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Senate

The Senate met at 10 a.m. and was called to order by the Honorable JEANNE SHAHEEN, a Senator from the State of New Hampshire.

PRAYER

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

Let us pray.

O God our Father, shine Your light on Capitol Hill and give light to each lawmaker. Illuminate their lives so that their beliefs may be certain and true. May the light of Your knowledge guide them in all their decisions. Grant that, guided by Your light, they will reach the light that never fails. Grant that, illuminated by Your truth, they may reach the truth that is complete. Lead them, God, so that in the end they may see light in Your light and know even as they are known. We pray in Your great Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable JEANNE SHAHEEN led the Pledge of Allegiance, as follows:

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

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

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

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 22, 2012.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable JEANNE SHAHEEN, a Senator from the State of New Hampshire, to perform the duties of the Chair.

DANIEL K. INOUYE,
President pro tempore.

Mrs. SHAHEEN 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. I move to proceed to Calendar No. 400, S. 3187.

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

The legislative clerk read as follows:

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

SCHEDULE

Mr. REID. Madam President, we are now on the motion to proceed to the FDA user fees bill. The majority will control the first half hour today, Republicans the final half hour. We will recess from 12:30 to 2:15 today, to allow for our weekly caucus meetings. At 2:15 the motion to proceed to the FDA legislation will be adopted and the Harkin-Enzi substitute will be agreed to.

Madam President, there are 12 million people in the United States who face a cancer diagnosis today. Many have fought back against this terrible disease and won. Others are still fighting. Each one of them knows how difficult a cancer diagnosis can be. But imagine coming to terms with your diagnosis only to find out the lifesaving drug you need to survive is in short supply or is simply not available. I wish this were make-believe but it is not; it is real America. That is the situation faced by many Americans battling cancer and other life-threatening illnesses.

Through 20 weeks of chemotherapy, my wife Landra and I lived with the fear that the medicine she needed every Monday morning wouldn't be there because there were shortages. But fortunately for us the drug was always accessible. Many Americans have not been so fortunate. One Nevadan fighting bladder cancer was near the end of treatment when the medicine he was taking suddenly ran short. Only time will tell whether the alternative treatment he received was enough to save his life.

Another Nevada woman with bowel cancer was forced to choose a less effective chemotherapy treatment because the best drug on the market, one that cures bowel cancer in 75 percent of the cases, was not available. Only time will tell whether that second-choice medicine was effective.

Yet another Nevada man was relying on two cancer drugs to keep him alive longer and give him a greater quality of life, but one drug was in short supply. Since the drugs only work when taken together, doctors have only been able to treat him intermittently. That is not good. So only time will tell how many days or weeks or months or years he lost because he couldn't get the drug he needed.

Every day these stories play out in hospitals across our country. Every day, Americans experience shortages of lifesaving FDA-approved drugs and treatments. These shortages literally put Americans at risk. As the number of shortages increases each year, more patients are forced to wait for treatment, and worry. In the last 6 years, drug shortages have quadrupled. Last year the FDA reported shortages of 231 drugs, including many chemotherapy medicines. That is 231 drugs. How many tens of thousands of people did that affect? Public pressure has prompted some drugmakers to voluntarily notify the FDA of impending

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

shortages. But Congress must step in to improve communication among drugmakers, the FDA, and doctors—doctors who have to break the terrible news that lifesaving medicines are not available.

Voluntary cooperation between the drugmakers and the FDA prevented almost 200 drug shortages last year, but establishing effective lines of communication could further reduce the number of shortages and save patients' lives.

I am pleased that the spirit of bipartisanship begun by my colleagues Senator HARKIN and Senator ENZI continued yesterday. I look forward to an orderly amendment process and I am optimistic the Senate will move this legislation without unnecessary delays. I hope I am not disappointed.

Each year more than 1.5 million Americans are diagnosed with some form of cancer. It is up to us to ensure that not one of them waits or wonders if the medicine he or she needs to stay alive will be there when the need arises.

RECOGNITION OF THE MINORITY LEADER

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

ECONOMIC CHALLENGES

Mr. MCCONNELL. Madam President, I want to call attention to a couple of stories from the last 2 days. I think they say a lot about the difficulties of addressing the economic challenges we face.

The first is a story from Politico. It says the Budget Committee chairman can't remember the last time he talked to the President. The Budget Committee chairman can't remember the last time he talked to the President. Another chairman, dealing with student loans, says he has not talked to the President in months—in months. The Democratic point man on energy doesn't seem to talk to the President much at all.

If you want to know why we can't solve these economic problems, this is it. We have a President who is more interested in running around to college campuses, spreading some poll-tested message, than he is in actually accomplishing anything. That is the problem.

The second story, also interesting, is about HHS signing a $20 million contract to promote ObamaCare; $20 million of taxpayer money to promote a bill most Americans want to see repealed. That is $20 million of our tax money spent on commercials to promote ObamaCare. Let me suggest the President spend a little more time trying to do something about spending, debt, and gas prices, and a little less time trying to spin the unpopular things he has already done. It might require a little more work but it is what we need. It is time to lead.

I ask unanimous consent those two articles to which I referred be printed in the RECORD.

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

[From Politico, May 22, 2012]

DEMS WAIT BY PHONE FOR OBAMA

(By Manu Raju)

He doesn't call. He doesn't write. He doesn't drop by for a visit.

That's what some of the most senior Democrats in Congress are experiencing from President Barack Obama these days.

Senate Budget Committee Chairman Kent Conrad (D–N.D.) is trying to cut a deal on the nation's fiscal crisis, but he can't recall the last time he talked to the president. Sen. Tom Harkin (D–Iowa) is in charge of one of Obama's top priorities—preventing a rate increase on student loans—but he hasn't talked to the president in months. And Sen. Jeff Bingaman (D–N.M.) is the go-to guy on high gas prices, but the chairman of the Energy and Natural Resources Committee hasn't spoken to the president much since the previous Congress.

