reason to do this.

The goal of this amendment is clearly to render the FDA virtually incapable of addressing industry abuses. I think this amendment would have deleterious effects on the Dietary and Supplement Education Act, and the industry, and also on the FDA's ability to regulate prescription drugs. You can say just about anything about what your health claims would be on any kind of product and the only recourse, as I said, would be to go to Federal court.

Again, this is a consensus measure. We have built a very broad bipartisan support for this FDA user fee bill. It is must-pass legislation. We cannot jeopardize that consensus.

For those reasons, I oppose the amendment offered by the Senator from Kentucky.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, how much time remains on the amendments offered by the Senator from Maryland, Senator CARDIN?

The PRESIDING OFFICER. On amendment No. 2141, there is 11 minutes remaining in support and 15 minutes in opposition.

Mr. HARKIN. Mr. President, I ask the Senator from Colorado, how much time does the Senator seek?

Mr. BENNET. I would like to try for 10 minutes but if I can do it shorter——

Mr. HARKIN. I ask 10 minutes of the time from amendment No. 2141 be yielded to the Senator from Colorado.

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

Mr. BENNET. I thank the Senator from Iowa, the chairman of the HELP Committee, for his indulgence.

Yesterday I spoke about some of the process on the important issues of drug safety and making sure there is a good system for safer drugs, both in preparation and distribution. I know we seem to get close to reaching a resolution, which is tremendous. I have heard many of my colleagues praise different parts of the bill, which I will do as well in a minute. But I want to take 1 more minute again, while the chairman and the ranking member are on the floor, to recognize what an enormous accomplishment their leadership has resulted in, getting this bill to a close.

As I said yesterday, I think the work of the HELP Committee, both Democrats and Republicans, with the leadership of the chairman and the ranking member, is a model for this Congress. It is the reason why the quality of this bill is so high. We still have a few votes to go tomorrow, but people forget that it is rare to be working on a full extension of anything here. This has become the land of flickering lights, where we keep things on for 1 more month or 2 more months. Here we actually have a 5-year extension of this legislation. It is wonderful to be working in such a bipartisan and businesslike fashion. It is not lost on me how much work has been put into the bill by my colleagues on the HELP Committee, including the Presiding Officer, or the HELP Committee staff. I want to reiterate my thanks and gratitude for the work on the bill that will truly help patients and American families get the medical products they need when they need them.

That brings me to the subject of medical devices. Colorado is the sixth largest medical device sector in the country, with over 600 bioscience companies overall. We obviously need to strike a balance, as we think about this legislation, because as we speed the FDA approvals, we have to ensure that devices are safe. This year has represented a good-faith bipartisan effort among members on and off the HELP Committee to find policies that will empower the FDA to ensure safer devices and also ensure that our companies on the ground have more regulatory certainty and predictability.

The FDA has been upfront about the challenges the device center faces—reviewer turnover, young, less experienced reviewers, and management challenges. At the same time we have heard from venture capital investors who say that regulatory uncertainty at the FDA is a reason they have been hesitant about continued investments in the United States and thought about the future investment in Asia and Europe. The new medical device user fee will go a long way toward ensuring the FDA has the resources to provide safer, more effective medical devices in less time and with more predictability.

Over the course of a year we were also able to craft a balance of policies on both the innovation and safety side. This includes reinforcing regulations in place since 1997 that require the FDA to take the least burdensome approach to approving medical devices by not asking companies for unnecessary or unrelated information.

I see the Senator from Minnesota on the floor, and I thank her for her leadership on this piece of legislation. It also includes important safety provisions such as ensuring the medical devices have a tracking number so if there is any problem, doctors and patients can quickly know if their product is one that works.

I would like to say a word about drug shortage, which is a discussion issue every Member is hearing about in their States. In just the last year, the FDA was notified of about 220 drug shortages. We know that the amount of patients this affects is monumental. For

cancer alone, over 550,000 patients have been currently affected by our national drug shortage crisis.

In Colorado, our patients and providers are extremely frustrated. A pharmacist at St. Mary's Hospital in Grand Junction said that he keeps a 2-page list of 50 drugs that he cannot get or can barely get a hold of, including 12 chemotherapy drugs.

I want to share a couple of constituent stories from my home State.

Dawn Gibbs from Long Mount, CO, wrote:

> Dear Senator Bennet: I am contacting you to inform you of my grave concern of the national shortage of the preservative free cancer drug Methotrexate. My 2-year-old cousin receives this drug for her newly diagnosed leukemia of October 2011. Her doctors told her that they only have a 2 week supply left at their clinic. This drug keeps her leukemia from traveling to her brain. This shortage is life threatening to her and 3,000+ like her with this cancer.
>
> I thank you for your assistance in this matter. I know that my little 2-year-old cousin cannot speak out on her own behalf, so I am honored to be her voice. I feel my voice will not be enough alone to make a difference, and I hope that you will be our voice.

Dawn Gibbs' voice is being heard on behalf of her cousin, just as patients all across the country are lending their voices to this important debate.

Carol Gill from Morrison, CO, wrote:

> Dear Senator Bennet: I have stage 4 cancer. My current treatment regimen is doing a fine job of keeping the disease stable. This regimen includes a biweekly infusion of two generic drugs—5FU and leucovorin—and two other drugs still on patent. I receive treatment at the University of Colorado Hospital. My oncologist just called me to say that the University of Colorado Hospital is out of 5FU.
>
> Today oncologists at the University of Colorado Hospital are calling their patients to tell them some or all of their cancer treatment must be suspended.
>
> Thank you for taking this seriously and taking immediate steps to correct it.
>
> Carol Gill.

My hope is that this Senate bill can give some reprieve to these Coloradans in desperate need of their lifesaving drugs.

The Senate bill would give the Food and Drug Administration the much needed authority to require drug manufacturers to report any discontinuance or interruption or other adjustment that would likely result in a shortage, especially those drugs needed to provide emergency care. It would also immediately create a task force that would create a strategic plan to address drug shortages and submit recommendations to Congress as well as study the effect on drug pricing as it relates to shortages.

The people in my home State and every one of our home States need us to provide solutions to this problem yesterday. They cannot wait any longer, nor should they.

I will say again that it is because of the leadership of the two people sitting here, the ranking member of our committee and the chairman of our committee, that we have been able to get this bill to the floor for a vote. I think we should take that vote tomorrow and move forward on behalf of patients all across this country and the bioscience community.

I thank the Chair.

I yield the floor.

Mr. ENZI. I thank the Senator from Colorado, Mr. BENNET, for his comments, but he sold himself pretty short on the influence on this bill. He has worked dramatically on every portion of this bill and made some significant contributions that are now a part of the bill. He didn't have to do amendments at this point because he got them all in. That was very important across-the-aisle work that the Senator did by working with a number of people on both sides of the aisle and being faithful and helping committee and staff members, not to mention all the committee meetings held on Fridays throughout the year. This bill wouldn't have been possible without the Senator's efforts.

Mr. BENNET. I thank the ranking member.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I join Senator ENZI in thanking Senator BENNET for being a very valuable member of our committee and for all of the great work the Senator did on this bill. His fingerprints are all over this bill, and, as he pointed out, it is a great bill. There was great bipartisan support.

I thank the Senator for all of his work in our working groups, especially the drug supply chain. This is a key part of this bill. The FDA will have the authority and the wherewithal to go back up the chain to where these drugs come from. The Senator was the first one to point out to me at the committee hearing that I think about 80 percent of all of the ingredients that go into our drugs in this country come from outside this country, but we had no real idea on where and how, and now we can insist on good manufacturing practices. So I would say this singular addition to this bill can be traced right back to the Senator from Colorado, and I thank him very much for his leadership on this issue and in helping us to get this bill to where we are today. I thank the Senator.

I would like to yield 10 minutes off of the opposition of the Grassley amendment 2121 to the Senator from Minnesota.

The PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, this bill means so much to my State. I spoke earlier today about the need to improve the approval process at the FDA, and this bill will speed that up with the agreement reached between industry and the FDA on the fees. I thank the Senator for his leadership on that issue.

We have literally tens of thousands of employees in our State who have incredibly good jobs in the high-tech industry. This is a huge potential export. It is already an export, but even more could come if we do this right as we look at the growing middle class in countries such as China and India who are going to the hospital and using medical devices. So this bill is speeding up that process but still keeping the very important safety standards in place, which couldn't be more important—as well as for patients who have been waiting for lifesaving treatment. So I thank the Senator for that.

I also thank the Senator for including, as Senator BENNET referenced, my drug shortage provision. We worked on that for 2 years. We gathered support as the years went on.

I thank Senator HARKIN for the hearing we had on that bill and for the work of his staff in bringing people together. We got Senator CASEY's and Senator COLLINS' provisions in this bill.

We all know what has been going on. As several Senators have mentioned, we are talking about 4-year-old boys with leukemia whose parents find out they have no cancer treatment drug and literally are put into a panic, so they book flights to Canada so this little child can complete his treatment, or the woman with breast cancer who has to call around for Prudoxin and is then faced with the ethical dilemma that she explained to us that she knew she was taking it away from another patient. That should not happen in the United States of America, and this early notification of the FDA, as we have seen, has been very positive.

Over 200 drug shortages have been averted because of the early notification with orphan drugs in the last few years, so this provision will truly make a difference. I thank the Senator for including that.

I am here to talk about another matter the two Senators have been involved in negotiating. These are bills that Senator SCHUMER, Senator GRASSLEY, and I have been working on. We each had one of the three bills that covered different synthetic drugs.

My drug bill covered 2C-E, which is a synthetic hallucinogen, which, sadly, is something a young man died from taking in Minnesota. There was actually a murder prosecution because of it, and, again, we have seen it go like wildfire through our State with these synthetic drugs. Senator PORTMAN and myself and Senator GRASSLEY will be offering this amendment, and I thank the Senator for his work on it. I also encourage my colleagues to support this amendment, and I hope it will pass overwhelmingly.

As members of the Judiciary Committee, Senator GRASSLEY, Senator SCHUMER, and I have been working on this, as I mentioned, for years. There have been reports from every State in the country of people acting violently while under the influence of these drugs, which leads to death or injuries to themselves and others. While taking these drugs, people can experience elevated heart rates and blood pressure,

hallucinations, seizures, and extreme agitation, which is dangerous, but they are also dangerous to themselves.

Up in Moorhead, MN, with the Fargo sheriff, we did a forum. A group of people were sitting in the front row. I actually thought they were there to object to our provisions. They were there to support them because they had lost a loved one who thought he was taking what he considered to be synthetic marijuana, and it turned out to be very different from any marijuana. It turned out to be much stronger, and he ended up hitting a tree and killing himself. They were sobbing while telling their story.

Until 2006, I was a Hennepin County attorney. During my time there we just didn't have this as an issue. We can see how quickly it has changed. Listen to these numbers. In 2011 poison control centers across America received more than 13,000 calls about synthetic drugs. How many calls did they get in 2010? They only got 3,200. Look at that—3,200 to 13,000 in just 1 year. In Minnesota there were a total of 392 calls to poison control relating to synthetic drugs in 2011 compared to 107 in 2010—a tripling of calls about this problem in just 1 year.

This all hit home, as I mentioned in my State, with the tragic death of a 19-year-old man, Trevor Robinson, in Blaine, MN, when he overdosed on 2C-E. It is a synthetic hallucinogen. Another young man was thought to have shot himself in Minnesota while under the influence of synthetic drugs. We can imagine the pain of these families, and that is why I introduced a bill to add 2C-E and similar drugs to the substance list so they will be treated in the same manner as other banned drugs they claim to represent.

I am also a cosponsor of the two bills authored by Senators GRASSLEY and SCHUMER. All three of these bills are contained in the amendment we are offering with Senator PORTMAN. These drugs can kill, and if we don't take action, they are going to become more and more prevalent. They are available on the Internet. The Federal Government has to make clear that they are illegal. That is what is going on today because people literally buy these drugs that have numbers like 2C-E. They don't really know what they are. They get them, and they turn out to be deadly. That is what happened in Blaine, MN.

I am hopeful that we vote to ban these drugs as part of the debate on this bill. We have seen what happened in Minnesota. We know the DEA has been taking action on its own, and they temporarily banned some of these drugs, but most of the substances covered in our three bills have not been banned, including all of the substances in my bill. That is why, in fact, we are offering this amendment.

On the State level, roughly 40 States have banned some synthetic drugs, including my State, where a major law regarding synthetic drugs took effect in July. We need a Federal law. This crosses State lines. A lot of it is done on the Internet. We cannot simply have this State by State, and passing a Federal law will help create the partnership we need to send a strong message that we need to eradicate these substances.

I am pleased this amendment is being offered. We need to get it done now, ban these drugs, and make a clear statement that these drugs are illegal.

I again thank Senator HARKIN and Senator ENZI for working it out so we can offer this amendment, and also my colleagues, Senators PORTMAN, SCHUMER, and GRASSLEY, for their hard work. I know we are committed to getting this done.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I ask unanimous consent to speak for 15 minutes in morning business and not to take time away from the debate on the bill.

The PRESIDING OFFICER. Is there objection?

Mr. ENZI. Mr. President, it was my understanding that because of the special event tonight, we were going to be out of here at 6 pm. I am not sure what leadership has in mind at this point.

Mrs. MURRAY. Mr. President, I have had a conversation with them——

The PRESIDING OFFICER. Is there objection to the Senator's request?

Without objection, it is so ordered.

VETERANS EMPLOYMENT

Mrs. MURRAY. Mr. President, next week Americans are going to spend time honoring and commemorating the men and women who died fighting for our great country. Memorial Day is a day to reflect on and give thanks to the sacrifices made by those who made the ultimate sacrifice. It is also a day to look forward and to think about what we all can do to help our veterans who sacrificed so much and who deserve our support when they come home.

So I come to the floor today to discuss an issue that, quite frankly, defies common sense. The high rate of unemployment among recently separated veterans is an issue that continues to make the transition home for veterans harder than ever. Despite the fact that our veterans have the leadership ability and the discipline and technical skills to not only find work but to excel in the workforce of the 21st century, our veterans continue to struggle.

Despite the skill and talent and training of our veterans, statistics continue to paint a grim picture.

According to the Department of Labor, young veterans between the ages of 18 and 24 have an unemployment rate that is nearly 20 percent. One in five of our Nation's heroes can't find a job to support their family, doesn't have an income that provides stability, and doesn't have work that provides them with the self-esteem and pride that is so critical to their transition home.

We know this should not be the case. We shouldn't let the skills and training our Nation's veterans have attained go to waste. That is why all of us joined together to overwhelmingly pass my VOW to Hire Heroes Act here in the Senate late last year. Among many other things, that law would provide tax incentives to encourage businesses to hire veterans; it makes participation in the transition assistance program mandatory for most separating servicemembers, and expands the education and training we provide to transitioning servicemembers.

Thanks to that legislation, we have been able to take real concrete steps toward putting our veterans to work. The tax credit is working, and VA is set to begin accepting applications for a retraining program that will benefit unemployed veterans ages 35 to 60 and help them get back to work.

But that bill is only that, a first step. Today I am here to talk about the next step, and that step is to build partnerships with private businesses, large and small, all across our country, to hire our Nation's heroes. Recently I was up in New York where I participated in a lively roundtable discussion hosted by the Robin Hood Foundation. This discussion on veterans employment was moderated by Tom Brokaw on the USS *Intrepid* and brought together people of various backgrounds, including former Chairman of the Joint Chiefs ADM Mike Mullen, and Housing and Urban Development Secretary Shaun Donovan, to talk about this important issue.

What is very apparent is that there is momentum to build public-private partnerships. What is also apparent is there is a lot of room for improvement in this area.

I want to first make clear that a lot of companies across the country are far ahead of the curve. In fact, many private sector companies have already joined our efforts in addressing this critical issue. J.C. Penney, one of America's largest retailers, and Joseph Abboud, a men's clothing company, partnered with Iraq and Afghanistan Veterans of America to launch the Welcome Home Joe—Thanks A Million Program.

To prepare veterans for job interviews, this program has provided 5,000 veterans with certificates to purchase business attire. For the last decade, we have expected our brave men and women in uniform to prepare for the battlefield. In the process, they have become accustomed to wearing combat boots and battle dress uniforms. Now they are expected to wear a suit and tie for job interviews—something that sometimes seems pretty foreign to them. But thanks to this program, thousands of transitioning veterans can now hang up their battle dress uniforms and dress for their next challenge.

Other companies such as Schneider National, one of America's largest

trucking companies, are realizing the skills our veterans have gained over the last decade of work are directly applicable to their business. Schneider National recognizes that a veteran who has driven a 7-ton truck across Afghanistan's dangerous and rugged terrain is more than qualified to drive a freight truck across our Nation's roads. In addition to providing many veterans with new jobs, Schneider National also provides newly separated veterans with on-the-job training through their military apprenticeship program. As part of that program, veteran employees are eligible to earn a monthly educational benefit check from the VA in addition to a paycheck. Schneider National serves as a great example of how companies can hire veterans who have proven they can perform on the job but lack proper certifications for civilian employment.

The U.S. Chamber of Commerce also should be commended for launching its Hiring Our Heroes initiative which has sponsored 150 hiring fairs in 48 of our States. At one of these recent hiring fairs, General Electric, the employer of 10,000 veterans, launched its veterans network transition assistance program. As part of that program, General Electric has vowed to hire 1,000 additional veterans every year for the next 5 years and provides job-seeking veterans with one-on-one mentoring sessions. Those sessions help transitioning veterans improve resume writing and interviewing techniques so they can capitalize on the skills they have developed during their military service.

That is just a fraction of the work being done by our Nation's employers. There are many success stories at big companies such as Home Depot and small companies such as General Plastics in my home State which has created a pipeline to hire veterans at its aerospace composite factory. All of these companies are not only examples of success stories but they have also created a roadmap about how best to find, hire, and train veterans. It is our job to make sure those lessons are being heard.