''I think the reality is the current Congress is not constituted in a way that makes it likely that we can do very much,'' Bingaman said, ''and that's reflected in what we wind up doing on the floor and understandably the president is not as engaged—at least with me.''

Obama is certainly in regular touch with the top Democratic leaders on the Hill—Nancy Pelosi and Harry Reid—but when it comes to some key policymakers and chairmen in Democratic congressional politics, he's far less engaged than earlier in his presidency. The lack of communication not only reflects a gridlocked Congress in an election year, but it speaks to the president's personal style—he's never been much of a schmoozing, back-slapping type in the spirit of Bill Clinton or Lyndon B. Johnson. And even though he came from the Senate, Obama wasn't there long enough to develop deep, bonding friendships with some of the old bulls in Congress.

Obama's disengagement is also a sharp reflection of political reality: Congress is punting on virtually every major issue until after the election. So even some of those GOP deal makers whom Obama may need to court—whether that's Sens. Olympia Snowe of Maine or Lindsey Graham of South Carolina—aren't getting as much presidential attention as they have in the past.

''I don't think governing is a high priority right now,'' said Graham, who said he hasn't spoken to the president ''in forever'' after speaking with him frequently in the first couple years of his administration on issues like immigration and energy policy.

White House officials scoff at those criticisms, saying they work ''tirelessly'' on the economy.

Jamie Smith, a White House spokeswoman, said the president and his administration ''have regular and repeated interactions with members of Congress from both parties in the House and Senate, and we welcome Republican willingness to pass the congressional 'to-do' list,'' referring to the president's economic agenda.

But both policy meetings and social gatherings with committee chairmen, ranking members, back bench freshmen and GOP swing voters—all hallmarks of the early part of Obama's term—have been few and far between with the president these days, lawmakers say.

''There was a while for various reasons where groups of us were coming to the White House for meetings for one kind or another, but . . . he's busy,'' said Sen. Joe Lieberman (I–Conn.), chairman of the Homeland Security and Governmental Affairs Committee, saying the two last spoke in February when the president offered support for his cybersecurity bill.

''I'm afraid that may be related to the feeling that not much is actually going to get done here.''

Cutting out committee chairmen is also another sign of the ongoing decline in influence of the gavel-holders on Capitol Hill, who in a previous era ran their panels like fiefdoms, but now have taken a back seat to congressional leaders who spearhead the legislative deal making. And it's also sign of the non-stop campaign that dominates politics and has made it harder to legislate.

Obama has often been criticized for being aloof from Capitol Hill, but White House officials argue that there's been regular outreach to lawmakers throughout his entire term, including by senior aides, legislative liaisons, Cabinet secretaries and Vice President Joe Biden. Just last week, congressional leaders from both parties met with Obama, the first such meeting in months, and there's been an uptick in coordination between the White House and Senate Democratic leaders over legislative strategy and political messaging.

Moreover, Democrats argue that when Obama has taken a more hands-on role in the legislative process, Republicans have been quick to criticize his involvement and less willing to embrace his ideas. In this Congress, Obama inserted himself in the messy deals to avert a government shutdown last spring and a debt default last summer. But those were reached between a handful of leaders and the president—meaning most lawmakers have been cut out of the process.

When Obama has gotten involved at times this year, he's done so quietly. He made a series of calls to Democratic senators in March to kill a measure calling for the construction of the controversial Keystone XL oil pipeline. And when Harkin threatened in February to filibuster an extension of the Social Security payroll tax break, the president made assurances to the Iowa Democrat that persuaded him to back down, Harkin told Politico.

''If you put two and two together, you can see what happened,'' Harkin said last week. ''As you know, we're not taking any money out of the [health care] prevention fund.''

With Congress's approval ratings at all-time lows, there's far more incentive for the president to divorce himself from the sausage-making on Capitol Hill—particularly with little chance of replicating the legislative successes from his first two years, like on health care and financial services, which came at a heavy political price.

Rep. Barney Frank (D–Mass.), whose name is affixed to the Dodd-Frank financial services law, spoke with Obama at least twice a month when negotiations over that bill were taking shape in 2010.

''The last time I talked to him was a couple months ago,'' he says of his interactions with the president now.

It's not as though Congress doesn't have major issues to resolve. Unless Congress acts, come Jan. 1, $1.2 trillion in automatic spending cuts will take effect, with half coming from defense and national security programs; the Bush-era tax rates for all income groups will expire; and the payroll tax break affecting 160 million Americans will end. And it's only a matter of time before Congress has to deal with a host of expired business tax breaks, as well as whether to renew jobless benefits and how to craft a budget deal to again raise the national debt ceiling.

Some say the president—along with congressional leaders—needs to begin laying the groundwork now to avoid a catastrophic logjam that could ensue after the November elections.

''We could get some more done if he was meeting with a broad group of people to address key issues certainly, including the leadership, on a continuous basis,'' said Snowe, who was a periodic Oval Office guest in the first year-and-a-half of the administration but said she hasn't met with the

president since spring 2010 over energy policy.

Arizona Sen. John McCain, Obama's old rival, said he was last in for a White House visit soon after the January 2011 Tucson shootings, at which the two discussed acting on immigration reform and the line-item veto.

''He said they'd be getting back to me very shortly, and I haven't heard from him since,'' McCain said last week.

But Democrats are quick to argue that Republicans—particularly in the House—have shown little willingness to work with the president. And several senior Democrats who haven't spoken with Obama in a while don't hold it against him, with the president facing a full slate of competing interests and a challenging reelection.

Conrad said he still speaks with Biden, senior White House budget officials and chief of staff Jack Lew.

''We can communicate without the two of us speaking directly,'' Conrad said of the president.

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[From The Hill, May 21, 2012]

HHS SIGNS $20M PR CONTRACT TO PROMOTE HEALTHCARE LAW

(By Sam Baker)

The Health and Human Services Department has signed a $20 million contract with a public-relations firm to highlight part of the Affordable Care Act.

The new, multimedia ad campaign is designed to educate the public about how to stay healthy and prevent illnesses, an HHS official said.

The campaign was mandated by the Affordable Care Act and must describe the importance of prevention while also explaining preventive benefits provided by the healthcare law. The law makes many preventive services available without a co-pay or deductible, and provides new preventive benefits to Medicare patients.

The PR firm Porter Novelli won the contract after a competitive bidding process. The $20 million contract was first reported by PR Week. Porter Novelli did not immediately respond to a request for comment.

JACZKO RESIGNATION

Mr. MCCONNELL. Madam President, yesterday, we learned about the resignation of the chairman of the Nuclear Regulatory Commission, Dr. Gregory Jaczko. As I said yesterday, I am not surprised by Jaczko's resignation. Even Democrats on the Commission testified before Congress that his inappropriate conduct as chairman resulted in a hostile work environment for women and threatened to undermine the mission of the NRC itself. But what should surprise us all, is how this administration could remain silent for more than a year after the allegations of Jaczko's offensive behavior first surfaced.

Jaczko's alleged behavior is unacceptable in any workplace. The fact that it was allowed to persist at a critical agency that oversees the safety of our Nation's nuclear power plants is astonishing. The White House must now move swiftly with a replacement for Jaczko and I urge the Senate to move quickly to reconfirm the nomination of Kristine Svinicki as NRC commissioner before her term expires on June 30th. The only reason her nomination was held up by the White House and the Democrat-led Senate in the first place was because she had the courage to stand up to a hostile work environment, and to the bully who was responsible for it. Now that Jaczko has submitted his resignation, it's time for the Senate to move forward on Kristine Svinicki.

Commissioner Svinicki's credentials are unmatched. She is one of the world's leading experts on nuclear safety. She was confirmed by the Senate to her current term without a single dissenting vote.

It's time we act. Svinicki has served as commissioner with distinction, is enormously qualified, has bipartisan support and deserves a speedy reconfirmation. The American people are best-served by a commission that is fully functional.

I yield the floor.

RESERVATION OF LEADER TIME

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

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

Mr. MCCONNELL. 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.

The ACTING PRESIDENT pro tempore. The Senator from Maryland.

Mr. CARDIN. 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. CARDIN. Madam President, I ask unanimous consent to speak as in morning business.

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

NATIONAL SMALL BUSINESS WEEK

Mr. CARDIN. Madam President, I take this time to bring to the attention of my colleagues that we are celebrating National Small Business Week, which is a very important occasion because, as the Senator from New Hampshire understands, the growth engine for America is our small businesses. When we are looking at job growth, which we all know we need in order to get our economy moving again, we know there will be more jobs created from small companies than from large companies. About two out of every three jobs created in America will come from small companies.

We also know when we are looking at innovation, it is the small businesses that file the patents and come up with the creative new ideas for America to become as competitive as we need to be. There are an incredibly larger number of patents per employee from small companies than from large companies. So the growth engine for America's economy rests with our small businesses.

I am proud to serve on the Small Business Committee under the leadership of Chairman LANDRIEU. We have brought forward many initiatives that help small businesses, and I think it has made a huge difference as our economy is starting to recover. We are now looking at 25 consecutive months of continuous private sector job growth where we have turned around the economy and we are now growing. In large measure I think it is because of the attention we have paid to the small business community. We are proud of what it has meant for our entire country.

Let me speak a little bit about my State of Maryland. We have over 500,000 small businesses in Maryland that employ over 1 million people. So it is by far a huge part of the Maryland economy. Our strategy over the last several years during the Obama administration has been to concentrate on small businesses and, in particular, to help them recover from this economic recession.

The first effort was to increase the capacity of the Small Business Administration. I was proud of the Obama budget that put more money back into the Small Business Administration. I was proud of the initiative we had in the Senate to add funds to the Small Business Administration so that the SBA could indeed be the advocate for the small business community; so that small businesses have an agency in the government that is fighting for their issues. It has made a huge difference. When I speak with the small businesses in Maryland, they tell me they now have a much greater capacity for help through counselors and advocates at the Small Business Administration.

We then dealt with the No. 1 issue that was brought to our attention—and I am sure the Presiding Officer has heard the same stories in New Hampshire I have heard in Maryland—that small businesses have had a hard time getting access to capital; that we need to do a better job of providing capital, particularly during a tough economic period where small businesses don't have the same deep pockets as the larger companies.

So we increased the SBA loan limits, increased the amount of the Federal loan guarantee in order to make it more attractive for banks to lend money to small businesses, knowing full well the government was standing behind those loans. That made some monies available. We looked for creative new programs to help our small businesses, including one in the Treasury Department. We also looked at helping our States by initiating partnerships with our States.

The additional funds we made available in Washington to help build the State programs has made many more loans available to small companies in Maryland. All of that has helped in providing opportunities for our small businesses.

The reauthorization of the SBIR Program and the STTR Program has made

a huge difference. Since 1983, in my State of Maryland, $1.5 billion of funding has come from the SBIR Program. For those who are listening who may not know what this program is about, it is about innovation. It is small companies that are involved in biotech and cybertech areas where they use innovation to create jobs. In my State and in the Presiding Officer's State, they are using these funds to create opportunities for America to be competitive internationally.

We can state chapter and verse for our national defense research or for clean energy technology where small businesses are taking advantage of these innovative research grants and have been able to build jobs in our communities and make America more competitive for the future. The reauthorization and thus predictability of funding under the SBIR Program and the increased amounts that are available will create, and has already created, more job opportunities. We got that done, and that was certainly a major step forward.

We passed bills providing tax breaks to small businesses, including the expensing of their equipment, so they can go out and buy equipment and keep things moving.