Today I am here on the floor to lay out a few things that all businesses, large and small, can do to bring our Nation's heroes into their companies. First, get the word out to companies to educate their human resources teams about the benefits of hiring veterans and how skills they learned in the military translate to the work a company does. I can't tell my colleagues how often I hear from veterans who tell me the terms they use in interviews and on resumes fail to get through to the interviewer.

Second, help our companies provide job training and resources for transitioning servicemembers. This is something I have seen done at large organizations such as Amazon and Microsoft, but also at smaller companies in conjunction with local colleges. In fact, the most successful of these programs capitalizes on skills developed during military service but also utilizes on-the-job training.

Third, let business leaders know how important it is to publicize job openings with our Veterans Service Organizations at local military bases so we can help connect veterans with jobs, and to work with local one-stop career centers.

Fourth, develop an internal veterans group within our companies to mentor recently discharged veterans.

Finally, if possible, please reach out to local community colleges and universities to help develop a pipeline of the many veterans who are using GI bill benefits to gain employment in a particular area.

If we can spread the message on just a few of these steps, I am confident we will be able to continue to build on the success we have had in hiring veterans.

There is one other even more important step we have to take to ensure that businesses are taking, and it has to do with the difficult issue that some potential employees face. I have heard repeatedly from veterans that they do not put their military service on their resume because they fear it stigmatizes them. They fear that those who have not served see them all as damaged or unstable. We have to understand what mental health challenges are and what they are not.

As we seek to employ more veterans, we need future bosses and coworkers to understand that issues such as posttraumatic stress or depression are natural responses to some of the most stressful events a person can experience. We need them to understand that these illnesses do not afflict every veteran and, most importantly, we need to understand that for those who are affected by these illnesses, they can get help, they can get better, and they can get back to their lives. We need to let businesses know if they have a veteran who is facing some challenges, we should do the right thing and encourage him or her to get help. They need to know it is OK to reach out. Help them take advantage of the excellent mental health care the VA is capable of providing. The veteran will be better and they will be an even stronger member of a company's team.

Those are some steps our employers can take, but we also need to make sure our veterans are taking steps to stand out as candidates. Unfortunately, too often our veterans don't see how the skills they learned in the military translate from the battlefield to the working world. One of the biggest reasons for that is often our veterans don't understand the vernacular of the working world.

A few weeks ago I was home in Washington State talking about this issue when I met a woman named Anne Spurte. Anne is a veteran. She helps other local veterans find work through an organization called The Unfinished Mission. Anne told me how often she has heard from veterans who told her they were not qualified for the jobs they had seen on line or in the paper. Repeatedly they told her they didn't see how their experiences mattered to employers in the area. So one day in front of a whole group of veterans, Anne pulled out this job advertisement from Boeing for a position as a fabrication specialist. Anne could once again sense that the veterans who sat there and read this ad thought they weren't qualified for this manufacturing job that is listed in Boeing's space exploration division. But then Anne concentrated all the attention of the veterans in the room on the competency and qualifications section that was listed on that job advertisement and she asked all of them: Did you spend time in the service working together to remove obstacles to help a team accomplish its goals? Did you work to fully involve others on the team in decisions and actions? Were you held responsible? Did you demonstrate your commitment to the team? Around the room, all of these veterans' heads were nodding as she read verbatim from the Boeing job announcement. Every veteran understood they had the core skills employers at Boeing were looking for, but they just didn't realize it.

What Anne made those veterans come to understand was that their skills were being lost in translation, and what many of them needed to do was simply articulate their experiences in a way that employers could understand.

So today I want to reiterate to all of our veterans that no matter what branch you served in or when you served or how long you served, the skills you learned are valuable and it is up to you to make sure employers see that.

Our veterans don't ask for a lot. Oftentimes they come home and don't even acknowledge their own sacrifice. My own father never talked about his time fighting in World War II. In fact, I never saw his Purple Heart or knew that he had a wallet with shrapnel in it from when he was hit or a diary that detailed his time in combat, until after he died and my family gathered to start sorting through his belongings. But our veterans shouldn't have to ask. We should know to provide for them.

When my father's generation came home from the war, they came home to opportunity. My father came home to a community that supported him. He came home to college and a job—a job that gave him pride and helped him start a family and one that ultimately led to me starting my own.

That is the legacy of opportunity we have to live up to for today's veterans. Together, working with the private sector, we can ensure that the brave men and women who have worn our uniform have that real opportunity. We can make sure they get a fair shot from America's employers, that they are not measured by fear or stigma but by what they can do, what they have done, and what they will do.

I thank those companies that are leading the way as our veterans transition from military service to the civilian workforce. The Veterans Affairs' Committee, which I chair, has a Web site with a list of some of those companies that are contributing to this effort. I would encourage all of our colleagues to visit that Web site and suggest companies that can be added to our list. I look forward to working with all of them, and many more of our Nation's businesses, on this important next step in bringing our veterans home to opportunity.

As we celebrate our fallen heroes on Memorial Day next week, let's all keep thinking about how we can make sure our veterans are getting everything they need after they have given so much.

Before I yield the floor, I wish to take a moment to acknowledge a young Marine reservist, an Afghanistan combat veteran, who has been working part time on my Veterans' Affairs Committee staff for the last year. Carlos Fuentes is a hard-working, well-liked young man who graduated from American University earlier this month. He has helped our committee get a better understanding of what our veterans are facing when they are looking for work, and I want to thank him for his continued service to our Nation. I need my colleagues to know that Carlos is going to be getting married this weekend and I wish him and his bride many happy years to come.

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

The PRESIDING OFFICER (Mr. BENNET). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2151, AS MODIFIED

Mr. MANCHIN. Mr. President, I ask unanimous consent to set aside the pending amendments, so I may call up my amendment No. 2151, as modified, with the changes at the desk.

The PRESIDING OFFICER. Without objection, the clerk will report.

The legislative clerk read as follows:

The Senator from West Virginia [Mr. MANCHIN], for himself, Mr. KIRK, Mrs. GILLIBRAND, Mr. SCHUMER, and Mr. ROCKEFELLER, proposes an amendment numbered 2151, as modified.

The amendment, as modified, is as follows:

(Purpose: To amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug)

At the end of subtitle C of title XI, add the following:

SEC. 1133. HYDROCODONE AMENDMENT.

The Controlled Substances Act is amended—

(1) in schedule III(d) in section 202(c) (21 U.S.C. 812(c)), by—

(A) striking paragraphs (3) and (4); and

(B) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively; and

(2) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

''(F) In the case of any material, compound, mixture, or preparation containing—

''(i) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; or

''(ii) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts,

subparagraph (C) shall not apply and such case shall be subject to subparagraph (E).''.

Mr. MANCHIN. Mr. President, I wish to give a brief explanation of the amendment and hope it will be accepted. Basically, what we are doing is changing the hydrocodone combination drugs to be schedule II drugs rather than schedule III drugs. That makes it much harder for people to have access to this drug that has been wreaking havoc throughout our States and throughout the country.

I would appreciate adoption of this amendment.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, as the Senator said, his amendment would amend the Controlled Substances Act to make any substance containing hydrocodone—Vicodin—a schedule II drug. As he said, this is presently a schedule III drug. The most significant difference is, for patients, schedule II drugs are not allowed to be refilled. That is the key to the amendment.

I applaud the Senator. I have great concerns regarding the increased abuse of prescription drugs. According to the Centers for Disease Control and Prevention:

Overdoses involving prescription painkillers are at epidemic levels—

Epidemic levels—

and now kill more Americans than heroin and cocaine combined.

That is a quote from the Centers for Disease Control and Prevention.

According to CDC, more than 40 people die in America every day from overdoses involving narcotic pain relievers such as hydrocodone.

For this reason, I applaud Senator MANCHIN for his amendment and the efforts he has undertaken to reschedule this drug. It is the most frequently abused narcotic and that is a strong reason to reschedule it into section II.

Again, I thank the Senator for this amendment. At the appropriate time I will ask for its adoption. Again, I thank the Senator from West Virginia. This is a great amendment. It improves the bill. It is widely accepted, and the Senator has been on the right track on this issue for a long time. I applaud him for doing this and, believe me, a lot of people in America are going to thank the Senator for getting this drug rescheduled to cut down on the terrible overuse of this drug in America. I thank the Senator very much.

The PRESIDING OFFICER. The Senator from West Virginia.

Mr. MANCHIN. Mr. President, if I may say this: Senator KIRK, as you know, has worked very closely with me on this matter, and we have many other Senators—GILLIBRAND, SCHUMER, ROCKEFELLER—so many people who are having this problem in their States. This is one way for us to fight this abuse.

I have said this: If we do nothing else—if we go to some of these communities that have been ravaged, and we speak to these young children, they will come up to us and say: Please help me to help my daddy or my mommy get off of this addiction. It will tear your heart out.

This gives us a chance—one more tool with which we can fight the drug abuse that is going on with prescription drugs. I appreciate its consideration and would ask unanimous consent that it be adopted, if we can do that.

I thank the Senator.

Mr. HARKIN. If the Senator would withhold the unanimous consent request.

Mr. MANCHIN. OK.

Mr. HARKIN. We have a number of amendments we are putting together, and at the appropriate time I will make sure that happens.

Mr. MANCHIN. Absolutely.

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

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

AMENDMENT NO. 2126

Mr. HARKIN. Mr. President, I ask unanimous consent to set aside all pending amendments in order to call up Reed amendment No. 2126, and I ask that the clerk report the amendment by number.

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

The legislative clerk read as follows:

The Senator from Iowa [Mr. HARKIN], for Mr. REED, proposes an amendment numbered 2126.

The amendment is as follows:

(Purpose: To make effective the proposed rule of the Food and Drug Administration relating to sunscreen drug products)

At the end of title XI, add the following:

SEC. 11___. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-

the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

Mr. HARKIN. Mr. President, I further ask unanimous consent that the following amendments be agreed to en bloc: Cardin No. 2125; Cardin No. 2141; Grassley No. 2121; Grassley No. 2129; Manchin No. 2151, as modified; and Reed No. 2126.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The amendments (Nos. 2125; 2141; 2121; 2129; 2151, as modified; and 2126) were agreed to.

Mr. LEAHY. Mr. President, I thank Chairman HARKIN and ranking member ENZI for including the Counterfeit Drug Penalty Enhancement Act in their substitute amendment to S. 3187. I introduced the Counterfeit Drug Penalty Act, S. 1886, last year along with Senator GRASSLEY and others, and the Senate passed it by unanimous consent in March. Unfortunately, the House of Representatives has yet to take action on it.

The Counterfeit Drug Penalty Enhancement Act has the support of industry and consumer groups and bipartisan backing in the House of Representatives. It will strengthen the provisions already included in S. 3187 that are intended to improve the safety of our supply chain and increase penalties for adulterated drugs.

This provision increases penalties for trafficking counterfeit drugs to a level commensurate with counterfeit cases in which the offender knowingly or recklessly causes or attempts to cause serious bodily injury. By strengthening the penalties appropriately, it will deter the sale of dangerous counterfeit drugs.

Few things are more important to consumer well-being than ensuring the safety of our pharmaceutical supply chain. Law enforcement is finding counterfeit versions of drugs that patients rely on to treat blood clots, cholesterol, prostate cancer, influenza, Alzheimer's, and other serious conditions. Counterfeit drugs reportedly result in 100,000 deaths globally each year and account for an estimated $75 billion in annual revenue for criminal enterprises. We must do more to prevent and deter this conduct.

In addition to protecting consumers, deterring the manufacture and sale of counterfeit drugs also protects American intellectual property, helping American workers and manufacturers. That is why this legislation has the broad support of not only the pharmaceutical industry and consumer groups such as the Alliance for Safe Online Pharmacies and Easter Seals but also the U.S. Chamber of Commerce.

I appreciate the work of Chairman HARKIN and Ranking Member ENZI to protect American consumers from adulterated and counterfeit drugs, and I thank them for including the Counterfeit Drug Penalty Enhancement Act as part of that effort in this legislation.

Mr. WHITEHOUSE. Mr. President, I rise today to speak in support of the Food and Drug Safety and Innovation Act. This measure includes a number of important reforms to promote the development of new treatments for patients in need and to ensure that drugs and other medical products are safe and effective for American families. I commend Chairman HARKIN and Ranking Member ENZI for their hard work and leadership on this bill.

As a participant in the drug supply chain integrity working group, along with the chairman and ranking member and Senators BENNET, BURR, and GRASSLEY, I am especially proud of the strong, bipartisan measures to protect patients that have been included in this bill. The not-too-distant incidents concerning adulterated Heparin and counterfeit Avastin demonstrate the critical importance of protecting Americans from unsafe medical products manufactured overseas. The new tools and authorities in this law should help safeguard Rhode Island families from dangerous drugs, while leveling the playing field for U.S. manufacturers and providing more transparency and accountability across our drug supply chain.

I particularly want to thank the chairman and ranking member for working with me to include the Expanding and Promoting Expertise in Rare Treatments Act of 2012, or EXPERT Act, which I introduced earlier this year, in the bill on the floor.

During my time in office, I have been moved by the personal stories of dozens of Rhode Islanders with rare conditions. In the last year, I have met with Rhode Island advocates who have or whose family member has a rare disease, like Fragile X, spinal muscular atrophy, and CLOVES syndrome, among many others. Treatments for these rare conditions often do not exist or are so early in the development pipeline that it will take years for patients to benefit. Rather than simply waiting for the products to come to market, these families want to play a role in educating others about the rare disease that affects their loved one and working toward a successful treatment.

The EXPERT Act is intended to give patients and experts a role in strengthening and expediting the FDA's review of new treatments for rare diseases. The measure encourages the agency to take advantage of the wisdom and insights of rare disease experts in order to speed the development of therapies for patients suffering from rare diseases. The bill also gives rare disease patients and their advocates a role in consulting with the FDA on topics like the severity of the disease, unmet medical needs, and the benefits and risks of therapies to treat the disease.

We have seen that when the FDA gets the technical and scientific assistance it needs from rare disease experts, incredible progress can be made. The Cystic Fibrosis Foundation's recent work with Vertex Pharmaceuticals on a treatment named Kalydeco, which specifically targets the underlying causes of the disease in some patients, is a good example. As a result of close consultation with the CF Foundation and renowned experts, FDA approval for this treatment was one of the fastest in the agency's history.

Rhode Islanders are already benefiting from Kalydeco. Sheri, a former resident of Narragansett, was diagnosed with cystic fibrosis when she was 16 years old. This past year, Sheri was surprised with the news that she is one of the 4 percent of cystic fibrosis patients who can be treated by the newly approved Kalydeco. For the past months Sheri has been on Kalydeco and says that she already feels the difference in her health, and, most importantly, it has given her hope to start thinking about her future. Recently engaged in February, Sheri shared, ''I can think about having children and seeing them grow up . . . even living to see my grandchildren!''

I hope the EXPERT Act will lead to more good stories for other Rhode Island patients and families afflicted with rare diseases. I have great admiration for the determination and optimism of the Rhode Islanders with rare disease I have met over the years, and I wanted to share a few more of those stories here today.

I heard from Susan, a Providence resident and mother of 3½-year-old Phoebe. Susan describes her daughter as a ''bright, happy, and beautiful'' child. When Phoebe was 5 months old, Susan and her husband noticed that their daughter did not reach for or look at objects placed on the left side of her body. After numerous tests and doctor's visits, Phoebe was finally diagnosed with developmental dyspraxia, a motor-processing disorder. Because of the rarity of their daughter's condition, Susan and her husband found that specialists ''looked at us like we had two heads when we told them what her diagnosis was.'' Phoebe is reaching milestones in her development and is continuing to improve, but because so little is known about dyspraxia, Susan and her husband have encountered several hurdles to getting Phoebe the treatment and therapy she needs. Susan said, ''It breaks our hearts to think that Phoebe is being held back from reaching her full potential because of lack of awareness and education about her disease.''

Dorrie, from Warwick, wrote to share her family's story with me. Her youngest son was diagnosed with an extremely rare disorder called atypical non-ketotic hyperglycinemia, or NKH, when he was 4 years old. He is the only child living in Rhode Island with this disorder, which has no known cure or treatment. However, doctors have

found several products can be used off label to improve their son's speech and alertness. Dorrie notes that ''he has progressed farther than we could ever have hoped possible. He is not only walking, but riding a two-wheel bicycle and playing kickball with his peers.'' Because they are using products off label, their private insurance will not cover their costs, and so they are forced to shoulder the burden of paying for their son's treatments out-of-pocket. This has caused anxiety and extreme stress on their family. As her son grows older, Dorrie is faced with more uncertainty about his future and says they are ''living on eggshells'' as he experiences increased and more severe symptoms.

For these Rhode Islanders and others like them, the challenge of having a rare disease or having a family member with a rare disease comes not just from the symptoms of the disease but the loneliness of having something that so few people understand, let alone have. The EXPERT Act is one step toward empowering patients and their families with an opportunity to participate in a process that is critically important for their future. I am pleased that the act is supported by 64 national organizations, including the Rhode Island Rare Disease Foundation. I again thank the chairman and ranking member for including this measure in this legislation so that more families in Rhode Island and around the country can receive the same kind of good news that Sheri and many other cystic fibrosis patients received earlier this year.

Mr. WARNER. Mr. President, I rise today to add my voice to the bipartisan support for the Food and Drug Administration Safety and Innovation Act, S. 3187.

In addition to continuing the fee-based funding system for timely FDA reviews, S. 3187 also calls for strengthening early scientific dialogue and transparency, promotion of innovation through enhanced communications, and modernization of regulatory science.

These provisions, including enhancing dialog between the FDA and medical device, pharmaceutical, generic and biotechnology companies early in their new product development cycle, will facilitate a clearer understanding of the specific criteria the FDA will require in its review process and provide a succinct roadmap for successful product approval.

The ultimate goal is to reduce misunderstandings and expensive superfluous testing, with the hope of reducing the time and costs to bring new medical technologies safely to patients in need.

I want to commend the chairman of the HELP committee, my friend Senator HARKIN, and the ranking member, Senator ENZI, who worked to find bipartisan consensus on these provisions.