The ACTING PRESIDENT pro tempore. The Senator's time has expired.

Mr. CARDIN. I ask unanimous consent for an additional 5 minutes.

The ACTING PRESIDENT pro tempore. Is there objection?

Without objection, it is so ordered.

Mr. CARDIN. Madam President, I thank my friend from Arizona for his courtesy. I will try not to use the entire 5 minutes.

There are other areas where we have also moved forward to help our small businesses, including credits for their health insurance so they can cover their employees. In my own State of Maryland, we have set up an African Trade Office which has provided opportunities in international trade—an area where we think we can still make progress.

I could talk about many of the success stories of Maryland small businesses that have used the SBIR Program, including one to develop new treatment for smallpox vaccines to make them more efficient. We have had examples of where we are now developing a vaccine to deal with the common cold.

I was at an SBA event where we honored the leading entrepreneurs in our State, and I can cite an example of a small businessperson, Janet Amirault, who was the small businessperson of the year—the CEO of a software development company. She has had some personal issues with her health, but despite that, for the last 3 years she has had 90 percent growth in her revenues. This is the innovation we have in Maryland that comes out of the small business community.

Taylor Made Transportation Services, which first qualified under the 8(a) program, has now graduated from that. They started with a small transportation company that provided transportation for people with special needs and is now providing for diverse transportation needs in our communities. All of that has developed through small business programs that we helped develop.

So I come to the floor today to announce a new initiative that I will be filing today, the Small Business Goaling Act, to deal with another problem we have with small businesses that I hope we will be able to take up on the floor of the Senate in the very near future. It would increase the prime goals for small businesses in government procurement from 23 percent to 25 percent and increase the subcontracting goals to 40 percent, adding transparency to how government provides procurement opportunities for government contracts to small businesses.

We have also taken some action in dealing with bundling and trying to prevent the bundling of small contracts into large contracts that makes it more difficult for small businesses to get prime contracts. I believe this legislation will improve transparency and visibility so we can, in fact, provide more opportunities; so the government leads by example, by using small companies more to help them grow. It will help a variety of small businesses, including disabled veteran companies, women-owned companies, and minority-owned companies so that all will benefit from these opportunities.

I wish to thank the chairperson of the Small Business Committee, Senator LANDRIEU, for her extraordinary help in getting this bill together. It will help small businesses by allowing them to grow and create jobs, thereby helping our country in recovery.

Once again, I thank my friend from Arizona for giving me these extra few minutes. The best way to help celebrate National Small Business Week is for us to pay more attention to helping small businesses grow.

With that, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arizona.

THE ECONOMY

Mr. KYL. Madam President, today I would like to add a little context to the discussion of the fiscal cliff our Nation approaches, a reference to the combination of the largest tax increase in history, new taxes under ObamaCare, sequestration, and the expiration of the payroll tax holiday, all of which take effect in January of 2013 unless the President and the Congress act.

This is a key discussion to have because how we view this so-called fiscal cliff defines our perspective on how an economy grows and prospers. Edward Lazear, who is a former Chairman of the President's Council of Economic Advisers, recently wrote an op-ep that outlines the various perspectives. I will focus on the two most prominent: the Keynesian view and the view of supply-side economics.

The Keynesian theory holds that spending is the key to growth—government spending. Keynesians believe that in recessionary times, increased government spending can take the place of private sector activity. That is why they present a false choice between government spending cuts—in other words, austerity—and growth. Their perspective holds that growth is contingent on government spending.

This was the thinking behind the President's 2009 stimulus spending package, the so-called Cash for Clunkers, and a litany of other recent government spending programs, transfer payments, and temporary tax credits. I believe the administration's insistence on enacting these temporary Keynesian spending policies to stimulate consumption is misguided and the evidence reveals has failed. Remember, the stimulus was sold as a measure to keep unemployment from topping 8 percent. But, in fact, unemployment has not dipped below 8 percent for 39 months, and growth is very anemic. We are experiencing a recovery in name only. So there is not much evidence that spending can revitalize a sagging economy; that is to say, government spending, and even if government spending could be a boost, as Lazear points out, the costs would be massive. Here is what he writes:

> Even if a fiscal stimulus has some benefit, the cost of fiscal policy is likely to be very large. In order to stimulate the economy, growth in—not high levels of—government spending is required. To provide a stimulus comparable to the 2009 legislation, we would need to increase government spending by $250 billion.

He goes on:

> The Keynesian view implies that keeping spending constant at the higher level in 2014 would generate no simulative growth for 2014 . . . because there is no increase in spending over the 2013 level. . . . If we want to delay our day of reckoning, we must keep spending at a higher level for each year that we want to postpone the negative consequences for growth.

Supply-side economics, on the other hand, holds a different perspective on growth: that government spending does not increase prosperity, that tax hikes hurt the economy and stifle growth.

We believe that economic growth stems from combining three inputs: labor, capital, and technology. These three factors of production result in output that we can then consume. Without labor, capital, and technology, there can be no consumption. Focusing on policies that stimulate consumption targets the wrong side of the equation. In order to get the economy going, we need to focus on the inputs—labor, capital, and technology. We also believe government spending cuts are beneficial because they free up private capital and help align revenues with government spending.

Lazear argues that supply-siders stand on the firmest ground when it comes to fiscal policy's effect on economic growth. Here is what he writes:

> On the tax side, there is strong evidence that supports the supply-siders.

And he cites, for example, research from Christina Romer. By the way, Christina Romer was President Obama's first Chair of his Council of Economic Advisers. Her research shows that raising taxes by 1 percent of GDP—raising taxes, which is what the administration proposes—lowers our gross domestic product by nearly 3 percent. So increase taxes by 1 percent, you lose 3 percent of gross domestic product.

I recently joined 40 of my Republican colleagues in sending a letter to Leader REID to make this point, that tax increases will have a deleterious effect on economic growth. The letter asks that he join us in working to take the tax threat off the table before the election in order to create more economic certainty. We know that so-called ''taxmageddon'' is coming. There is no good reason not to act. The election is not an acceptable excuse. In fact, I would posit that politicians could be rewarded for acting to avert the catastrophic effect of this huge tax increase.

In addition to acting to prevent tax hikes, Congress should also pursue spending cuts to help unleash private capital, boost growth, and reduce our nearly $16 trillion national debt in the process. To be clear, cutting government spending does not mean the government should take a sledge hammer approach and cut indiscriminately. We should be careful where we cut. We should prioritize. For example, I oppose the defense cuts on national security grounds, not Keynesian grounds. In other words, while it is true that cuts in defense spending will result in job losses, big job losses under sequestration, our national security is even more important. The automatic spending cuts under sequestration mean that across-the-board spending to the Department of Defense will, in the words of the Secretary of Defense, devastate our national security.

Allowing the sequester to begin as planned would cut 10 percent from defense in fiscal year 2013 alone and dramatically shrink the size and capabilities of our military. To avoid this, the Senate should follow the lead of the House of Representatives, which recently passed legislation to replace the sequester with other spending reductions. The legislation will cut $315 billion in spending and will reduce the deficit by over $242 billion. It is not a perfect bill, but I do believe it is a good place to start.

My overarching point is this: We should not shy away from prudent spending cuts for fear that they will hurt growth. It should not be difficult to find cuts in our $3.7 trillion budget. These cuts certainly will not derail economic growth if they are done the right way.

The choice, in other words, between spending cuts and growth is a false choice. If the President is not truly concerned about boosting growth and reversing the trends of the last 3½ years, he should stop presenting this false choice, as he did, for example, at the G8 summit last weekend, where he actually encouraged German Chancellor Angela Merkel and other leaders to embrace what he called a ''growth package'' modeled in part after his own budget-busting stimulus spending. I hope Chancellor Merkel and other leaders around the world take a very close look at whether the Obama growth package is something they wish to bring home after observing the American economy for the last 4 years.

Preventing tax increases and reducing out-of-control spending is a better approach to long-term prosperity.

I ask unanimous consent that at the conclusion of my remarks, the op-ed I referred to by Edward Lazear in the Wall Street Journal of May 21 be printed in the RECORD.

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

[From the Wall Street Journal, May 21, 2012]

THREE VIEWS OF THE 'FISCAL CLIFF'

(By Edward P. Lazear)

Discussion of the so-called fiscal cliff—the combination of tax increases and spending cuts that will come in 2013 if Congress and the president don't act—confuses a number of different issues. The evidence suggests that we should fear the tax hikes, but not necessarily the spending cuts.

Anyone who uses the term ''fiscal cliff'' accepts a Keynesian view of the economy, knowingly or not. Both tax increases and constrained spending are assumed to be bad for the economy.

But there are two other views: that of the budget balancer and that of the supply-sider. Rather than term the impending changes that will occur in 2013 a ''fiscal cliff,'' the budget balancer thinks of this as ''fiscal consolidation.'' Tax increases reduce the deficit, as do cuts in government spending. Both are austerity measures that make the government more responsible and, therefore, both are conducive to long-run economic growth.

Those who support the Simpson-Bowles plan subscribe, at least in part, to this view. Various proponents of the plan may place different weights on the tax-increase side or the spending-decrease side because they believe the economic consequence of one or the other is more adverse. But fundamentally, the target is to decrease the deficit. The budget balancer regards both tax increases and spending cuts as moves in the right direction.

The supply-sider has a different view from both the Keynesian and the budget balancer. Fundamentally, supply-side advocates focus on the harmful effects of tax increases. Raising tax rates hurts the economy directly because tax hikes reduce incentives to invest and because they punish hard work. As such, tax increases slow growth. But budget cuts work in the right direction by making lower tax revenues sustainable. If spending exceeds revenues, then the government must borrow and this commits future governments to raising taxes in order to service the debt.

Consequently, the supply-sider thinks of 2013 primarily as a tax increase and fears what that will do to the economy. The spending cuts are a positive. Unlike the Keynesians who view the fiscal cliff as being bad on two counts, or the budget balancer who views it as being good on two counts, the supply-sider scores it one-and-one. The tax increases have negative effects on the economy; the controls on spending are a positive side effect of the 2013 sunsets.

Which of the three views is correct? Until recently, most economists believed that fiscal policy was inappropriate for business-cycle management, and that if stimulus was needed at all, monetary policy was the best way. Spending ''stimulus'' does not have a strong track record in recent decades. There is more ambiguity now about the choice between monetary and fiscal policy, in large part because with interest rates near zero, the effectiveness of monetary policy is thought to be more limited.

But even if a fiscal stimulus has some benefit, the cost of fiscal policy is likely to be very large. In order to stimulate the economy, growth in—not high levels of—government spending is required. To provide a stimulus in 2013 comparable to the 2009 legislated stimulus, we would need to increase government spending by about $250 billion.

But the Keynesian view implies that keeping spending constant at the higher level in 2014 would generate no stimulative growth effect for 2014. Despite the higher level of spending in 2014, we would get no additional growth because there is no increase in spending over the 2013 level. Were we to retreat to current levels of spending, there would be a contractionary effect on the economy as government spending decreases. If we want to delay our day of reckoning, we must keep spending at a higher level for each year that we want to postpone the negative consequences for growth. Given the state of the labor market, this could mean a few years. If we waited four years, we would spend $1 trillion to get $250 billion in stimulus.

On the tax side, there is strong evidence that supports the supply-siders. Christina Romer, President Obama's first chairwoman of the President's Council of Economic Advisers, and David Romer document the strong unfavorable effect of increasing tax rates on economic growth (American Economic Review, 2010). They report that an increase in taxes of 1% of gross domestic product lowers GDP by almost 3%. The evidence on government spending also suggests that high spending means lower growth.