By creating a more user friendly and accessible FDA, innovative U.S. companies built on the principle of American ingenuity, will be attracted and encouraged to develop new medical devices, technologies and pharmaceuticals.

With this new cooperation, together we will extend the quality of life for our citizens, reduce healthcare complexities and costs, create new U.S.-based jobs, and move this current national crisis to a financially manageable level for individuals, employers and tax payers.

For example, in my State of Virginia, medical and bioscience research and development is vibrant in our academic institutions and among our companies, both large and small. The biopharmaceutical companies employ nearly 77,000 workers in Virginia, both directly and indirectly. In the bioscience field alone employment has grown by 23 percent, compared to 6 percent total growth statewide and 3.5 percent across all sectors in the U.S.

We have a number of companies rushing to develop and market new products and technologies that are focused on improving healthcare delivery at a lower cost premium—companies like Engineered BioPharmaceuticals in Danville, VA, who is focused on repositioning current and future pharmaceutical therapeutics to be more effective at lower doses, with longer shelf-lives and better consumer compliance.

To help these companies, and encourage more innovation, I am glad to see that the FDA has committed to being more open with applicants about using more appropriate data, but also communicating why certain data is not able to be used. I look forward to working with stakeholders and the FDA in monitoring this issue.

One of the most exciting innovations in health care is related to mobile and health IT markets. Estimates indicate that the number of smartphone consumers using medical apps will grow to 500 million by 2015.

How these innovations are regulated matters a great deal. It is important to balance market creativity, with patient safety issues and the intended use of the medical software.

A number of agencies have jurisdiction over pieces of mobile medical applications, including FDA, Office of National Coordinator, ONC, and the Federal Communications Commission, FCC,—to properly regulate health information technology as well as address proper regulations of mobile medical applications.

I am pleased that language has been included in this bill which asks for the Secretary to work across the different agencies—the FDA, ONC, and FCC—to come up with guidance that makes sense. It also encourages an outside stakeholder group to be consulted.

I would like to thank my colleagues Senator BENNET, Senator BURR, HATCH and COBURN for their leadership on this as well.

I would also like to briefly acknowledge language in the FDA bill regarding the use of data from clinical trials conducted outside the United States. As many in industry will tell you, there are a number of countries around the world that have comparable safety standards as the U.S.

I have been interested in learning more about the application of appropriate clinical data across borders. I believe that if the FDA can do more to establish comparability between its guidelines for clinical trials and those set by countries in the European Union, for instance, we may be able to reduce the need for duplicative work and we may be able to get safe products to market sooner.

The FDA has committed to being more open with applicants about using this type of data. They have agreed to provide applicants with more information about why certain data is not appropriate for use in the U.S. The FDA will also report on regulatory science, which will specifically indicate which specific metrics can be used to determine comparability.

I am hopeful that there will soon be measurable improvement on this issue, and I look forward to working with interested stakeholders and the FDA to do more in this area in the future.

One final point I would like to make is about something that is not directly included in this bill, a new innovation—biomarkers.

Preeclampsia is a disorder that affects hundreds of thousands of pregnant women every year which undiagnosed can put a woman at risk for death and the fetus at risk of stillbirth.

Doctors currently use a mix of imprecise signs and symptoms to diagnose it but oftentimes such signs and symptoms are wrong. However, researchers have found a biomarker—a particular biological process or sign—that can accurately identify women with preeclampsia that are at risk for pregnancy complications.

Unfortunately, tests for novel biomarkers are taking 5 or more years to get approved by the FDA, delaying patients from receiving the benefits of more accurate diagnoses and treatments.

I was pleased that a recent commitment letter between FDA and industry specifically mentions the FDA's commitment to work together with industry to create a transitional IVD, or ''T–IVD'' process for the development of tests for novel biomarkers.

I look forward to seeing how this T–IVD process develops in discussions between FDA and industry and am interested in progress towards its implementation which supports advances in the sciences and promotes access to these emerging diagnostics.

If reducing healthcare costs is a national priority, we need to act today. I encourage my colleagues to pass S. 3187 and allow the FDA to work more closely with the medical industry to safely bring new technologies to the marketplace.

Let's increase the quality of life of our citizens, structurally reduce

healthcare costs without increasing risks to patients and stimulate the growth of American ingenuity and U.S.-based jobs.

Mr. HARKIN. Mr. President, we are finished with business for today. We do have some more amendments to be called up and voted on tomorrow. I understand we are coming in—I do not know exactly what time has been set for the morning, but after the leaders' time has been used, we will be back on this bill.

Again, I remind Senators and their staffs that we have until 2 p.m. for their amendments to be brought up and to be debated. The sooner we get to those in the morning, the better off we will be.

So as soon as the leader time is exhausted tomorrow morning, we will be back on our bill.

So, Mr. President, I suggest the absence of a quorum and ask unanimous consent that the time in the quorum call not be taken off our bill.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

MORNING BUSINESS

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

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

150TH ANNIVERSARY OF USDA

Mr. INOUYE. Mr. President, last week we celebrated the 150th anniversary of the United States Department of Agriculture, also known as the USDA. On May 15, 1862, President Abraham Lincoln signed legislation to create the USDA. Since this day, the USDA has made major contributions to agriculture that have benefited the people of the United States.

Hawaii has a historic relationship with the USDA that began during Hawaii's territorial days. Our very own University of Hawaii at Manoa campus began as a land-grant college of agriculture and mechanic arts in 1907. John Washington Gilmore, the first president of the College of Hawaii, the predecessor of the University of Hawaii, was the son of a farmer who was tasked to build Hawaii's first agricultural school. During the past 100 years, the University helped Hawaii diversify its economy, sustain its environment, and build stronger families and communities.

Hawaii faces unique challenges when it comes to food security. Hawaii depends on imported food for approximately 85 percent of its food supply. For the United States as a whole, imports make up about 15 percent of total food consumption. In addition, higher energy-related transportation costs, and rapidly escalating commodity prices translate into very high food costs for Hawaii consumers. Further, if there is a shipping disruption of any kind, it is estimated that Hawaii has a 4 to 7 day food supply.

The magnitude for Hawaii of this potential and unprecedented food security crisis has prompted a restructuring of Hawaii's agriculture, with a move from large-scale plantation agriculture to smaller scale, more diversified agriculture, with an initial emphasis on import substitution. This process has been occurring over the past 20 years with many large scale plantations either closing or shifting to overseas locations. Our situation remains a struggle. There is only one sugarcane and one pineapple operation remaining in the State. There are no dairies on the Island of Oahu and the only two remaining in the State are on the Big Island. There are no slaughter or meat processing facilities on Oahu. A major employer on the Island of Molokai is gone and, with it, agricultural production and water supplies for residents. Finally, the only poultry operations remaining are four egg producers on Oahu.

The rapid closures of these farming and farm-related operations continues to pose a serious challenge for our agriculture industry in Hawaii as these operations were attempting a transition to agriculture supportive of local consumption through import substitution. Accordingly, efforts to support those remaining in agriculture to make the transition to an agriculture supportive of Hawaii food security is also critical to the continued sustainability and viability of our agriculture industry in the State of Hawaii.

The USDA plays a major role in preservation. The U.S. Forest Service, part of the USDA, protects and manages our Nation's forests and grasslands. Hawaii's rainforests contain numerous plant species that are not found anywhere else in the world, and they are part of a unique, delicate ecosystem consisting of countless native Hawaiian animal species. The Forest Service has helped protect the beauty of Hawaii's rainforests by fighting invasive species and destructive human practices.

The USDA hopes to protect the environments of Hawaii and the rest of the United States with the Animal and Plant Health Inspection Service, also known as APHIS. The mission of APHIS is to protect our Nation's agriculture and animal and plant resources from diseases and pests. APHIS plays a major role in the protection of Hawaii's environment. Invasive species such as fruit flies, coffee berry borers, and Varroa mites have been devastating to Hawaii's agriculture and fragile ecosystem. If Hawaii fails to stop potential invasive species including the Brown Tree Snake, the results will be catastrophic. Even though Hawaii may be small compared to the continental United States, our islands contain one the most diverse ecosystems in the world. It is in our country's interest to keep these protective programs. APHIS also protects the continental United States from potential destructive invasive species that can wreak havoc on our Nation's agriculture. Programs such as APHIS protect both Hawaii and the continental United States and are vital for economic and environmental security for everyone.

In addition to preservation, the USDA helps with innovation. The Agricultural Research Service is responsible for conducting basic, applied and developmental research on: soil, water, and air sciences; plant and animal productivity; commodity conversion and delivery; human nutrition; and the integration of agriculture systems. Through research, development, and other federal programs, the USDA has helped farmers produce food efficiently and sustainably. The United States is a world leader in agricultural production, and our agriculture research infrastructure continues to give our country a competitive edge.

Agriculture has been, and remains, an important pillar of the American economy. The USDA touches all Americans and will continue to contribute to our society far into the future. I wish nothing but the best for the USDA in the years to come.

HUMAN RIGHTS IN U.S. PRISONS

Mr. DURBIN. Mr. President, I rise to speak about the human rights issue of sexual assault in U.S. prisons, jails, and detention centers—and the historic release of our country's first-ever national standards to eliminate prison rape.

When the government takes people into custody, and puts them behind bars, their human rights become our responsibility. And we are accountable for the results. In studying this issue for nearly a decade, we learned that sexual assault in detention has become an epidemic. It is occurring at the hands of other inmates, and it is occurring at the hands of prison officials whose job it is to protect.

We learned that hundreds of thousands of inmates are victims of sexual assault every year. According to a Bureau of Justice Statistics report released this month, approximately one out of ten former state prisoners reported incidents of sexual victimization during their most recent stay behind bars. Approximately a third of former inmates reported other types of sexual harassment or victimization. Many say these are conservative estimates of those brave enough to report.

It is also disturbing that ''prison rape'' has become an accepted part of our culture. We hear people make light

of it in jokes, in movies, in television shows. It is a common pop culture reference. This is unacceptable, and it sends the message that this brutal, terrorizing conduct is actually part of a United States prison sentence. As our Supreme Court has said, it is not. The Court stated, in the 1994 case of Farmer v. Brennan, that being violently assaulted in prison is not part of the penalty offenders should pay for their offenses against society.

Winston Churchill declared in 1910:

> The mood and temper of the public in regard to the treatment of crime and criminals is one of the most unfailing tests of the civilisation of any country.

We are utterly failing the test when it comes to prison rape. Our status quo is intolerable for a country that prides itself on its commitment to civil liberties, to civil rights, and to human rights.

And this issue affects so many individuals and their families so deeply. We have more than two million people incarcerated in America today. We incarcerate more individuals, and at a higher per capita rate, than any other country on earth.

Congress passed the Prison Rape Elimination Act, ''PREA,'' in 2003. This was a bipartisan effort so important that its champions included unlikely bedfellows like Senators JEFF SESSIONS and Edward M. Kennedy. I was an original cosponsor of this legislation. Just last week, the Department of Justice finally issued the first-ever national standards to prevent, detect, and respond to prison rape, which are required under PREA.

These are historic regulations that aim to eliminate sexual assault in all federal, state, and local facilities. I applaud President Obama and Attorney General Eric Holder on their achievement. This nearly 300-page document represents one of the most comprehensive and challenging rulemaking processes the Department of Justice has undertaken in decades.

In particular, I want to thank the Attorney General for incorporating my concerns and suggestions into the Justice Department's final standards. As an original cosponsor of PREA, I have been following the progress of these long-delayed standards for nearly 9 years. The Department's proposed standards, released early last year, were missing important protections. I sent a letter to the Attorney General, emphasizing the need for stronger provisions in certain key respects. For example: The sea change we need requires, above all, accountability. In my letter, I expressed concern that the proposed standards did not require regular audits of detention facilities by external, objective auditors. The final standards require external audits every 3 years to ensure the regulations are being implemented.

One of the biggest problems with custodial sexual assault is underreporting and fear of retaliation. I learned it was key that inmates have access to ''outside reporting''—a way to report abuse to someone entirely separate from the facility and agency holding them. According to one Illinois inmate, this ''could make all the difference.'' Heeding these concerns, the final standards now require this outside reporting.

I expressed concern about imposing short timelines for reporting abuse and hampering the ability of victims to seek appropriate redress. I also asked the Department to ensure inmates weren't chilled from reporting emergency situations due to fear of reprimand for false reporting. I am pleased that the final rule made these changes.

I commented on the need for increased protections related to certain staff practices we know can contribute to instances of sexual abuse—so-called ''cross-gender pat-downs and cross-gender viewings.'' I am pleased that many of the critical protections were added.

I have long been concerned about the use of solitary confinement, where some inmates spend prolonged periods in extreme isolation. I learned one reason some do not report abuse is a fear of placement in solitary confinement. Placing those who report abuse in extreme confinement can make a ''victim'' even more of victim. I asked the Department to impose important safeguards in this regard, and I am pleased to see these changes were included in the final standards.

Finally, I am concerned about younger inmates who are especially vulnerable and easily victimized—namely, children serving time in adult prisons. The final standards include important protections for this population.

I am grateful to Attorney General Holder for considering my input and for making these changes to the Justice Department's historic national standards.

Of course, the standards are not perfect. I look forward to working with the Department of Justice on remaining issues like ensuring that inmates have access to confidential reporting and services—and making sure that staff practices, like cross-gender pat-downs, with regard to male inmates are appropriate.

But the bottom line is that the Department's strong standards make clear that the federal government will not tolerate this conduct, and that a culture change is necessary.

My work on this issue has been inspired by hearing from sexual abuse victims. For example, I received an account from one Illinois inmate who was incarcerated for a non-violent offense. He described multiple threats he received in jail, and how he tried to get help from prison officials, to no avail. He explained how he was knocked to the floor, choked, and raped in the shower. He now wants to spend his life putting an end to prison rape.

I received a report from another survivor in Illinois, a father of two who explained how he contracted HIV after being sexually assaulted in prison. He talked about the stress, hyperventilating, nightmares, and shame. He explained that he wakes some nights and can ''smell the soap from the washcloth that had been crammed in [his] mouth to silence [the] screams.''

Criminal detainees aren't the only detainees at risk. Last week, the White House made another important announcement. It confirmed that Prison Rape Elimination Act standards will apply to all federal confinement facilities, including immigration facilities. This is an important step that speaks to the Administration's commitment to ending sexual assault in all forms of detention.

The Department of Homeland Security will be promulgating its own regulations that will apply to immigration detainees. I have long been concerned about the sexual assault of immigration detainees. We have heard about truly horrific instances of assault occurring in immigration detention facilities. A troubling episode of Frontline, the PBS program, detailed one woman's story in great detail recently. But that was hardly an isolated incident.

When we drafted and passed PREA, it was always our intent that it would apply to all those in detention—including immigration detainees. I discussed this issue with Secretary Napolitano at a recent Judiciary Committee hearing. And I also—working with Senator LEAHY—included a provision in the current Violence Against Women Reauthorization Act to clarify that standards to prevent rape must apply to all immigration detainees.

I am disappointed that nearly 9 years after PREA was passed, our immigration detainees still do not have the strong protections they deserve. But I look forward to working with the Department of Homeland Security to ensure that its forthcoming regulations effectively address this issue. It was never our intention to have those accused of violating civil immigration laws left with fewer protections than those serving criminal sentences.

Again, I applaud President Obama and Attorney General Holder for their efforts to end this serious human rights abuse. I also give special recognition to the bipartisan Prison Rape Elimination Commission, whose impressive work, expertise, and strong proposed standards were the lynchpin of this effort.

I want to recognize my former colleague, the late, great Senator Ted Kennedy, for his leadership on this issue, as he led us on so many civil rights issues over the years.

I also want to thank my colleague Senator SESSIONS for his leadership as the lead sponsor of the Prison Rape Elimination Act. Senator SESSIONS and I often disagree, but we have been able to come together across the political divide to work on civil rights issues like prison rape and the sentencing of nonviolent drug offenders. As Senator Kennedy stated about prison rape:

It is not a liberal issue or a conservative issue. It is an issue of basic decency and human rights.

Finally, I thank the organizations that worked with me and my office to address this issue: Just Detention International, the ACLU, the National Immigrant Justice Center, Human Rights Watch, Human Rights First, Campaign for Youth Justice, and so many others.

I look forward to confronting what may be the most challenging part of this process ahead—ensuring that these standards protect the rights of all detainees, and that they are adopted and enforced expeditiously. I look forward to working with my colleagues to put an end to one of the more alarming criminal justice and human rights crises in our country today.

REMEMBERING EDDIE BLAZONCZYK, SR.

Mr. DURBIN. Mr. President, on Monday morning, Eddie Blazonczyk, Sr., passed away in Palos Heights, IL. He was known in the greater Chicago area as the Polka King. Eddie was born in Chicago in 1941 to Polish immigrant parents—both musicians. It is no surprise, then, that Eddie started playing the accordion at the age of 12. Eddie's first love was rock and roll, but, influenced by his mother's fondness for the music of her homeland, he was soon playing polka music.

In 1962, Eddie Blazonczyk joined a local polka band called the Versatones, a union that would last for the rest of his life. His son, Eddie Blazonczyk, Jr, still plays with the band. Today, the Versatones are the most sought after polka band in the music industry. While they are popular in communities all over the country, Chicago has always been home to the band, and Chicago knows polka.

The Chicago metropolitan area is steeped with Polish customs and heritage. It has the largest Polish population outside of Poland, and the Polish language is the third most commonly spoken language in the greater Chicago area. In Illinois, the first Monday of March is Casimir Pulaski Day, a day when all State government buildings are closed in remembrance of ''the father of the American cavalry.'' The International Polka Association moved to Chicago in 1968. We even have a Chicago style of polka music, distinguished by heavier clarinet and trumpet and, of course, the button-box accordion. Eddie Blazonczyk helped define Chicago style polka, even as he grew into his unofficial role as polka royalty.