For example, Swedish economists Andreas Bergh and Magnus Henrekson (Journal of Economic Surveys 2011) survey a large literature and conclude that an increase in government size by 10 percentage points of GDP is associated with a half to one percentage point lower annual growth rate.

The evidence suggests that we should move away from worry over the impending ''fiscal cliff'' and focus more heavily on concern about raising taxes. And although some Keynesians may view this as not the best time to control spending growth, promising to change our ways in the future is as credible as Wimpy's promise to pay on Tuesday for the hamburger that he eats today.

The ACTING PRESIDENT pro tempore. The Senator from Iowa.

LIGHTSQUARED DANGER

Mr. GRASSLEY. Madam President, I am pleased to see that Jessica Rosenworcel and Ajit Pai have been confirmed to the Federal Communications Commission. They are both highly qualified, and it is unfortunate that the FCC's stubborn refusal to respond to my very simple request for information forced me to place a hold on their nominations for the past 4 months in order to get the FCC to move on giving me the information to which any Member of Congress ought to be entitled.

The FCC needs to learn a simple lesson from this episode: The public's business ought to be public, and transparency brings accountability. Eventually, the truth will be known, so you

might as well get it out there when the questions first come up.

I initially placed my hold on the FCC Commissioner nominees because the FCC had stonewalled a document request that I submitted on April 27 last year regarding their actions related to a company called LightSquared and the hedge fund, Harbinger Capital, that owns LightSquared.

Before I wrote my letter on LightSquared, many concerns had already been raised regarding the company's plans for a terrestrial network and its potential to interfere with the global positioning system, or sometimes that is referred to as GPS. In my first letter, I raised those concerns as well. Unfortunately, the FCC does not appear to have taken those concerns seriously, but months later, independent testing verified the danger LightSquared posed to industries, from commercial aviation to even our own Armed Forces.

It seems strange that a project that was so obviously flawed was allowed to go so far. But LightSquared had help. In total, LightSquared has paid 53 different lobbyists, some registered, some unregistered. They paid one former Governor, three former Senators, nine former Members of Congress, including a former Speaker and former minority leader, and a former White House Counsel to advocate for them. These lobbyists provided entry into the FCC and the White House. But they could not change the fact that LightSquared's network simply could not coexist with GPS.

LightSquared has now declared bankruptcy, and it appears its plan to build a terrestrial network is over, but many questions still remain. Some of those questions: Why did the FCC give LightSquared this unusual waiver in the first place? Why did LightSquared's lawyers mention campaign contributions when they sought meetings at the White House? Why did a four-star general claim he had been pressured by the Obama administration not to criticize LightSquared?

When I first asked the FCC for documents, I was told they would take about 2 years to respond to my request through the Freedom of Information Act. Then they told me they do not voluntarily turn over documents to the 99.6 percent of the Members of Congress who do not chair a committee with direct jurisdiction over FCC. After a lot of back and forth with the FCC, they told me the reason they do not respond to 99.6 percent of Congress is because of just a one-line statement in the Congressional Research Service report. The line reads, ''Oversight is most effective if it is conducted by Congressional committees of jurisdiction.'' Now, the FCC somehow took this quote and conveniently came up with the idea that they do not have to give this Senator any documents. Of course, to anybody in the Congress, this makes no sense whatsoever, but that is what the FCC hid behind. And, of course—you know me—I did not give up. The FCC's response to me is just another variation on what the Justice Department told me when I started asking questions about Operation Fast and Furious.

Fortunately, we have Members of the House of Representatives who are not afraid to ask this administration some tough questions. In Fast and Furious, it was Chairman ISSA who held the Justice Department's feet to the fire to make sure they responded fully and responded completely. With LightSquared, it was another committee in the House of Representatives, the House Energy and Commerce Committee. Chairmen WALDEN, UPTON, and STEARNS and their staff have done an excellent job in making sure the FCC is open, transparent, and provides documents to Congress, even when they do not want to give those documents to a Senator who asked for them, meaning this Senator.

I would also like to thank Commerce Committee Chairman ROCKEFELLER here in the Senate for pressing the FCC personally to release documents. With all of this help, we are making sure the FCC is open with the American people about the way they operate because transparency brings accountability.

In over 30 years of conducting oversight, I can say that when it comes to providing documents to the Congress, the FCC is one of the worst Federal agencies I have ever had to deal with. Even after receiving a document request from the Energy and Commerce Committee in the House of Representatives, the FCC still tried to play the tired old games agencies play when they are not acting in good faith.

When they finally turned over their first batch of documents—would you believe it?—those documents were already publicly available on the Internet through the Freedom of Information Act. So they weren't giving us anything we didn't already have access to.

When they didn't convince us they were acting in good faith—because, quite frankly, they weren't—they gave us a second production. But in that production, of the first 1,968 pages they produced, all but 3—in other words, 1,965 pages—were newspaper clippings. Again, the FCC was playing games. And, of course, that is not acceptable.

Fortunately, we have continued to press the FCC, and we now, with the help of the House of Representatives, have approximately 8,000 nonpublic internal documents. Still, we have not received all responsive documents from the FCC yet. We just received another 4,000 pages of documents, and I have been told that approximately 7,000 more documents are on their way to Congress. We now at least have a path forward. That is why I lifted my holds a couple weeks ago, so these nominations could move forward.

I trust the House committee will ensure that the FCC provides those 7,000 or so additional documents. I have always said if you are hiding something, it is best to get it out in the open, because the longer you stonewall—in this case the FCC—the worse you are going to look when those facts finally come out.

The FCC has attempted to stonewall my request for documents for almost a year, and they have failed. But they failed only thanks to the help provided by the House Energy and Commerce Committee, and because of that help we are finally able to review internal documents from the FCC—the very same documents we should have gotten when we first asked in our request on April 27 of last year.

As I said when I initially filed my intent to object, I strongly believe it is critical for Congress to have access to documents in order to conduct vigorous and independent oversight. Whether it takes 1 day, 1 week, 1 month, or even 1 year—as it did in this case—I will continue to pursue transparency across the Federal Government because transparency brings accountability. That is essential so that Congress can practice its constitutional role of oversight over the Federal Government.

The role of oversight is this simple: Congress passes laws and appropriates money. That is not the end of it. Our government is a government of checks and balances. We have a responsibility, after passing laws and appropriating money, to make sure the laws are faithfully executed and the money spent according to the intent of Congress. That is oversight.

Even now as we review these documents we have already gotten and begin conducting interviews with key FCC staff, the investigation, obviously, continues. Step one was getting access to the FCC e-mails. We took this step so we could make sure we had the facts before we jumped to conclusions.

Now it is time for step two—asking hard questions of the key FCC personnel who approved the LightSquared waiver. This process may continue to take more time, but however long the process takes, I will continue to press for transparency at the FCC because, again, with transparency comes accountability.

This agency must operate in an open and transparent manner, and we must have answers regarding the LightSquared waiver. The people at the FCC work for the American people, they don't work for themselves.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. MANCHIN). 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, we are now on the motion to proceed, as you know, to the Food and Drug Administration Safety and Innovation Act of

2012, which is basically the reauthorization of FDA for the prescription drug user fees and the medical device user fees. There are a couple of new provisions in this bill dealing with the generic drug user fees and the biosimilar drug user fees as well. So this bill is extremely important.

We have been working in our committee for over a year on it, working with colleagues on both sides of the aisle. As both Senator ENZI, my ranking member, and I pointed out yesterday, this has been a true bipartisan effort. We did not divide up in terms of party—Democrat or Republican—we divided up in terms of interest areas, and we had working groups within our committee so that Senators who had a particular interest in one area or another were on that working group. We also had Senators who were not on the committee but who had interest areas in it involved in our working groups. So they and their staffs had full working knowledge of what was going on all the time and it was a true collegial effort. Those working groups completed their work earlier this year.

We also called in all the stakeholders—the prescription drug manufacturers, the pharmacists, the drugstores, consumer groups, and practitioners. So we had all the stakeholders involved in this too. And now we have come up with a bill that has very broad support. I put in the RECORD yesterday a list of over 100 different organizations, everything from the drug manufacturers to consumer protection groups and consumer groups that are supporting this bill. It has very broad-based support. And, again, I believe that is due to the fact we proceeded on the reauthorization of this bill in the time-honored tradition of the Senate, which is for the committee to take the reauthorization prospect, to do its due diligence—and we did that for over a year, as I mentioned—and to make sure people were involved at every step of the process on both sides of the aisle. We brought in the stakeholders and continued this effort, as I said, for over a year to the point where we now have a bill that is broadly supported.

As I said, everyone has a common interest in ensuring our products don't hurt patients. I have said in our hearings, and I continue to believe, safety is the paramount consideration. We cannot sacrifice patient safety on the altar of other considerations. Patient safety is still the highest standard, the highest mark at which we aim our sights. But getting the products to patients quickly is also important.

I have heard heartwrenching stories of patients desperately waiting for treatments, and of inspiring accounts of small startup companies seeking to fill the needs of these patients with innovative medical products. Patient groups and industry alike have stressed the need for efficient FDA processes to get products to patients quickly.

Again—and I will be pointing out later also—FDA does a very good job of getting products, both drugs and devices, to market quickly. In fact, of the 154 drugs approved in both the United States and Canada, in a study done by the New England Journal of Medicine, 132 were approved here first. So we have not been dragging our heels and FDA hasn't been dragging its heels in terms of getting the job done.

Some say, well, sometimes products get approved more rapidly in Europe than they do here. That is true, but it is important to note that foreign approval standards are different. So it is kind of an apples-and-oranges kind of comparison. The FDA here approves drugs and devices based on their safety and effectiveness—safety and effectiveness. Are they safe and do they actually do what they say they are supposed to do?

Other countries—basically in Europe—only consider safety and not whether the device is effective. So as long as it is safe, they approve it. So, yes, they have a shorter approval time, but they don't take into consideration effectiveness.

I strongly believe the United States should keep this high standard of both safety and effectiveness. It is important to know if a device is effective because that affects a patient's decision whether to accept the device's risks and whether to forego maybe alternative treatments.

FDA officials testified before our committee this year. They submitted documentation showing that 95 percent of medical device applications were reviewed within the deadlines set in the past user fee agreement. Now, despite all this good work FDA is doing, patients were sick or dying. Promising therapies can't be approved quickly enough. So the bill we have before us will continue to support the agency and its good work, but it will allow for some very big improvements.

The medical device industry has agreed to double its user fees, to pay twice as much, and in return the FDA has agreed to speed review times, increase transparency, enhance communications—all of which will get devices to patients more quickly but still keep safety in mind. So anything we can do to both streamline the process, get drugs and devices to patients sooner, and make sure we keep our high standard of safety and effectiveness is not only good for business but critical for the patients who need them.

I expect the FDA Safety and Innovation Act will have significant impact on FDA's ability to approve medical products in an efficient and transparent way. As I said, that benefits everyone. Investors will feel better about putting their money into medical technologies, companies will translate their research and development work into sales more quickly, support for innovation will allow the United States to maintain its leadership position in the biotech industry, and this will preserve and create jobs all over America.

In this sector, as long as we preserve safety standards—which is, what is good for business is good for patients—then, again, if companies and their investors believe the climate is right to commit resources to new medical therapies, this means patients who did not previously have options will have treatments to turn to. So I say this bill is a win-win for everyone.