In 1967, a congressional committee awarded 26-year-old Eddie Blazonczyk and the Versatones the title of ''The Nation's #1 Polka Band.'' In 1970, Eddie was elected into the International Polka Association Polka Music Hall of Fame. The Versatones also have 16 Grammy nominations and a Grammy award in 1986 for their ''Another Polka Celebration'' album. First Lady Hillary Rodham Clinton presented him with the National Endowment for the Arts 1998 National Heritage Fellowship for preserving Polish Heritage Music.

I extend my sympathies to Eddie's wife Christine—Tish, as many know her; his daughter Kathy; his sons Eddie and Tony; his grandchildren Cayle, Anya, and Anthony; and his many nieces and nephews. Eddie took a traditional sound and infused it with rock and roll, Cajun, zydeco, and country, creating something both familiar and entirely different. The Polish American community lost a music hero this week, but his legacy will live on at weddings, celebrations, and parties for generations to come.

RYAN CROCKER DEPARTURE

Mr. MCCAIN. Mr. President, I ask unanimous consent to have printed in the RECORD a statement released yesterday by Senators GRAHAM, LIEBERMAN, and myself on the decision of Ambassador Ryan Crocker to depart his post in Kabul, Afghanistan.

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

The recent announcement by Ambassador Ryan Crocker that he will be departing his post in Kabul is a great loss to the United States and Afghanistan, but we fully understand his decision. We are grateful beyond words to Ryan for his decision to come out of retirement at the President's request to serve our country one last time in one of the most challenging jobs in the world. When the history of the past decade is written, Ryan Crocker will rightly be recognized as one of the genuine American heroes of this era. We have never met a finer, more capable, or more dedicated diplomat than Ryan Crocker.

Ambassador Crocker arrived in Afghanistan at a critical moment in the relations between our two countries. Thanks to his efforts, we believe that the Afghan-U.S. relationship is now on a much better path. In the last year, Ambassador Crocker and General Allen, working with our Afghan and NATO partners, successfully negotiated a Strategic Partnership Agreement. If properly implemented, this Agreement could be the ultimate guarantee that Al-Qaeda and the Taliban will never again control Afghanistan. For this, and for so much else in his long and distinguished career, Ryan Crocker deserves the respect, gratitude, and admiration of all Americans. We will miss him greatly, and look forward to welcoming him back home to the United States.

REMEMBERING STEPHEN DAGGETT

Mr. MCCAIN. Mr. President, I was deeply saddened to learn of the sudden death on April 17 of Stephen Daggett, a highly respected defense expert at the Congressional Research Service and an authority on the U.S. defense budget.

Mr. Daggett provided Congress with authoritative analysis on many aspects of defense spending in the overall context of defense policy and U.S. national security strategy. His briefs to Members of Congress and his written reports captured the complexity of issues ranging from the Department of Defense's Quadrennial Defense Review to the budget priorities of the Armed Services.

Very few ''defense experts'' could do what he could do. Mr. Daggett was admired by his professional colleagues in CRS and earned many awards for his dedication and outstanding performance. His appraisals were sought-after by Members of Congress and their staffs, by others in the Department of Defense, and by industry. Mr. Daggett's particular interest in providing an unbiased, unvarnished assessment to diverse constituencies, especially outside Congress, was laudable.

In an era of wide political gulfs, he supplied irrefutable ground truths—which often became the basis for common understanding and problem solving. His accounts of the interrelated nature of defense policy, strategy, and budgets continue to be the standards of the discipline. Thought leaders on and off the Hill, in industry, associations and think tanks, on the right and the left, will feel his absence.

Mr. Daggett was a national asset who provided the Congress with invaluable expertise on defense issues for over 20 years and during three U.S. wars. He will be sorely missed by his professional colleagues and friends, by his wife, Diana, his sons Thomas and Sam, and by the many in Congress who depended on him.

TRIBUTE TO JAMES HANLON

Mr. REED. Mr. President, today I would like to recognize Mr. James A. Hanlon, who is retiring this month after nearly 40 years of Federal service at the U.S. Environmental Protection Agency.

Jim has spent his long and distinguished career at EPA focusing on water quality issues and helping States and communities comply with Federal clean water requirements. He began his career at EPA as a staff engineer in September 1972, 1 month prior to the passage of the Clean Water Act, and has served in a number of senior positions within the Office of Water and Office of Research and Development.

Although he has many accomplishments, I want to particularly acknowledge Jim's role in managing the Clean Water State Revolving Fund Program, a program that has been so important to my home State of Rhode Island.

Jim was there at the program's inception, working for several years to design and lead the implementation of the program after it was first created by Congress in 1987. A decade ago, he was appointed Director of the Office of Wastewater Management, where he has continued to manage the Clean Water State Revolving Fund Program and to oversee EPA's broader wastewater regulatory portfolio. Thanks in large part to his leadership, the Clean Water State Revolving Fund Program has successfully provided more than $90 billion nationwide to date to fund critical

water infrastructure improvements through Federal grants and contributions from State matching funds and leveraging.

For the past several years, Jim has also served as an important resource to the Senate Committee on Appropriations on wastewater policy issues. I am particularly grateful for the assistance he provided to implement the critical $4 billion investment in wastewater projects included in the American Recovery and Reinvestment Act. With Jim's guidance, EPA and the States worked to get an unprecedented 1,870 clean water projects under contract within a year of the law's passage, including ten in my home State. His experience and guidance will be missed.

I congratulate Jim on a job well done. He leaves a proud and enduring legacy of public service.

ADDITIONAL STATEMENTS

TRIBUTE TO REAR ADMIRAL CHRISTOPHER C. COLVIN

• Mr. BEGICH. Mr. President, today I wish to recognize a friend of Alaska for his extraordinary 34 years of service to the U.S. Coast Guard and our Nation. In Alaska, we know him best for his service as the commander of the Coast Guard 17th District, but he has served valiantly across our Nation throughout his long and distinguished career. On June 1, he will retire as the deputy commander of the Coast Guard's Pacific Area Command in Alameda, CA.

Rear Admiral Colvin is a native of Erie, PA. He graduated from the University of North Carolina at Chapel Hill in 1976 with a bachelor of arts degree in political science and entered Coast Guard Officer Candidate School in November 1978, earning his commission in March 1979. His 34-year Coast Guard career has included a variety of operational and staff assignments on both coasts. He served aboard eight Coast Guard cutters and commanded three. In 2003 he commanded Coast Guard Cutter DALLAS, WHEC 716, while attached to the USS *Truman*/USS *Roosevelt* battle force conducting combat operations during the first 6 months of Operation Iraqi Freedom. In 2004, Rear Admiral Colvin served as commander of Coast Guard forces off Haiti and as the maritime component commander to Joint Task Force Haiti, helping prevent a mass migration and preserving order in Port au Prince Harbor following the unexpected departure of former Haitian President Aristide. He is a 1999 graduate of the Naval War College in Newport, RI, earning a master of arts degree in national security and strategic studies. His staff expertise is in cutter management, operations, strategy, and readiness. He has enforced U.S. sovereignty in the maritime arena by interdicting illegal drugs, detaining illegal migrants, seizing foreign fishing vessels, and saving lives.

Rear Admiral Colvin's first flag assignment was as the deputy director of operations for U.S. Northern Command in Colorado Springs, CO. From there he was assigned as the commander of the 17th Coast Guard District in Juneau, AK, from 2009 to 2011, when he was responsible for Coast Guard operations throughout Alaska and the U.S. Arctic. He currently serves as the deputy commander of the Coast Guard's Pacific Area Command in Alameda, CA. His many notable accomplishments from his current assignment include coordinating USCGC HEALY's historic 2011 to 2012 icebreaking mission to mitigate a critical fuel shortage in the city of Nome, AK.

Rear Admiral Colvin married his wife Kristin in 1985, and they have two children. Their son Mark is a high school freshman and their daughter Meagan is a student at the University of Central Florida. Rear Admiral Colvin's parents are Dr. Charles and Evelyn Colvin of Erie, PA.

Mr. President, on behalf of the State of Alaska, I ask my distinguished colleagues to join me in recognizing Rear Admiral Colvin's exceptional career. We owe him a debt of gratitude for his commitment to the Coast Guard and to our Nation. We wish him well in his retirement.•

COMMENDING MISSISSIPPI LEVEE BOARDS

• Mr. COCHRAN. Mr. President, a year ago my State of Mississippi suffered one of the worst disasters in our history when the Mississippi River and its tributaries were confronted with record flood levels that threatened the well-being of residents and property over much of our State. The 2011 flood put our people and flood control structures to the test. Federal, State, and local entities worked heroically to prevent this disaster from becoming an outright catastrophe. I would like to especially commend the Mississippi Levee Board and the Yazoo-Mississippi Delta Levee Board for their impressive leadership during the flood and for taking the necessary actions to protect our population and to limit flood damage.

The Mississippi Levee Board is responsible for operating and maintaining a roughly 212-mile levee system along the river, as well as 360 miles of interior drainage streams. The Yazoo-Mississippi Delta Levee Board maintains 98 miles of mainline levees and 18 miles of backwater levees. Each board has worked efficiently and effectively with the U.S. Army Corps of Engineers to reduce the threat of high water and flood damage.

The great flood of 2011 reminded us of the importance of diligence, preparation, and cooperation to ensure that our levees remain strong and that the lives and property in our State are protected.•

EDGELEY, NORTH DAKOTA

• Mr. CONRAD. Mr. President, I am pleased to honor a thriving community in North Dakota that will soon be celebrating its 125th anniversary. On June 15 through June 17 of this year, the residents of Edgeley will be celebrating their community's history and founding.

Replacing the pioneer settlement of Saint George, the city of Edgeley has had a rich history. Edgeley is named after the birthplace of Englishman Richard Sykes, who was a significant developer and true believer in the potential of Edgeley and the surrounding area. In 1881, Mr. Sykes traveled from England to explore increasing his land holdings in America. Not surprisingly, he settled on the rich soil and beautiful country of Wells, Stutsman, LaMoure, and Morton counties in North Dakota.

Edgeley is home to many bustling small businesses and farmers who grow wheat, corn, soybeans, sunflowers, barley, oats, potatoes, and all manner of small grains, in addition to raising cattle and other types of livestock. North Dakota's first wind farm was built 8 miles west of Edgeley, providing 1.5 megawatts of sustainable electricity to many residents of the State.

Sponsored by the Edgeley Lions Club, the city is celebrating its 125th anniversary this summer. Among the events planned are a pageant, kids games on Main Street, a 5k run-walk, a golf tournament, two parades, and a commemorative gun raffle. Residents are also eagerly awaiting the grand opening of the new swimming pool.

I ask the United States Senate to join me in congratulating Edgeley, ND, and its residents on their 125th anniversary and in wishing them a warm future.•

BALTA, NORTH DAKOTA

• Mr. CONRAD. Mr. President, I am pleased to honor a vibrant community in North Dakota that will soon celebrate its 100th anniversary. From June 15 through June 17 of this year, the residents of Balta will commemorate their community's history and founding.

Originally named Egan when the town was founded in 1912, its rail station was an important spot on the Soo Line Railroad. However, when it was discovered that a rail station in South Dakota had already claimed the name of Egan, the small village changed its name to Balta when the post office opened on February 6, 1913. This new name was taken from a town in southern Russia, which is not surprising considering the heritage of the settlers, who were mostly Germans from Russia. Balta enjoys a reputation for some of the best duck and deer hunting in the State, and the community especially enjoys boating, swimming, and fishing at the Balta Dam Recreation Area.

The citizens of Balta are proud of their accomplishments and will celebrate the town's centennial with a

number of activities and hold an all-school reunion. Among the planned festivities are a ''Dam Fun Run'' at Balta Dam, an alumni basketball game, a parade, car show, street fair, pedal tractor pull, beer garden, and street dance. The activities should prove to be entertaining for all and a celebration of both the past and future of the town.

I ask the United States Senate to join me in congratulating the residents of Balta, ND, on their 100th anniversary and in wishing them a bright future. Growing up in Balta has shaped many generations of North Dakotans and instilled in them the ''North Dakota Way,'' bringing pride not only to North Dakota, but to our great Nation. This fine community is deserving of our recognition.

Balta has a proud past and a bright future.●

RECOGNIZING NEXSTRAPS

● Ms. SNOWE. Mr. President, each year on the last Monday in May we, as a nation, remember those who gave their lives while serving in the U.S. Armed Forces. Memorial Day is a chance to honor those who protect our freedom, giving others the opportunity to pursue the American dream. And it is our veteran entrepreneurs who know the sacrifices and struggles both of military service and of pursuing that dream firsthand. Today I rise to recognize and commend a family and veteran-owned small business that embodies the American entrepreneurial spirit, Nexstraps located in Blue Hill, ME.

For those who have had the pleasure to visit my home State, they know that it is blessed with an abundance of natural beauty. From the rugged wilderness of Mount Katahdin at the northern terminus of the Appalachian Trail, to the picturesque rivers and expansive forests, to the shores of Acadia National Park, Maine's beauty is derived from the physical splendor of the land. Moreover, Maine's great outdoors delivers a wealth of activities throughout every season. That is why Jeff and Kate Wright, who share a love of nature and believe life should be lived actively, outdoors, founded Nexstraps in 2007 based on those principles. Together with their family, they pursued a business plan and way of life that harmoniously marries their love of nature with creative and practical problem-solving products designed with an active lifestyle in mind.

In starting Nexstraps, necessity truly was the mother of creation. Jeff, a former Reconnaissance Marine and Navy Seal with tours of duty in Iraq and Afghanistan, was confronted with the simple challenge of holding on to his glasses during daily operations. With the goal of remedying this problem, Jeff and Kate endeavored to design and manufacture a solution. Unlike a conventional sports glasses strap that merely connects the two eyewear legs with a band behind the head, the Nexstrap secures the glasses with a single band which serves as a tether looping from the legs of the frame, around the front of the neck, and meeting at a point behind the head. This unique design ensures that should the glasses become displaced over the head, they will remain leashed around the wearer's neck. The strap can further be looped through a baseball cap, securing the hat as well. Handmade from neoprene, the Nexstrap is designed to withstand whatever challenge the extreme sportsman can throw at it, whether that is rock climbing, snowboarding, or base-jumping. They even float! This problem solving innovation is a perfect example of the ingenuity that is characteristic of Maine entrepreneurs.

I applaud Nexstraps for demonstrating the epitome of Maine innovation and entrepreneurship. The Wrights' creativity and can-do attitude is truly a reflection of the talent and entrepreneurial spirit found in my home State of Maine. As we pay tribute to our servicemembers this coming Memorial Day, I offer my gratitude and congratulations to our Nation's veteran-owned small business and extend my best wishes to Jeff and Kate Wright at Nexstraps for their continued success.●

MEASURES PLACED ON THE CALENDAR

The following bills were read the second time, and placed on the calendar:

S. 3220. A bill to amend the Fair Labor Standards Act of 1938 to provide more effective remedies to victims of discrimination in the payment of wages on the basis of sex, and for other purposes.

S. 3221. A bill to amend the National Labor Relations Act to permit employers to pay higher wages to their employees.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred as indicated:

EC–6205. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Prohydrojasmon; Amendment of Temporary Exemption from the Requirement of a Tolerance'' (FRL No. 9347–9) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6206. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Natamycin; Exemption from the Requirement of a Tolerance'' (FRL No. 9349–2) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6207. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''1, 2-Ethanediamine, N1-(2-aminoethyl)-, polymer with 2, 4-diisocyanato-1-methylbenzene; Tolerance Exemption'' (FRL No. 9349–1) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6208. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates; Pesticide Tolerances'' (FRL No. 9350–4) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6209. A communication from the Acting Under Secretary of Defense (Personnel and Readiness), transmitting the report of an officer authorized to wear the insignia of the grade of rear admiral and an officer authorized to wear the insignia of the grade of rear admiral (lower half) in accordance with title 10, United States Code, section 777; to the Committee on Armed Services.

EC–6210. A communication from the Acting Under Secretary of Defense (Personnel and Readiness), transmitting a report on the approved retirement of Vice Admiral Richard K. Gallagher, United States Navy, and his advancement to the grade of vice admiral on the retired list; to the Committee on Armed Services.

EC–6211. A communication from the Under Secretary of Defense (Personnel and Readiness), Department of Defense, transmitting, pursuant to law, a report entitled ''2012 Report to Congress on Sustainable Ranges''; to the Committee on Armed Services.

EC–6212. A communication from the Secretary of the Treasury, transmitting, pursuant to law, a six-month periodic report on the national emergency that was declared in Executive Order 13405 with respect to Belarus; to the Committee on Banking, Housing, and Urban Affairs.

EC–6213. A communication from the Chairman of the Board of Governors, Federal Reserve System, transmitting, pursuant to law, a report entitled ''Report to the Congress on the Profitability of Credit Card Operations of Depository Institutions''; to the Committee on Banking, Housing, and Urban Affairs.

EC–6214. A communication from the Chairman of the Board of Governors, Federal Reserve System, transmitting, pursuant to law, the 98th Annual Report of the Federal Reserve Board covering operations for calendar year 2011; to the Committee on Banking, Housing, and Urban Affairs.

EC–6215. A communication from the Secretary of Commerce, transmitting, pursuant to law, a report relative to the export to the People's Republic of China of items not detrimental to the U.S. space launch industry; to the Committee on Commerce, Science, and Transportation.

EC–6216. A communication from the Administrator, Transportation Security Administration, Department of Homeland Security, transmitting proposed legislation to authorize the Assistant Secretary of Homeland Security (Transportation Security Administration) to modify screening requirements for checked baggage arriving from preclearance airports and for other purposes; to the Committee on Commerce, Science, and Transportation.

EC–6217. A communication from the Attorney-Advisor, Office of the General Counsel, Department of Transportation, transmitting, pursuant to law, a report relative to a vacancy in the Saint Lawrence Seaway Development Corporation in the position of Administrator, received in the Office of the President of the Senate on May 16, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6218. A communication from the Director, Office of Surface Mining, Department of

the Interior, transmitting, pursuant to law, the report of a rule entitled ''Virginia Regulatory Program'' (Docket No. VA–126–FOR) received in the Office of the President of the Senate on May 21, 2012; to the Committee on Energy and Natural Resources.

EC–6219. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; Portion of York County, South Carolina within Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 1997 8-Hour Ozone Nonattainment Area; Ozone 2002 Base Year Emissions Inventory'' (FRL No. 9673–9) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6220. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; Oregon: Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standard'' (FRL No. 9673–7) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6221. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Regional Haze'' (FRL No. 9674–3) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6222. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Maine; Reasonably Available Control Technology (RACT) for the 1997 8-Hour Ozone Standard'' (FRL No. 9673–4) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6223. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Maryland; Baltimore Nonattainment Area Determinations of Attainment of the 1997 Annual Fine Particulate Standard'' (FRL No. 9674–5) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6224. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Vermont; Regional Haze'' (FRL No. 9674–4) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6225. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Protection of Stratospheric Ozone: The 2012 Critical Use Exemption from the Phaseout of Methyl Bromide'' (FRL No. 9668–3) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Environment and Public Works.

EC–6226. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Update of Weighted Average Interest Rates, Yield Curves, and Segment Rates'' (Notice 2012–36) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Finance.

EC–6227. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to law, certification for the export of defense articles, to include technical data, and defense services related to the export of firearms to the Assistant Inspector General (Training), Special Protection Group of India in the amount of $1,000,000 or more; to the Committee on Foreign Relations.

EC–6228. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed license to include the export of defense articles, including, technical data, or defense services sold commercially under contract to the Australian Government for installation of AN/PRC–150 and AN/PRC–152 Falcon Radio Systems in the amount of $100,000,000 or more; to the Committee on Foreign Relations.

EC–6229. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed amendment to a manufacturing assistance agreement to include the export of defense articles, including, technical data, and defense services to the United Kingdom for the manufacture of C–17 Globemaster III Transport Aircraft, Wing Trailing Edge Panels and Flap Hinge Fairings in the amount of $100,000,000 or more; to the Committee on Foreign Relations.

EC–6230. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed amendment to a technical assistance agreement to Mexico for the sale of T–6C Trainer Aircraft in the amount of $50,000,000 or more; to the Committee on Foreign Relations.

EC–6231. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed technical assistance agreement for the export of defense articles, including technical data, and defense services to Mexico for the manufacture of T–16B Inertial Sensor Assemblies (ISAs) and Accelerometer with Higher Level Triad Assembly and associated Circuit Card Assemblies in the amount of $50,000,000 or more; to the Committee on Foreign Relations.

EC–6232. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed amendment to a technical assistance agreement to New Zealand for the sale of 11 SH–2G(I) helicopters in the amount of $100,000,000 or more; to the Committee on Foreign Relations.

EC–6233. A communication from the Secretary of Commerce, transmitting, pursuant to law, a report relative to the export to the People's Republic of China of items not detrimental to the U.S. space launch industry; to the Committee on Foreign Relations.

EC–6234. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed technical assistance agreement for the sale and export of defense articles, including technical data, and defense services to the Kingdom of Brunei for delivery, operation and maintenance of 12 Sikorsky S–70i helicopters with an option to purchase an additional 10 Sikorsky S–70i helicopters in the amount of $100,000,000 or more; to the Committee on Foreign Relations.

EC–6235. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to law, a report relative to the notification that groups designated by the Secretary of State as Foreign Terrorist Organizations will be published in the Federal Register; to the Committee on Foreign Relations.

EC–6236. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed amendment to a technical assistance agreement to Canada for the manufacture of aft and forward landing gear assemblies, subassemblies, parts and components for the CH–47/MH–47 Chinook Helicopter in the amount of $50,000,000 or more; to the Committee on Foreign Relations.

EC–6237. A communication from the Chair, Advisory Council on Alzheimer's Research, Care, and Services, transmitting, pursuant to law, a report relative to recommendations for improving federally and privately funded Alzheimer's programs; to the Committee on Health, Education, Labor, and Pensions.

EC–6238. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, a report entitled ''National Plan to Address Alzheimer's Disease''; to the Committee on Health, Education, Labor, and Pensions.

EC–6239. A communication from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Disaster Assistance; Crisis Counseling Regular Program; Amendment to Regulation'' ((RIN1660–AA23) (Docket No. FEMA–2010–0064)) received in the Office of the President of the Senate on May 16, 2012; to the Committee on Homeland Security and Governmental Affairs.

EC–6240. A communication from the Under Secretary and Director, Patent and Trademark Office, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Changes in Requirements for Specimens and for Affidavits or Declarations of Continued Use or Excusable Nonuse in Trademark Cases'' (RIN0651–AC49) received in the Office of the President of the Senate on May 18, 2012; to the Committee on the Judiciary.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. KERRY, from the Committee on Foreign Relations, without amendment:

S. 414. A bill to protect girls in developing countries through the prevention of child marriage, and for other purposes (Rept. No. 112–170).

By Mr. LEAHY, from the Committee on the Judiciary, with an amendment in the nature of a substitute:

S. 2276. A bill to permit Federal officers to remove cases involving crimes of violence to Federal court.

EXECUTIVE REPORTS OF COMMITTEE

The following executive reports of nominations were submitted:

By Mr. LEVIN for the Committee on Armed Services.

*Katharina G. McFarland, of Virginia, to be an Assistant Secretary of Defense.

Air Force nomination of Lt. Gen. Herbert J. Carlisle, to be General.

Air Force nomination of Maj. Gen. Michael D. Dubie, to be Lieutenant General.

Air Force nomination of Col. Bobby V. Page, to be Brigadier General.

Air Force nomination of Gen. Philip M. Breedlove, to be General.

Air Force nomination of Lt. Gen. Larry O. Spencer, to be General.

Air Force nomination of Maj. Gen. Noel T. Jones, to be Lieutenant General.

Air Force nomination of Col. Wayne A. Zimmet, to be Brigadier General.

Army nomination of Maj. Gen. Theodore C. Nicholas, to be Lieutenant General.

Army nomination of Col. Francisco A. Espaillat, to be Brigadier General.

Army nomination of Brig. Gen. William R. Phillips II, to be Major General.

Army nominations beginning with Brigadier General Leslie J. Carroll and ending with Colonel Michael S. Tuomey, which nominations were received by the Senate and appeared in the Congressional Record on May 8, 2012.

Army nomination of Lt. Gen. Michael T. Flynn, to be Lieutenant General.

Marine Corps nomination of Lt. Gen. Thomas D. Waldhauser, to be Lieutenant General.

Marine Corps nomination of Maj. Gen. Jon M. Davis, to be Lieutenant General.

Marine Corps nomination of Lt. Gen. Robert E. Schmidle, Jr., to be Lieutenant General.

Marine Corps nomination of Lt. Gen. Terry G. Robling, to be Lieutenant General.

Marine Corps nomination of Col. Burke W. Whitman, to be Brigadier General.

Marine Corps nomination of Brig. Gen. James M. Lariviere, to be Major General.

Marine Corps nomination of Lt. Gen. John M. Paxton, Jr., to be Lieutenant General.

Marine Corps nomination of Maj. Gen. John A. Toolan, Jr., to be Lieutenant General.

Marine Corps nomination of Col. Paul K. Lebidine, to be Brigadier General.

Marine Corps nomination of Lt. Gen. Robert B. Neller, to be Lieutenant General.

Navy nomination of Vice Adm. William E. Gortney, to be Admiral.

Navy nomination of Rear Adm. Kurt W. Tidd, to be Vice Admiral.

Navy nomination of Vice Adm. David H. Buss, to be Vice Admiral.

Navy nomination of Rear Adm. Michelle J. Howard, to be Vice Admiral.

Navy nomination of Rear Adm. Thomas H. Copeman III, to be Vice Admiral.

Navy nomination of Vice Adm. Richard W. Hunt, to be Vice Admiral.

Navy nomination of Capt. John F. Kirby, to be Rear Admiral (lower half).

Navy nomination of Capt. Brian B. Brown, to be Rear Admiral (lower half).

Mr. LEVIN. Mr. President, for the Committee on Armed Services I report favorably the following nomination lists which were printed in the RECORDS on the dates indicated, and ask unanimous consent, to save the expense of reprinting on the Executive Calendar that these nominations lie at the Secretary's desk for the information of Senators.

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

Air Force nomination of Tonya R. Everleth, to be Lieutenant Colonel.

Air Force nominations beginning with Craig W. Hinkley and ending with Chad A. Spellman, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Air Force nominations beginning with Johann S. Westphall and ending with Eliesa A. Ing, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Air Force nominations beginning with Mark J. Batcho and ending with Frederick C. Weaver, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Air Force nomination of Robert M. Ague, to be Colonel.

Air Force nominations beginning with Leslie A. Wood and ending with Matthew L. Smith, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Air Force nominations beginning with Nathan Barry Alholinna and ending with Craig M. Ziemba, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Air Force nomination of James J. Renda, to be Major.

Air Force nomination of August S. Hein, to be Colonel.

Air Force nominations beginning with Christopher J. Mathews and ending with Timothy K. Williams, which nominations were received by the Senate and appeared in the Congressional Record on May 14, 2012.

Army nomination of Israel Mercado, Jr., to be Lieutenant Colonel.

Army nominations beginning with Francis J. Evon, Jr. and ending with Mark S. Wellman, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Army nomination of Chadwick B. Fletcher, to be Major.

Army nominations beginning with Rhanda J. Brockington and ending with Vickie M. Schnackel, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Army nominations beginning with Richard A. Daniels and ending with Daniel J. Holdwick, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Army nominations beginning with Andrew C. Gallo and ending with Christa M. Lewis, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Army nomination of John C. Moffitt, to be Major.

Army nomination of Mimms J. Mabee, to be Colonel.

Army nomination of Jonelle J. Knapp, to be Major.

Army nomination of Robert E. Bessey, to be Major.

Army nomination of Laurel A. Thurston, to be Major.

Army nomination of Tina M. Morgan, to be Major.

Army nominations beginning with Karl W. Hubbard and ending with Benjamin N. Hoffman, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Army nominations beginning with Joann B. Couch and ending with Richard J. Yoon, which nominations were received by the Senate and appeared in the Congressional Record on May 10, 2012.

Army nomination of Ricardo A. Bravo, to be Lieutenant Colonel.

Army nomination of Matthew W. Moffitt, to be Lieutenant Colonel.

Army nomination of Nathaniel V. Chittick, to be Major.

Army nomination of Lauri M. Zike, to be Major.

Army nomination of Timothy A. Crane, to be Major.

Army nomination of Ryan L. Jerke, to be Major.

Army nomination of Matthew R. Sun, to be Major.

Army nominations beginning with Gregory P. Chaney and ending with Lawrence E. Schloegl, which nominations were received by the Senate and appeared in the Congressional Record on May 14, 2012.

Army nominations beginning with Amy F. Cook and ending with Paul S. Tamaribuchi, which nominations were received by the Senate and appeared in the Congressional Record on May 14, 2012.

Army nominations beginning with Michael I. Allen and ending with Matthew S. Wysocki, which nominations were received by the Senate and appeared in the Congressional Record on May 14, 2012.

Marine Corps nominations beginning with Martin L. Abreu and ending with Robert C. Zyla, which nominations were received by the Senate and appeared in the Congressional Record on February 1, 2012.

Navy nomination of John D. Wilshusen, to be Captain.

Navy nomination of Peter J. Oldmixon, to be Commander.

Navy nomination of Guillermo A. Navarro, to be Commander.

Navy nomination of Raymond J. Houk, to be Captain.

Navy nomination of Jason D. Weddle, to be Commander.

Navy nomination of Andrew J. Strickler, to be Commander.

Navy nomination of Andrew K. Ledford, to be Commander.

Navy nominations beginning with John L. Grimwood and ending with Robyn M. Treadwell, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Navy nominations beginning with Darius V. Ahmadi and ending with Scott D. Woods, which nominations were received by the Senate and appeared in the Congressional Record on April 23, 2012.

Navy nomination of Matthew F. Phelps, to be Commander.

Navy nomination of Eric J. Skalski, to be Lieutenant Commander.

Navy nomination of Ted J. Steelman, to be Lieutenant Commander.

Navy nomination of David A. Moore, to be Lieutenant Commander.

Navy nomination of Steven J. Porter, to be Commander.

*Nomination was reported with recommendation that it be confirmed subject to the nominee's commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.

(Nominations without an asterisk were reported with the recommendation that they be confirmed.)

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. CARDIN (for himself, Mr. ROBERTS, and Ms. SNOWE):

S. 3223. A bill to amend the Internal Revenue Code of 1986 to permanently extend the reduction in the recognition period for built-in gains for S corporations; to the Committee on Finance.

By Ms. STABENOW:

S. 3224. A bill to amend the Internal Revenue Code of 1986 to prevent an unfair tax burden for veterans and homeowners who have received assistance from the National

Mortgage Settlement, and for other purposes; to the Committee on Finance.

By Mr. WYDEN:

S. 3225. A bill to require the United States Trade Representative to provide documents relating to trade negotiations to Members of Congress and their staff upon request, and for other purposes; to the Committee on Finance.

By Ms. KLOBUCHAR (for herself and Ms. MIKULSKI):

S. 3226. A bill to amend the Internal Revenue Code of 1986 to provide an income tax credit for eldercare expenses; to the Committee on Finance.

By Mr. NELSON of Florida (for himself and Mr. BLUNT):

S. 3227. A bill to enable concrete masonry products manufacturers and importers to establish, finance, and carry out a coordinated program of research, education, and promotion to improve, maintain, and develop markets for concrete masonry products; to the Committee on Commerce, Science, and Transportation.

By Mr. THUNE (for himself, Mr. SESSIONS, Mr. MCCONNELL, Ms. AYOTTE, Mr. ROBERTS, Mr. WICKER, Mr. BOOZMAN, Mr. BARRASSO, Mr. COATS, Mr. INHOFE, Ms. MURKOWSKI, Mr. COCHRAN, Mr. JOHNSON of Wisconsin, Mr. VITTER, Mr. DEMINT, Mr. TOOMEY, Mr. GRASSLEY, Mr. ISAKSON, Mr. JOHANNS, Mr. CHAMBLISS, Mr. GRAHAM, Mr. BURR, Mr. COBURN, Mr. RISCH, Mr. BLUNT, Mr. PAUL, Mr. MORAN, Mr. CORNYN, Mr. HATCH, and Mr. ENZI):

S. 3228. A bill to require the President to provide a report detailing the sequester required by the Budget Control Act of 2011 on January 2, 2013; to the Committee on the Budget.

By Ms. KLOBUCHAR (for herself and Mr. KOHL):

S. 3229. A bill to develop a model disclosure form to assist consumers in purchasing long-term care insurance; to the Committee on Health, Education, Labor, and Pensions.

By Ms. KLOBUCHAR:

S. 3230. A bill to require issuers of long term care insurance to establish third-party review processes for disputed claims; to the Committee on Health, Education, Labor, and Pensions.

By Mr. KERRY (for himself, Mr. GRASSLEY, Ms. LANDRIEU, Mr. CARDIN, Mr. WYDEN, and Mr. COCHRAN):

S. 3231. A bill to provide for the issuance and sale of a semipostal by the United States Postal Service to support effective programs targeted at improving permanency outcomes for youth in foster care; to the Committee on Homeland Security and Governmental Affairs.

By Mr. MENENDEZ:

S. 3232. A bill to amend the Internal Revenue Code of 1986 and the Patient Protection and Affordable Care Act to extend, expand, and improve the qualifying therapeutic discovery project program; to the Committee on Finance.

By Mr. CASEY (for himself and Mr. WYDEN):

S. 3233. A bill to amend title 38, United States Code, to improve the enforcement of employment and reemployment rights of members of the uniformed services, and for other purposes; to the Committee on Veterans' Affairs.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. ENZI (for himself, Mr. BARRASSO, Mr. BAUCUS, Mr. BINGAMAN, Mr. CONRAD, Mr. CRAPO, Mr. HOEVEN, Mr. INHOFE, Mr. JOHANNS, Mr. JOHNSON of South Dakota, Mr. MERKLEY, Mr. REID, Mr. RISCH, and Mr. TESTER):

S. Res. 470. A resolution designating July 28, 2012, as ''National Day of the American Cowboy''; to the Committee on the Judiciary.

By Ms. COLLINS (for herself, Mrs. SHAHEEN, Mr. LIEBERMAN, Mr. NELSON of Florida, Ms. SNOWE, Mr. INHOFE, Mr. COCHRAN, Mr. PRYOR, Mrs. HUTCHISON, Ms. LANDRIEU, Ms. MIKULSKI, Mrs. BOXER, and Mrs. FEINSTEIN):

S. Res. 471. A resolution commending the efforts of the women of the American Red Cross Clubmobiles for exemplary service during the Second World War; to the Committee on the Judiciary.

ADDITIONAL COSPONSORS

S. 687

At the request of Mr. CONRAD, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 687, a bill to amend the Internal Revenue Code of 1986 to permanently extend the 15-year recovery period for qualified leasehold improvement property, qualified restaurant property, and qualified retail improvement property.

S. 845

At the request of Mr. ENZI, the names of the Senator from North Dakota (Mr. CONRAD), the Senator from Montana (Mr. TESTER) and the Senator from Michigan (Ms. STABENOW) were added as cosponsors of S. 845, a bill to amend the Internal Revenue Code of 1986 to provide for the logical flow of return information between partnerships, corporations, trusts, estates, and individuals to better enable each party to submit timely, accurate returns and reduce the need for extended and amended returns, to provide for modified due dates by regulation, and to conform the automatic corporate extension period to longstanding regulatory rule.

S. 930

At the request of Mr. SCHUMER, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 930, a bill to amend the Internal Revenue Code of 1986 to provide the same capital gains treatment for art and collectibles as for other investment property and to provide that a deduction equal to fair market value shall be allowed for charitable contributions of literary, musical, artistic, or scholarly compositions created by the donor.

S. 1171

At the request of Mr. SCHUMER, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 1171, a bill to amend the Internal Revenue Code of 1986 to extend the exclusion from gross income for employer-provided health coverage for employees' spouses and dependent children to coverage provided to other eligible dependent beneficiaries of employees.

S. 1512

At the request of Mr. CARDIN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1512, a bill to amend the Internal Revenue Code of 1986 and the Small Business Act to expand the availability of employee stock ownership plans in S corporations, and for other purposes.

S. 1884

At the request of Mr. DURBIN, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. 1884, a bill to provide States with incentives to require elementary schools and secondary schools to maintain, and permit school personnel to administer, epinephrine at schools.

S. 2076

At the request of Mr. LEAHY, his name was added as a cosponsor of S. 2076, a bill to improve security at State and local courthouses.

S. 2134

At the request of Mr. BLUMENTHAL, the names of the Senator from Vermont (Mr. SANDERS) and the Senator from Kansas (Mr. ROBERTS) were added as cosponsors of S. 2134, a bill to amend title 10, United States Code, to provide for certain requirements relating to the retirement, adoption, care, and recognition of military working dogs, and for other purposes.

S. 2168

At the request of Mr. BLUMENTHAL, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 2168, a bill to amend the National Labor Relations Act to modify the definition of supervisor.

S. 2179

At the request of Mr. WEBB, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 2179, a bill to amend title 38, United States Code, to improve oversight of educational assistance provided under laws administered by the Secretary of Veterans Affairs and the Secretary of Defense, and for other purposes.

S. 2250

At the request of Ms. STABENOW, the names of the Senator from Minnesota (Ms. KLOBUCHAR), the Senator from New York (Mrs. GILLIBRAND) and the Senator from Michigan (Mr. LEVIN) were added as cosponsors of S. 2250, a bill to prevent homeowners from being forced to pay taxes on forgiven mortgage loan debt.

S. 2257

At the request of Ms. STABENOW, the name of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of S. 2257, a bill to increase access to community behavioral health services for all Americans and to improve Medicaid reimbursement for community behavioral health services.

S. 2276

At the request of Mr. GRASSLEY, the names of the Senator from New York (Mr. SCHUMER), the Senator from Connecticut (Mr. BLUMENTHAL) and the

Senator from Illinois (Mr. DURBIN) were added as cosponsors of S. 2276, a bill to permit Federal officers to remove cases involving crimes of violence to Federal court.

S. 2288

At the request of Ms. LANDRIEU, the name of the Senator from Maine (Ms. SNOWE) was added as a cosponsor of S. 2288, a bill to amend title XXVII of the Public Health Service Act to preserve consumer and employer access to licensed independent insurance producers.

S. 2554

At the request of Mr. LEAHY, the name of the Senator from Oregon (Mr. MERKLEY) was added as a cosponsor of S. 2554, a bill to amend title I of the Omnibus Crime Control and Safe Streets Act of 1968 to extend the authorization of the Bulletproof Vest Partnership Grant Program through fiscal year 2017.

S. 2620

At the request of Mr. SCHUMER, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 2620, a bill to amend title XVIII of the Social Security Act to provide for an extension of the Medicare-dependent hospital (MDH) program and the increased payments under the Medicare low-volume hospital program.

S. 3049

At the request of Mr. BEGICH, the name of the Senator from Montana (Mr. TESTER) was added as a cosponsor of S. 3049, a bill to amend title 39, United States Code, to expand the definition of homeless veteran for purposes of benefits under the laws administered by the Secretary of Veterans Affairs.

S. 3083

At the request of Mr. RUBIO, the names of the Senator from Kentucky (Mr. MCCONNELL), the Senator from Oklahoma (Mr. INHOFE), the Senator from Utah (Mr. LEE), the Senator from Indiana (Mr. COATS), the Senator from Arkansas (Mr. BOOZMAN), the Senator from Idaho (Mr. RISCH), the Senator from Kansas (Mr. ROBERTS), the Senator from New Hampshire (Ms. AYOTTE), the Senator from Mississippi (Mr. WICKER), the Senator from Wyoming (Mr. BARRASSO), the Senator from North Carolina (Mr. BURR), the Senator from Missouri (Mr. BLUNT), the Senator from Kentucky (Mr. PAUL), the Senator from North Dakota (Mr. HOEVEN), the Senator from Nebraska (Mr. JOHANNS) and the Senator from Tennessee (Mr. CORKER) were added as cosponsors of S. 3083, a bill to amend the Internal Revenue Code of 1986 to require certain nonresident aliens to provide valid immigration documents to claim the refundable portion of the child tax credit.

S. 3205

At the request of Mr. SCHUMER, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 3205, a bill to amend the Internal Revenue Code of 1986 to provide that persons renouncing citizenship for a substantial tax avoidance purpose shall be subject to tax and withholding on capital gains, to provide that such persons shall not be admissible to the United States, and for other purposes.

S. 3221

At the request of Mr. MCCONNELL, his name was added as a cosponsor of S. 3221, a bill to amend the National Labor Relations Act to permit employers to pay higher wages to their employees.

S.J. RES. 40

At the request of Mr. RUBIO, the name of the Senator from South Dakota (Mr. THUNE) was added as a cosponsor of S.J. Res. 40, a joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rules submitted by the Department of the Treasury and the Internal Revenue Service relating to the reporting requirements for interest that relates to the deposits maintained at United States offices of certain financial institutions and is paid to certain nonresident alien individuals.

AMENDMENT NO. 2117

At the request of Mr. ROCKEFELLER, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor of amendment No. 2117 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2118

At the request of Mr. ROCKEFELLER, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor of amendment No. 2118 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2119

At the request of Mr. ROCKEFELLER, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor of amendment No. 2119 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2146

At the request of Mr. PORTMAN, the names of the Senator from Iowa (Mr. GRASSLEY) and the Senator from New York (Mr. SCHUMER) were added as cosponsors of amendment No. 2146 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. WYDEN:

S. 3225. A bill to require the United States Trade Representative to provide documents relating to trade negotiations to Members of Congress and their staff upon request, and for other purposes; to the Committee on Finance.

Mr. WYDEN. Mr. President, right now, the Obama Administration is in the process of negotiating what might prove to be the most far-reaching economic agreement since the World Trade Organization was established nearly twenty years ago.

The goal of this agreement—known as the Trans Pacific Partnership, TPP—is to economically bind together the economies of the Asia Pacific. It involves countries ranging from Australia, Singapore, Vietnam, Peru, Chile and the United States and holds the potential to include many more countries, like Japan, Korea, Canada, and Mexico. If successful, the agreement will set norms for the trade of goods and services and includes disciplines related to intellectual property, access to medicines, Internet governance, investment, government procurement, worker rights and environmental standards.

If agreed to, TPP will set the tone for our nation's economic future for years to come, impacting the way Congress intervenes and acts on behalf of the American people it represents.

It may be the U.S. Trade Representative's, USTR, current job to negotiate trade agreements on behalf of the United States, but Article 1 Section 8 of the U.S. Constitution gives Congress—not the USTR or any other member of the Executive Branch—the responsibility of regulating foreign commerce. It was our Founding Fathers' intention to ensure that the laws and policies that govern the American people take into account the interests of all the American people, not just a privileged few.

Yet, the majority of Congress is being kept in the dark as to the substance of the TPP negotiations, while representatives of U.S. corporations—like Halliburton, Chevron, PHRMA, Comcast, and the Motion Picture Association of America—are being consulted and made privy to details of the agreement. As the Office of the USTR will tell you, the President gives it broad power to keep information about the trade policies it advances and negotiates, secret. Let me tell you, the USTR is making full use of this authority.

As the Chairman of the Senate Finance Committee's Subcommittee on International Trade, Customs, and Global Competitiveness, my office is responsible for conducting oversight over the USTR and trade negotiations. To do that, I asked that my staff obtain the proper security credentials to view the information that USTR keeps confidential and secret. This is material that fully describes what the

USTR is seeking in the TPP talks on behalf of the American people and on behalf of Congress. More than two months after receiving the proper security credentials, my staff is still barred from viewing the details of the proposals that USTR is advancing.

We hear that the process by which TPP is being negotiated has been a model of transparency. I disagree with that statement. And not just because the Staff Director of the Senate subcommittee responsible for oversight of international trade continues to be denied access to substantive and detailed information that pertains to the TPP talks.

Congress passed legislation in 2002 to form the Congressional Oversight Group, or COG, to foster more USTR consultation with Congress. I was a senator in 2002. I voted for that law and I can tell you the intention of that law was to ensure that USTR consulted with more Members of Congress not less.

In trying to get to the bottom of why my staff is being denied information, it seems that some in the Executive Branch may be interpreting the law that established the COG to mean that only the few Members of Congress who belong to the COG can be given access to trade negotiation information, while every other Member of Congress, and their staff, must be denied such access. So, this is not just a question of whether or not cleared staff should have access to information about the TPP talks, this is a question of whether or not the administration believes that most Members of Congress can or should have a say in trade negotiations.

Again, having voted for that law, I strongly disagree with such an interpretation and find it offensive that some would suggest that a law meant to foster more consultation with Congress is intended to limit it. But given that the TPP negotiations are currently underway and I—and the vast majority of my colleagues and their staff—continue to be denied a full understanding of what the USTR is seeking in the agreement, we do not have time to waste on a protracted legal battle over this issue. Therefore, I am introducing legislation to clarify the intent of the COG statute.

The legislation, I propose, is straightforward. It gives all Members of Congress and staff with appropriate clearance access to the substance of trade negotiations. Finally, Members of Congress who are responsible for conducting oversight over the enforcement of trade agreements will be provided information by the Executive Branch indicating whether our trading partners are living up to their trade obligations. Put simply, this legislation would ensure that the representatives elected by the American people are afforded the same level of influence over our nation's policies as the paid representatives of PHRMA, Halliburton and the Motion Picture Association.

My intent is to do everything I can to see that this legislation is advanced quickly and becomes law, so that elected Members of Congress can do what the Constitution requires and what their constituents expect.

By Mr. KERRY (for himself, Mr. GRASSLEY, Ms. LANDRIEU, Mr. CARDIN, Mr. WYDEN, and Mr. COCHRAN):

S. 3231. A bill to provide for the issuance and sale of a semipostal by the United States Postal Service to support effective programs targeted at improving permanency outcomes for youth in foster care; to the Committee on Homeland Security and Governmental Affairs.

Mr. KERRY. Mr. President, as we recognize May as National Foster Care Month, we should take a minute to think about what foster care means for children in America. We currently have over 408,000 children in our foster care system due to abuse or neglect by their biological families, with 107,000 as eligible for adoption. Every year nearly 28,000 of these children age out of our foster care system with no place to call home. On average, foster children spend over 3 years in the system and around 16 percent languish in the foster care system for over 5 years. These numbers are a stark reminder that we must do more to connect children in our foster care system with a safe, loving, and permanent home.

I have worked with my colleague Senator GRASSLEY on a bipartisan bill that will provide supplemental funds to programs that directly impact children in our foster care system. The Families for Foster Youth Stamp Act will provide additional funding for the Court Improvement Program and the Adoption Opportunities Program by giving an easy option for individuals to pay a few cents more for their postage stamps if they choose to.

By providing a boost in resources to the Court Improvement Program, states can enhance their capacity to serve children in the system, build upon best practices, and improve the quality of representation our children receive. Funds going to the Adoption Opportunities Program will support programs that target improvement in permanency outcomes for youth in foster care through adoption, guardianship, or kinship care. We know that youth who are served by effective programs targeting permanent placement options have shown to be more likely to find a forever family than the national average. No teenager should exit our foster care system alone, facing possible homelessness and without the type of support system that only a family can provide. The Families for Foster Youth Stamp Act provides a unique funding option to supplement programs that make a real and tangible difference in the lives of our most at-risk children.

A number of organizations are supportive of this bill, including the American Professional Society on the Abuse of Children, Children's Action Network, Children's Advocacy Institute, Child Welfare League of America, First Focus Campaign for Children, Foster Club, National Association of Council for Children, National Children's Alliance, National Council for Adoption, Northwest Adoption Exchange, The Adoption Exchange, and Voice for Adoption.

I would like to recognize Senators GRASSLEY, LANDRIEU, CARDIN, WYDEN, and COCHRAN as original cosponsors of this bill. I look forward to continued progress in developing a more effective child welfare system and ask all of my colleagues to support this important legislation.

By Mr. CASEY (for himself and Mr. WYDEN):

S. 3233. A bill to amend title 38, United States Code, to improve the enforcement of employment and reemployment rights of members of the uniformed services, and for other purposes; to the Committee on Veterans' Affairs.

SERVICEMEMBERS ACCESS TO JUSTICE ACT OF 2012

Mr. CASEY. Mr. President, the brave men and women serving our country in the military, the National Guard and the Reserves have sacrificed time away from their families, jobs and lives throughout Operation Enduring Freedom and Operation Iraqi Freedom. Even upon their safe return, many of these men and women suffer physical, personal, and financial effects from their deployment and time in combat. This is compounded when our servicemembers return home from their deployment or service to find that their employers will not promptly reinstate them in their civilian jobs, as required by the Uniformed Services Employment and Reemployment Rights Act of 1994, USERRA. Although USERRA should protect servicemembers against this type of discrimination, the process for filing a complaint can be unwieldy and expensive. No single Federal agency has oversight over this process, and investigations can drag on for months, including while servicemembers are deployed overseas. Our military personnel and their families should not be burdened by this additional stress and financial strain.

Pennsylvania has the nation's largest Army National Guard and fourth-largest Air National Guard. We owe it to these brave men and women to renew America's social commitment to the National Guard and Reserve, and to update National Guard and Reserve programs and benefits to reflect the operation tempo of their service. This is why I am today reintroducing the Servicemembers Access to Justice Act, which would eliminate loopholes and strengthen protections in the current law. Furthermore, this bill would bring a newfound clarity and understanding of the law for courts and employers.

The Servicemembers Access to Justice Act makes it easier for our servicemembers to fight for their USERRA rights in court if their employer requires them to relinquish them in order to be hired for or keep their job. This legislation would mandate studies of current employer education programs and solicit recommendations for ways in which government agencies could cooperate to enhance employer education. Additionally, the Servicemembers Access to Justice Act would enhance the remedies available to servicemembers who prove their rights under USERRA were violated, by adding increased penalties for willful violations.

We owe it to our servicemembers to ensure the fair enforcement of their employment rights. These men and women deserve our gratitude, and I am committed to supporting them during and after their service. Please join me in supporting this legislation.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 470—DESIGNATING JULY 28, 2012, AS ''NATIONAL DAY OF THE AMERICAN COWBOY''

Mr. ENZI (for himself, Mr. BARRASSO, Mr. BAUCUS, Mr. BINGAMAN, Mr. CONRAD, Mr. CRAPO, Mr. HOEVEN, Mr. INHOFE, Mr. JOHANNS, Mr. JOHNSON of South Dakota, Mr. MERKLEY, Mr. REID of Nevada, Mr. RISCH, and Mr. TESTER) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 470

Whereas pioneering men and women, recognized as ''cowboys'', helped establish the American West;

Whereas the cowboy embodies honesty, integrity, courage, compassion, respect, a strong work ethic, and patriotism;

Whereas the cowboy spirit exemplifies strength of character, sound family values, and good common sense;

Whereas the cowboy archetype transcends ethnicity, gender, geographic boundaries, and political affiliations;

Whereas the cowboy is an excellent steward of the land and its creatures, who lives off the land and works to protect and enhance the environment;

Whereas cowboy traditions have been a part of American culture for generations;

Whereas the cowboy continues to be an important part of the economy through the work of many thousands of ranchers across the United States who contribute to the economic well-being of every State;

Whereas millions of fans watch professional and working ranch rodeo events annually, making rodeo one of the most-watched sports in the United States;

Whereas membership and participation in rodeo and other organizations that promote and encompass the livelihood of cowboys span every generation and transcend race and gender;

Whereas the cowboy is a central figure in literature, film, and music and occupies a central place in the public imagination;

Whereas the cowboy is an American icon; and

Whereas the ongoing contributions made by cowboys and cowgirls to their communities should be recognized and encouraged: Now, therefore, be it

Resolved, That the Senate—

(1) designates July 28, 2012, as ''National Day of the American Cowboy''; and

(2) encourages the people of the United States to observe the day with appropriate ceremonies and activities.

Mr. ENZI. Mr. President, I am proud to submit a resolution today to designate Saturday, July 28, 2012 as National Day of the American Cowboy. My late colleague, Senator Craig Thomas, began the tradition of honoring the men and women known as ''cowboys'' seven years ago when he introduced the first resolution to designate the fourth Saturday of July as National Day of the American Cowboy. I am proud to carry on Senator Thomas's tradition.

The resolution celebrates the history of cowboys in America and recognizes the important work today's cowboys are doing in the United States. The cowboy Spirit is about honesty, integrity, courage, and patriotism, and cowboys are models of strong character, sound family values, and good common sense. The first cowboys relied on hard work and persistence to make their living in a tough country. Today's cowboys haven't changed all that much from the first wranglers and ranch hands who started herding cattle on the Great Plains.

Cowboys continue to make important contributions to our economy, Western culture and my home State of Wyoming today. They live and work in every State to manage nearly 100 million cattle. Cowboys work hard, but they also play hard. Rodeo is a sport that tests skill with a rope or challenges a cowboy's ability to stay on the back of bucking rough stock for 8 long seconds. Rodeos across the nation draw millions of fans every year.

This year's resolution designates July 28, 2012, as the National Day of the American Cowboy. I look forward to celebrating this day, and I hope my colleagues will join me in recognizing the important role cowboys play in our country.

SENATE RESOLUTION 471—COMMENDING THE EFFORTS OF THE WOMEN OF THE AMERICAN RED CROSS CLUBMOBILES FOR EXEMPLARY SERVICE DURING THE SECOND WORLD WAR

Ms. COLLINS (for herself, Mrs. SHAHEEN, Mr. LIEBERMAN, Mr. NELSON of Florida, Ms. SNOWE, Mr. INHOFE, Mr. COCHRAN, Mr. PRYOR, Mrs. HUTCHISON, Ms. LANDRIEU, Ms. MIKULSKI, Mrs. BOXER, and Mrs. FEINSTEIN) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 471

Whereas, during the Second World War, the American Red Cross was charged by the United States Armed Forces with providing recreational services to the soldiers serving in the war;

Whereas Harvey Gibson, the Red Cross Commissioner to Great Britain during the war, conceived of the Clubmobiles in 1942 as a means of providing hot coffee, fresh doughnuts, and a vital connection to home to thousands of servicemen at dozens of airfields, bases, and camps throughout Great Britain during the buildup to D-Day;

Whereas thousands of young women, from every State in the United States, volunteered to serve in the Clubmobiles, and were chosen after a rigorous interview process in which less than 20 percent of applicants were selected;

Whereas, less than 1 month after the invasion of Normandy, France in June 1944, 80 Clubmobiles and 320 American Red Cross volunteers crossed the English Channel and began providing coffee, doughnuts, and a friendly smile to servicemen fighting on the front lines;

Whereas the Clubmobile volunteers saw service across Europe in France, Belgium, Italy, Luxembourg, and Germany, and later in the Far East, touching the lives of hundreds of thousands of United States servicemen until victory was achieved;

Whereas, during the war, the American Red Cross purchased enough flour to produce more than 1,500,000,000 doughnuts, many served from the windows of a Clubmobile;

Whereas a visit from a Clubmobile, which could serve gallons of coffee and hundreds of doughnuts every minute, was often the most significant morale boost available to servicemen at war;

Whereas 52 women of the American Red Cross, some of whom served on the Clubmobiles, perished during the war as a result of their service; and

Whereas 70 years have passed since the Clubmobiles were founded, and only a few women who served in the Clubmobiles remain to share their stories: Now, therefore, be it

Resolved, That the Senate—

(1) commends the exemplary and courageous service and sacrifice of each of the patriotic women of the United States who served in the American Red Cross Clubmobiles during the Second World War;

(2) honors the Clubmobile women who lost their lives during the Second World War;

(3) calls upon historians of the Second World War to recognize and describe the service of the Clubmobiles, and to not let this important piece of United States history be lost; and

(4) urges the American Red Cross to publicly commemorate the stories of the Clubmobiles and the amazing women who served in them.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2150. Ms. SNOWE (for herself, Mr. MCCAIN, Mr. VITTER, Ms. KLOBUCHAR, and Mrs. SHAHEEN) submitted an amendment intended to be proposed by her to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2151. Mr. MANCHIN (for himself, Mr. KIRK, Mrs. GILLIBRAND, Mr. SCHUMER, and Mr. ROCKEFELLER) submitted an amendment intended to be proposed by him to the bill S. 3187, supra.

SA 2152. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 2150. Ms. SNOWE (for herself, Mr. MCCAIN, Mr. VITTER, Ms. KLOBUCHAR, and Mrs. SHAHEEN) submitted an amendment intended to be proposed by her to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE XII—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 1201. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2012''.

SEC. 1202. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring 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;

(5) Americans spend more than $200,000,000,000 on prescription drugs every year;

(6) 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; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. 1203. 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 amended by striking section 804.

SEC. 1204. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 1203, is further amended by inserting after section 803 the following:

''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 a 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 a 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—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(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;

''(III) an infused drug, including a peritoneal dialysis solution;

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(D) OTHER DEFINITIONS.—For purposes of this section:

''(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, 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.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

''(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

''(II) 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;

''(iii) a 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 regulation of human pharmaceutical products that has not expired; or

''(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

''(iv) Japan;

''(v) New Zealand;

''(vi) Switzerland; and

''(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 (vi).

''(III) The importation of drugs to the United States from the country will not adversely affect public health.

''(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

''(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

''(A)(i) In the case of an exporter, the name of the exporter and an identification of all 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) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

''(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

''(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the 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); or

''(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 as a pharmacist; conditions for individual importation; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B) against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter:

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000.

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines 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 termination 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 export or import 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) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(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 has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is 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 drug 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 report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition

agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(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 for distribution in a foreign country that is not a permitted country).

''(3) 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);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) the foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting 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 (3); 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 randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of 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 anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter 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 from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or 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 exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) 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.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(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 of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs 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 identity of the drug, 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;

''(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

''(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

''(J) such other information as the Secretary may require by regulation.

''(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(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.

''(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 anticounterfeiting or 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.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer 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 provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(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 necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) 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

''(iii) 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).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) 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 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 the estimate under clause (i) 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 by each registered importer 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 (ii) 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 importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER 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 importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—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) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

''(C) 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, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(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 provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(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 exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection 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).

''(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 exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters 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)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a 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 provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(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 exporter of the volume of qualifying drugs exported by exporters under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—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) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

''(C) 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, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection (a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling); or

''(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling).

''(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) 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, or with respect to which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a 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 submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—

''(I) IN GENERAL.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Fees collected by the Secretary under the preceding sentence are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(II) FEE AMOUNT FOR CERTAIN YEARS.—If no fee amount is in effect under section 736(a)(1)(A)(ii) for a fiscal year, then the amount paid by a person under subclause (I) shall—

''(aa) for the first fiscal year in which no fee amount under such section in effect, be equal to the fee amount under section 736(a)(1)(A)(ii) for the most recent fiscal year for which such section was in effect, adjusted in accordance with section 736(c); and

''(bb) for each subsequent fiscal year in which no fee amount under such section is effect, be equal to the applicable fee amount for the previous fiscal year, adjusted in accordance with section 736(c).

''(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 requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug 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 introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary shall—

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove 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) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration 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 subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under subsection (c) or (d)(3)(B)(i) of section 506A, require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved 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.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application 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.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug 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) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved 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) If the Secretary determines that such a supplemental application regarding 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 REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

''(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, 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).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

''(IV) include such additional information as the Secretary may require.

''(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

''(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

''(v) 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 qualifying drug bears—

''(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

''(II) the name of the manufacturer and location of the manufacturer;

''(III) the lot number assigned by the manufacturer;

''(IV) the name, location, and registration number of the importer; and

''(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

''(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

''(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

''(III) if required under paragraph (2)(B)(vi)(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 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 a registered exporter to 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 Packaging 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)(vi)(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—

''(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under subparagraph (C) or (D) of paragraph (2).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of 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 practice.

''(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.

''(I) The manufacturer of the drug has instituted a recall of the drug.

''(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

''(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

''(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.

''(h) 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—

''(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) 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.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

''(1) 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)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not more than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

''(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(ii) a list of the ingredients of the drug as would be required under section 502(e).

''(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

''(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under paragraphs (3), (4), and (5) of section 1204(e) of the Pharmaceutical Market Access and Drug Safety Act of 2012, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(iii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment,

manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

''(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

''(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 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 effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) 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 prescription 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 in the United States, or covered entity in the drug discount program under section 340B 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 to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, 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 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(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) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(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), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant 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 relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an 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 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 system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(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' means any entity, including 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 by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) 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 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(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 provided to the Secretary, under such section, or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i)(2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(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 shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, 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 510(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 drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this Act.

(d) EXHAUSTION.—

(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 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 ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—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 such 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 Act; 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 Act.

(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 Act 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 disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, 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 Act shall not serve as a basis, in whole or in part, for disapproving a registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as 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 Act, 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 any 1-year period beginning on a date that is 2 or more years after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, 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.

(3) LIMITS ON NUMBER OF 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 Act, 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 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 imported into 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 Act, 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 into 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 Act, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES 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 Act 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 Act 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 Act 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 Act 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 is first completed on the date that is 120 days after 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.

(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 Act 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 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 the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (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 the notices with respect to drugs 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 Act 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) REPORT.—Beginning with the first full fiscal year after the date of enactment of this Act, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in 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.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(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 exporters during 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.

(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) SECOND YEAR ADJUSTMENT.—

(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 subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), 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 be 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 fee due on April 1 of the second 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 does not exceed 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 reestimated 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 user 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 and the use, 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 PROTECTION.—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 of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to 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 by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional permitted 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 permitted countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) 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) NO 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.

(3) 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 by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) 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 and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. 1205. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

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

"SEC. 810. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) 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 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE 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, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(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 810 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 Act.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this Act.

SEC. 1206. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS 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 or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

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

''(B) The fact that a drug subject to subsection (b) is exported 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 statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2014.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 1204.

(3) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this Act.

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2014.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this Act.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this Act, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the 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

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(bb) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. 1207. 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 503B the following:

''SEC. 503C. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) 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 purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

''(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

''(C) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

''(i) are not intended to be accessed by purchasers or prospective purchasers; or

''(ii) 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)).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) 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 sales of prescription drugs through the Internet, other than a place of business that does not mail or ship prescription drugs 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 providing prescriptions, 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 or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) 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;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, 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;

''(D) the person knew, or had reason 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 consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(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 program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider 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 Secretary 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 relationship with the patient for purposes of this section if—

''(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

''(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

''(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

''(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

''(e) GENERAL DEFINITIONS.—For purposes of this section:

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

''(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive

computer service or of advertising services does not own or exercise corporate control over such person.

''(h) NO EFFECT ON OTHER REQUIREMENTS; COORDINATION.—The requirements of this section are in addition to, and do not supersede, any requirements under the Controlled Substances Act or the Controlled Substances Import and Export Act (or any regulation promulgated under either such Act) regarding Internet pharmacies and controlled substances. In promulgating regulations to carry out this section, the Secretary shall coordinate with the Attorney General to ensure that such regulations do not duplicate or conflict with the requirements described in the previous sentence, and that such regulations and requirements coordinate to the extent practicable.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503C.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503C of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. 1208. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) 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 connection with, or to facilitate, a restricted transaction, and includes—

''(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.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (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 may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system.

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This subsection, and the regulations promulgated under this subsection, shall be enforced exclusively 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)).

''(ii) FACTORS 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 regulators and the Federal Trade Commission shall consider the following factors:

''(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.

''(8) 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). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.

''(11) COMPLIANCE.—A payment system, and any person described in paragraph (2)(B), shall not be deemed to be in violation of paragraph (1)—

''(A)(i) if an alleged violation of paragraph (1) occurs prior to the mandatory compliance date of the regulations issued under paragraph (7); and

''(ii) such entity has adopted or relied on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; or

''(B)(i) if an alleged violation of paragraph (1) occurs after the mandatory compliance date of such regulations; and

''(ii) such entity is in compliance with such regulations.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (h)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this Act.

SEC. 1209. 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 combined of all such controlled substances.''.

SEC. 1210. 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 affected thereby.

SA 2151. Mr. MANCHIN (for himself, Mr. KIRK, Mrs. GILLIBRAND, Mr. SCHUMER, and Mr. ROCKEFELLER) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; as follows:

At the end of subtitle C of title XI, add the following:

SEC. 1132. HYDROCODONE AMENDMENT.

Schedule III(d) in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by—

(1) striking paragraphs (3) and (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively.

SA 2152. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

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

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

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

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

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

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

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

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

NOTICE OF HEARING

COMMITTEE ON INDIAN AFFAIRS

Mr. AKAKA. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on May 24, 2012, in room SD–628 of the Dirksen Senate Office Building, at 12:45 p.m., to conduct a hearing entitled ''Programs and Services for Native Veterans.''

Those wishing additional information may contact the Indian Affairs Committee at (202) 224–2251.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ARMED SERVICES

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on May 23, 2012, at 2:30 p.m.

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

COMMITTEE ON FINANCE

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on May 23, 2012, at 10 a.m., in room SD–215 of the Dirksen Senate Office Building, to conduct a hearing entitled ''Progress in Health Care Delivery: Innovations from the Field.''

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

COMMITTEE ON FOREIGN RELATIONS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on May 23, 2012, at 10 a.m., to hold a hearing entitled, ''The Law of the Sea Convention (Treaty Doc. 103–39): The U.S. National Security and Strategy Imperatives for Ratification.''

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

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on May 23, 2012, at 10:30 a.m. to conduct a hearing entitled ''Secret Service on the Line: Restoring Trust and Confidence.''

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

COMMITTEE ON VETERANS' AFFAIRS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be authorized to meet during the session on May 23, 2012, to conduct a hearing on ''Seamless Transition: Review of the Integrated Disability Evaluation System.''

The Committee will meet in room SD–562 of the Senate Dirksen Office Building, beginning at 10 a.m.

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

SUBCOMMITTEE ON ADMINISTRATIVE OVERSIGHT AND THE COURTS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on the Judiciary, Subcommittee on Administrative Oversight and the Courts, be authorized to meet during the session of the Senate, on May 23, 2012, at 10 a.m., in room SD–226 of the Dirksen Senate Office Building, to conduct a hearing entitled ''Protecting Our Children—The Importance of Training Child Protection Professionals.''

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

SUBCOMMITTEE ON SECURITY AND INTERNATIONAL TRADE AND FINANCE

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs Subcommittee on Security and International Trade and Finance be authorized to meet during the session of the Senate on May 23, 2012, at 2 p.m., to conduct a hearing entitled ''Reviewing the U.S.—China Strategic and Economic Dialogue.''

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

SUBCOMMITTEE ON STRATEGIC FORCES

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Subcommittee on Strategic Forces of the Committee on Armed Services be authorized to meet during the session of the Senate on May 23, 2012, at 9:30 a.m.

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

21ST CENTURY LANGUAGE ACT OF 2012

Mr. REID. Mr. President, I ask unanimous consent the Banking Committee be discharged from further consideration of S. 2367.

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

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 2367) to strike the world ''lunatic'' from Federal law, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I ask unanimous consent the bill be read a third time and passed; the motion to reconsider be laid upon the table, with no intervening action or debate; and any statements related to the bill be printed in the RECORD.

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

The bill (S. 2367) was ordered to a third reading, was read the third time, and passed, as follows:

S. 2367

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''21st Century Language Act of 2012''.

SEC. 2. MODERNIZATION OF LANGUAGE REFERRING TO PERSONS WHO ARE MENTALLY ILL.

(a) WORDS DENOTING NUMBER, GENDER, AND SO FORTH.—Section 1 of title 1, United States Code, is amended—

(1) by striking ''and 'lunatic' ''; and

(2) by striking ''lunatic,''.

(b) BANKING LAW PROVISIONS.—

(1) TRUST POWERS.—The first section of the Act entitled ''An Act to place authority over the trust powers of national banks in the Comptroller of the Currency'', approved September 28, 1962 (12 U.S.C. 92a), is amended—

(A) in subsection (a), by striking ''committee of estates of lunatics,''; and

(B) in subsection (b), by striking ''committee of estates of lunatics''.

(2) CONSOLIDATION AND MERGERS OF BANKS.—The National Bank Consolidation and Merger Act (12 U.S.C. 215 et seq.) is amended—

(A) in section 2 (12 U.S.C. 215)—

(i) in subsection (e), by striking ''receiver, and committee of estates of lunatics'' and inserting ''and receiver''; and

(ii) in subsection (f), by striking ''receiver, or committee of estates of lunatics'' and inserting ''or receiver''; and

(B) in section 3 (12 U.S.C. 215a)—

(i) in subsection (e), by striking ''receiver, and committee of estates of lunatics'' and inserting ''and receiver''; and

(ii) in subsection (f), by striking ''receiver, or committee of estates of lunatics'' and inserting ''or receiver''.

JOHN F. KENNEDY CENTER REAUTHORIZATION ACT OF 2012

Mr. REID. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of H.R. 4097.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 4097) to amend the John F. Kennedy Center Act to authorize appropriations for the John F. Kennedy Center for the Performing Arts, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I further ask that the bill be read three times and passed, the motion to reconsider be laid upon the table, with no intervening action or debate, and that any statements be printed in the RECORD.

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

The bill (H.R. 4097) was ordered to a third reading, was read the third time, and passed.

APPOINTMENTS

THE PRESIDING OFFICER. The Chair, on behalf of the President pro tempore, upon the recommendation of the Republican leader, pursuant to Public Law 105–292, as amended by Public Law 106–55, Public Law 107–228, and Public Law 112–75, appoints the following individual to the United States Commission on International Religious Freedom: Mary Ann Glendon of Massachusetts, vice Leonard Leo.

ORDERS FOR MAY 24, 2012

Mr. REID. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 9:30 a.m. tomorrow morning; that following the prayer and the pledge, the Journal of proceedings be approved to date, the morning hour be deemed to have expired, and the time for the two leaders be reserved for their use later in the day; that the Senate resume consideration of S. 3187, the FDA user fees legislation, under the previous order.

Before the Chair rules, we will have up to 13 rollcall votes tomorrow. Under the order, they will start at 2 p.m. There is no reason we could not start the votes earlier. If we come in at 9:30, we can start them early, as soon as debate stops. We cannot have any votes during the couple of meetings Senators have to attend from 1 to 2 o'clock. But we should dispose of some of these amendments. Thirteen votes on amendments will take a long time tomorrow. I hope that everybody will try to move these up and that we can vote sooner.

The Chair can rule now.

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

PROGRAM

Mr. REID. Mr. President, repeating, there will be up to 13 rollcall votes tomorrow starting at 2 p.m. The purpose is to complete action on the FDA user fees bill and to consider the student loan interest hike legislation.

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. REID. Mr. President, if there is no further business to come before the Senate, I ask unanimous consent that it adjourn under the previous order.

There being no objection, the Senate, at 6:39 p.m., adjourned until Thursday, May 24, 2012, at 9:30 a.m.

EXTENSIONS OF REMARKS

SENATE COMMITTEE MEETINGS

Title IV of Senate Resolution 4, agreed to by the Senate on February 4, 1977, calls for establishment of a system for a computerized schedule of all meetings and hearings of Senate committees, subcommittees, joint committees, and committees of conference. This title requires all such committees to notify the Office of the Senate Daily Digest—designated by the Rules Committee—of the time, place, and purpose of the meetings, when scheduled, and any cancellations or changes in the meetings as they occur.

As an additional procedure along with the computerization of this information, the Office of the Senate Daily Digest will prepare this information for printing in the Extensions of Remarks section of the CONGRESSIONAL RECORD on Monday and Wednesday of each week.

Meetings scheduled for Thursday, May 24, 2012 may be found in the Daily Digest of today's RECORD.

MEETINGS SCHEDULED

MAY 25

9:30 a.m.

Armed Services

Closed business meeting to continue markup of the proposed National Defense Authorization Act for fiscal year 2013.

SR–222

JUNE 7

2:15 p.m.

Indian Affairs

To hold an oversight hearing to examine Universal Service Fund Reform, focusing on ensuring a sustainable and connected future for native communities.

SD–628

JUNE 28

10 a.m.

Health, Education, Labor, and Pensions

To hold hearings to examine creating positive learning environments for all students.

Room to be announced

Daily Digest

Senate

Chamber Action

Routine Proceedings, pages S3459–3534

Measures Introduced: Eleven bills and two resolutions were introduced, as follows: S. 3223–3233, and S. Res. 470–471. **Pages S3515–16**

Measures Reported:

S. 414, to protect girls in developing countries through the prevention of child marriage. (S. Rept. No. 112–170)

S. 2276, to permit Federal officers to remove cases involving crimes of violence to Federal court, with an amendment in the nature of a substitute. **Page S3514**

Measures Passed:

21st Century Language Act: Committee on Banking, Housing, and Urban Affairs was discharged from further consideration of S. 2367, to strike the word ''lunatic'' from Federal law, and the bill was then passed. **Page S3534**

John F. Kennedy Center Reauthorization Act: Senate passed H.R. 4097, to amend the John F. Kennedy Center Act to authorize appropriations for the John F. Kennedy Center for the Performing Arts. **Page S3534**

Measures Considered:

Food and Drug Administration Safety and Innovation Act—Agreement: Senate began consideration of S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, after agreeing to the motion to proceed, and taking action on the following amendments proposed thereto: **Pages S3459–79, S3479–S3509**

Adopted:

Harkin/Enzi Amendment No. 2122, in the nature of a substitute. (By unanimous consent, the amendment will be considered as original text for the purpose of further amendment.) **Page S3479**

Cardin Amendment No. 2125, to ensure that adequate information is disseminated to health care providers and payors about the potential benefits and risks of medical products on all patient populations, particularly underrepresented subpopulations, including racial subgroups. **Pages S3497, S3500**

Cardin/Landrieu Amendment No. 2141, to require the Commissioner of Food and Drugs to report to Congress on issues with respect to small businesses. **Pages S3497–S3500, S3500–01**

Grassley Amendment No. 2121, to provide employee protections for the Commissioned Corps of the Public Health Service Act. **Pages S3491–92**

Grassley Amendment No. 2129, to provide deadlines for the issuance of certain regulations and to require a GAO report on the implementation of the clinical trial registration and reporting requirements under the Public Health Service Act. **Pages S3490–91**

Manchin Modified Amendment No. 2151, to amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug. **Page S3506**

Harkin (for Reed) Amendment No. 2126, to make effective the proposed rule of the Food and Drug Administration relating to sunscreen drug products. **Pages S3506–09**

Pending:

Durbin/Blumenthal Amendment No. 2127, to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration. **Pages S3482–85**

Sanders Amendment No. 2109, to revoke the exclusivity of certain entities that are responsible for violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other certain laws. **Pages S3485–88**

Coburn/Burr Amendment No. 2131, to require an independent assessment of the Food and Drug Administration's review of drug applications. **Pages S3488–89**

Coburn/Burr Amendment No. 2132, to provide that a portion of the performance awards of each employee of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research be connected to an evaluation of the employee's contribution to goals under the user fee agreements. **Pages S3489–90**

Burr/Coburn Amendment No. 2130, to ensure transparency in Food and Drug Administration user fee agreement negotiations. **Pages S3492–95**

Murkowski Amendment No. 2108, to prohibit approval by the Food and Drug Administration of genetically engineered fish unless the National Oceanic and Atmospheric Administration concurs with such approval. **Pages S3495–97**

Paul Amendment No. 2143, to amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, to prohibit employees of the Food and Drug Administration from carrying firearms and making arrests without warrants, and to adjust the mens rea of certain prohibited acts under the Federal Food, Drug, and Cosmetic Act to knowing and willful. **Pages S3501–06**

A unanimous-consent-time agreement was reached providing that the only first-degree amendments in order to the bill be the following: Bingaman Amendment No. 2111; McCain Amendment No. 2107; Sanders Amendment No. 2109; Murkowski Amendment No. 2108; Cardin Amendment No. 2125; Cardin Amendment No. 2141; Grassley Amendment No. 2121; Grassley Amendment No. 2129; Manchin Modified Amendment No. 2151; Portman Modified Amendment No. 2146; Portman Modified Amendment No. 2145; Reed Amendment No. 2126; Coburn Amendment No. 2132; Coburn Amendment No. 2131; Durbin Amendment No. 2127; Paul Amendment No. 2143; and Burr Amendment No. 2130; that there be no second-degree amendments in order prior to the votes in relation thereto; that there be no motions or points of order to the amendments or the bill other than budget points of order and the applicable motions to waive or motions to table; that there be up to 30 minutes of debate on each of the amendments, with the exception of McCain Amendment No. 2107 which will have 2 hours of debate, and 60 minutes on the bill with all time equally divided in the usual form; that at 2 p.m. on Thursday, May 24, 2012, all debate time be considered expired and the Senate vote on or in relation to the amendments in the order listed above; that there be two minutes of debate equally divided in the usual form prior to each vote; that all after the first vote be 10 minute votes; that the following amendments be subject to a 60 affirmative vote threshold: Bingaman Amendment No. 2111; McCain Amendment No. 2107; Sanders Amendments No. 2109; and Murkowski Amendment No. 2108; that upon disposition of the amendments, the bill be read a third time, and Senate vote on passage of the bill, as amended. **Page S3479**

A unanimous-consent agreement was reached providing for further consideration of the bill at approximately 9:30 a.m., on Thursday, May 24, 2012. **Page S3534**

Appointments:

United States Commission on International Religious Freedom: The Chair, on behalf of the President pro tempore, upon the recommendation of the Republican Leader, pursuant to Public Law 105–292, as amended by Public Law 106–55, Public Law 107–228, and Public Law112–75, appointed the following individual to the United States Commission on International Religious Freedom: Mary Ann Glendon of Massachusetts, vice Leonard Leo. **Page S3534**

Stop the Student Loan Interest Rate Hike Act—Agreement: A unanimous-consent-time agreement was reached providing that upon disposition of S. 3187, Senate proceed to the consideration of S. 2343, to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans; that the only amendment in order to the bill be an amendment from the Republican Leader, or his designee, the text of which is identical to S. 2366; that there be 10 total minutes of debate on the amendment and the bill, equally divided between the two Leaders, or their designees, prior to a vote on the McConnell, or designee, amendment; that no amendment be in order to the McConnell, or designee, amendment; that no motions or points of order be in order to the amendment or the bill other than budget points of order and the applicable motions to waive; that upon disposition of the amendment, Senate vote on passage of the bill, as amended, if amended; that the amendment and the bill be subject to a 60 affirmative vote threshold; that if the bill does not achieve 60 affirmative votes, S. 2343 be returned to the Calendar; and the motion to reconsider with respect to the cloture vote on the motion to proceed to S. 2343 be withdrawn. **Page S3479**

Measures Placed on the Calendar: **Pages S3459, S3513**

Executive Communications: **Pages S3513–14**

Executive Reports of Committees: **Pages S3514–15**

Additional Cosponsors: **Pages S3516–17**

Statements on Introduced Bills/Resolutions: **Pages S3517–19**

Additional Statements: **Pages S3512–13**

Amendments Submitted: **Pages S3519–33**

Notices of Hearings/Meetings: **Page S3533**

Authorities for Committees to Meet:

Pages S3533–34

Adjournment: Senate convened at 9:30 a.m. and adjourned at 6:39 p.m., until 9:30 a.m. on Thursday, May 24, 2012. (For Senate's program, see the remarks of the Majority Leader in today's Record on page S3534.)

Committee Meetings

(Committees not listed did not meet)

GUARD AND RESERVE BUDGET OVERVIEW

Committee on Appropriations: Subcommittee on Department of Defense concluded a hearing to examine the fiscal year 2013 Guard and Reserve budget overview, after receiving testimony from General Craig R. McKinley, USAF, Chief, National Guard Bureau, Lieutenant General William E. Ingram, Jr., USA, Director, Army National Guard, Lieutenant General Harry M. Wyatt III, USAF, Director, Air National Guard, Lieutenant General Jack Stultz, USA, Chief, Army Reserve, Vice Admiral Dirk Debbink, USN, Chief, Navy Reserve, Lieutenant General Steven A. Hummer, USMC, Director, Reserve Affairs, and Lieutenant General Charles E. Stenner, Jr., USAF, Chief, Air Force Reserve, all of the Department of Defense.

AUTHORIZATION: DEFENSE

Committee on Armed Services: Subcommittee on Strategic Forces met in closed session and approved for full committee consideration those provisions which fall within the jurisdiction of the subcommittee, of the proposed National Defense Authorization Act for fiscal year 2013.

BUSINESS MEETING

Committee on Armed Services: Committee ordered favorably reported the nomination of Katharina G. McFarland, of Virginia, to be an Assistant Secretary of Defense, and 655 nominations in the Army, Navy, Air Force and Marine Corps.

Also, committee began consideration of the proposed National Defense Authorization Act for fiscal year 2013, but did not complete action thereon, and will meet again on Thursday, May 24, 2012.

UNITED STATES–CHINA STRATEGIC AND ECONOMIC DIALOGUE

Committee on Banking, Housing, and Urban Affairs: Subcommittee on Security and International Trade and Finance concluded a hearing to examine reviewing the United States-China strategic and economic dialogue, after receiving testimony from Stephen S. Roach, Yale University, New Canaan, Connecticut; C. Fred Bergsten, Peterson Institute for International Economics, Annandale, Virginia; John R. Dearie, Financial Services Forum, Great Falls, Virginia; and Dean C. Garfield, Information Technology Industry Council, Washington, DC.

HEALTH CARE DELIVERY

Committee on Finance: Committee concluded a hearing to examine progress in health care delivery, focusing on innovations from the field, after receiving testimony from Richard Migliori, UnitedHealth Group, Minnetonka, Minnesota; Lee Sacks, Advocate Health Care, Oak Brook, Illinois; Marc Malloy, Renaissance Medical Management Company, Wayne, Pennsylvania; and Paul J. Diaz, Kindred Healthcare, Louisville, Kentucky.

LAW OF THE SEA CONVENTION

Committee on Foreign Relations: Committee concluded a hearing to examine The Law of the Sea Convention (Treaty Doc. 103–39), focusing on the United States National Security and Strategic Imperatives for Ratification, after receiving testimony from Hillary Rodham Clinton, Secretary of State; and Leon E. Panetta, Secretary, and General Martin E. Dempsey, USA, Chairman, Joint Chiefs of Staff, both of the Department of Defense.

SECRET SERVICE

Committee on Homeland Security and Governmental Affairs: Committee concluded a hearing to examine the Secret Service, focusing on trust and confidence, after receiving testimony from Mark Sullivan, Director, United States Secret Service, and Charles K. Edwards, Acting Inspector General, both of the Department of Homeland Security.

PROTECTING OUR CHILDREN

Committee on the Judiciary: Subcommittee on Administrative Oversight and the Courts concluded a hearing to examine protecting our children, focusing on the importance of training child protection professionals, after receiving testimony from Melodee Hanes, Acting Administrator, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, Department of Justice; Victor I. Vieth, Winona State University National Child Protection Training Center, Winona, Minnesota; Michael V. Johnson, Boy Scouts of America, Irving, Texas; Chris Newlin, National Children's Advocacy Center, Huntsville, Alabama; and Stephanie M. Smith, Northwest Arkansas Community College National Child Protection Training Center, Bentonville, Arkansas.

INTEGRATED DISABILITY EVALUATION SYSTEM

Committee on Veterans' Affairs: Committee concluded a hearing to examine a review of the Integrated Disability Evaluation System, focusing on seamless transition and preliminary observations on efforts to improve performance, after receiving testimony from Jo Ann Rooney, Acting Under Secretary of Defense for Personnel and Readiness; John R. Gingrich, Chief of Staff, Department of Veterans Affairs; and Daniel Bertoni, Director, Education, Workforce, and Income Security, Government Accountability Office.

House of Representatives

Chamber Action

The House was not in session today. The House is scheduled to meet at 10 a.m. on Friday, May 25, 2012 in pro forma session.

Committee Meetings

No hearings were held.

Joint Meetings

DEMOCRATIZATION IN THE CAUCASUS

Commission on Security and Cooperation in Europe: Commission concluded a hearing to examine democratization in the Caucasus, focusing on elections in Armenia, Azerbaijan, and Georgia, and how far free and fair elections have come in the Caucasus, and what the United States can do to promote progress in upcoming elections, after receiving testimony from Tom de Waal, Carnegie Endowment for International Peace, Cory Welt, George Washington University Institute for European, Russian and Eurasian Studies, Christopher Walker, Freedom House, Stephen B. Nix, International Republican Institute, and Anthony Bowyer, International Foundation for Electoral Systems, all of Washington, DC.

COMMITTEE MEETINGS FOR THURSDAY, MAY 24, 2012

(Committee meetings are open unless otherwise indicated)

Senate

Committee on Appropriations: business meeting to markup proposed budget estimates for fiscal year 2013 for Department of State, Foreign Operations, and Related Agencies, 10:30 a.m., SD–106.

Committee on Armed Services: closed business meeting to continue markup of the proposed National Defense Authorization Act for fiscal year 2013, 8:30 a.m., SR–222.

Committee on Banking, Housing, and Urban Affairs: to hold hearings to examine "The Responsible Homeowner Refinancing Act of 2012", 10 a.m., SD–538.

Committee on Foreign Relations: to hold hearings to examine the global implications of poaching in Africa, focusing on ivory and insecurity, 10:30 a.m., SD–419.

Committee on Homeland Security and Governmental Affairs: Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, to hold hearings to examine efforts to reform information technology spending, focusing on innovating with less, 10 a.m., SD–342.

Committee on Indian Affairs: to hold an oversight hearing to examine programs and services for native veterans, 12:45 p.m., SD–628.

Committee on the Judiciary: business meeting to consider S. 2076, to improve security at State and local courthouses, S. 2370, to amend title 11, United States Code, to make bankruptcy organization more efficient for small business debtors, the nominations of Robert E. Bacharach, of Oklahoma, to be United States Circuit Judge for the Tenth Circuit, Paul William Grimm, to be United States District Judge for the District of Maryland, John E. Dowdell, to be United States District Judge for the Northern District of Oklahoma, Mark E. Walker, to be United States District Judge for the Northern District of Florida, Brian J. Davis, of Florida, to be United States District Judge for the Middle District of Florida, and Charles Thomas Massarone, of Kentucky, to be a Commissioner of the United States Parole Commission, 10 a.m., SD–226.

Select Committee on Intelligence: to hold closed hearings to examine certain intelligence matters, 9 a.m., SH–219.

House

No hearings are scheduled.

Next Meeting of the SENATE

9:30 a.m., Thursday, May 24

Senate Chamber

Program for Thursday: Senate will continue consideration of S. 3187, Food and Drug Administration Safety and Innovation Act, with a series of votes on or in relation to amendments and passage of the bill at approximately 2 p.m.

Upon disposition of S. 3187, Food and Drug Administration Safety and Innovation Act, Senate will begin consideration of S. 2343, Stop the Student Loan Interest Rate Hike Act, with votes on or in relation to a McConnell, or designee, amendment and passage of the bill.

Next Meeting of the HOUSE OF REPRESENTATIVES

10 a.m., Friday, May 25

House Chamber

Program for Friday: The House will meet in pro forma session at 10 a.m.

Congressional Record

The *Congressional Record* (USPS 087–390). The Periodicals postage is paid at Washington, D.C. The public proceedings of each House of Congress, as reported by the Official Reporters thereof, are printed pursuant to directions of the Joint Committee on Printing as authorized by appropriate provisions of Title 44, United States Code, and published for each day that one or both Houses are in session, excepting very infrequent instances when two or more unusually small consecutive issues are printed one time. ¶Public access to the *Congressional Record* is available online through the U.S. Government Printing Office at *www.fdsys.gov*, free of charge to the user. The information is updated online each day the *Congressional Record* is published. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202–512–1800, or 866–512–1800 (toll-free). E-Mail, *contactcenter@gpo.gov*. ¶The *Congressional Record* paper and 24x microfiche edition will be furnished by mail to subscribers, free of postage, at the following prices: paper edition, $252.00 for six months, $503.00 per year, or purchased as follows: less than 200 pages, $10.50; between 200 and 400 pages, $21.00; greater than 400 pages, $31.50, payable in advance; microfiche edition, $146.00 per year, or purchased for $3.00 per issue payable in advance. The semimonthly *Congressional Record Index* may be purchased for the same per issue prices. To place an order for any of these products, visit the U.S. Government Online Bookstore at: bookstore.gpo.gov. Mail orders to: Superintendent of Documents, P.O. Box 979050, St. Louis, MO 63197–9000, or phone orders to 866–512–1800 (toll-free), 202–512–1800 (D.C. area), or fax to 202–512–2104. Remit check or money order, made payable to the Superintendent of Documents, or use VISA, MasterCard, Discover, American Express, or GPO Deposit Account. ¶Following each session of Congress, the daily *Congressional Record* is revised, printed, permanently bound and sold by the Superintendent of Documents in individual parts or by sets. ¶With the exception of copyrighted articles, there are no restrictions on the republication of material from the *Congressional Record*.

POSTMASTER: Send address changes to the Superintendent of Documents, *Congressional Record,* U.S. Government Printing Office, Washington, D.C. 20402, along with the entire mailing label from the last issue received.