Inspiring innovation and improving patient access to medical therapies are two of the many ways this bill modernizes our regulatory and oversight system to benefit both patients and the biomedical industry. The FDA Safety and Innovation Act is a truly bipartisan consensus bill that reflects the input and shared goals of a wide range of stakeholders. I hope we will be on the bill shortly after our noon caucuses and conferences for the two parties this afternoon. I trust that we will have only relevant amendments to the bill. I hope that has been accepted on both sides, and that we can discuss the bill and have the relevant amendments and have them disposed of sometime this week.

So I am hopeful we can get this bill done before we go home for the Memorial Day recess. But we will be back on the bill this afternoon. I urge all my colleagues to give this bill their support. We will have some amendments, I am sure, that will be relevant to the bill. They will be debated and voted upon. But, nonetheless, I hope we can expeditiously move this bill and get it done.

The clock is ticking. The FDA authorization runs out at the end of this summer. You might say, well, we have until then to get it done. We are out of here the month of August. We are out of here for the Fourth of July break. We have a Memorial Day break. We have appropriations bills to do. We have all kinds of things we have to do this summer. Plus, it is not waiting until the last minute.

FDA needs to know very soon whether they are going to have these resources. The drug companies need to know whether FDA will have the resources to continue to do its work. So sometime midsummer FDA will probably have to start sending out pink slips to people they will not be able to keep past the end of the summer because they will not have the funds. It has been estimated that up to 2,000 people could lose their jobs at the end of this summer if we don't do our work and get this bill reauthorized.

So time is of the essence. We need to get it done so we can go to conference with the House, work out whatever little disagreements we may have, and get the final bill to the President, hopefully sometime in June so the FDA then will not have to go through any processes of seeing who they are going to lay off and how they are going to close things down at the end of the summer.

So, again, time is of the essence. I urge all my colleagues to support this well-thought-out bill that has taken over a year to put together. All of the

stakeholders support it with broad support across America. So I hope we can get on the bill this afternoon and bring it to a close as soon as possible.

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

The PRESIDING OFFICER (Mr. TESTER). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BLUMENTHAL. 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. BLUMENTHAL. Mr. President, I am pleased and proud to follow Senator HARKIN, one of the chief authors of the FDA bill, and to thank him and Senator ENZI for this truly bipartisan, monumental work on a measure that is essential to the future of the health of our Nation as well as our economic security.

This bill is a big one. It is a big bill with complex provisions and an essential purpose: to safeguard the public, to protect patients, and encourage innovation and invention, which are so important to treating and curing diseases in this country as well as other problems. This measure is revolutionary in many ways. It contains complex new provisions with bipartisan support. Truly, the bipartisanship in support of this bill makes it noteworthy as well.

I am pleased to say it includes the GAIN Act, which I helped to author and champion with my colleague, Senator CORKER, and 15 other Senators who have joined in this effort to incentivize the development of new antibiotics, to treat, stop, and conquer the superbugs, as they are known, germs that are resistant to antibiotics that now exist. To provide more drug security, the supply chain needs greater safeguards. I have worked with Senators BURR, BENNET, HARKIN, GRASSLEY, and WHITEHOUSE on this measure. I am proud to say it is in here. The bill includes provisions on treatment and research on pediatric diseases and conditions that is the work of Senators REED, ALEXANDER, and MURRAY. I have been very proud to add to their efforts. Of course, it includes the work on medical device innovation and safety, which I have done with Senator GRASSLEY and Senator KOHL.

This measure, in a way, epitomizes the approach we should take to FDA regulation, which is to enable devices to reach the market more quickly, to make sure they are safe but available more promptly, to guarantee surveillance and oversight after they reach the market, and reporting by industry so we enlist industry as a partner and make the FDA an ally, not an adversary, with industry in innovation and patient care.

Nowhere is this approach more necessary than in addressing the drug shortage problem in this country. It is a problem, it is a crisis, it is an outrage. The United States should be embarrassed and outraged that the greatest country in the history of the world, the strongest on the planet, having developed lifesaving medicines and devoted extraordinary research and development to make those medicines available to the people of this country, still has shortages, crisis shortages in those very pharmaceutical drugs.

That crisis is inexcusable and unacceptable. The bill takes a step in the direction of addressing and solving this crisis. It is a first step. I leave no doubt, as I stand here, that I will continue to work on this problem, to advocate other steps—some that I will suggest today and others that will be forthcoming in measures I will propose later.

I first became aware of the drug shortage problem through contacts with people from Connecticut, patients who suffer as a result of these drug shortages and doctors who are hugely concerned about the choices they have to make and the dilemmas they face every day in their practices, and hospitals that engage in what they call triage, trying to find drugs to substitute for the ones that are in shortage so they can care for patients who are literally dealing with life-and-death situations.

We are not talking about just one or a couple of drugs. Methotrexate was recently the subject of a New York Times front-page article. It provides cancer treatment, but there are other cancer-treating drugs that are also in short supply, essential for both prolonging life and giving life to patients who otherwise would lose it more quickly. We are talking about Mitomycin, about Doxil, about Cytaraline. In other areas of treatment we are talking about epinephrine, which is important for allergy treatment, zinc injections, which are necessary for nutrition deficiencies, Propofol, a workhorse medicine commonly used in emergency rooms across the country when people arrive in need of anesthesia. For these drugs and hundreds of others, literally hundreds of others, to be in shortage is unacceptable and inexcusable.

What illustrates this problem perhaps most dramatically are the faces and voices of the people in Connecticut and in every State around the country who suffer because of these drug shortages. They are your neighbors, your friends—my colleagues' constituents. They are coping with pain, anxiety, sadness, grief, anger—and there are drugs available to them that would provide relief and remedies. Their docs cannot get them because they are in shortage.

We are talking about people of great courage and fortitude, such as Susan Block. She is just illustrative. I have her picture here. My office helped her to get a drug called Doxil to treat her cancer because halfway through her chemotherapy treatments for ovarian cancer she arrived at the hospital one day to learn from her doctor that Doxil would no longer be available. She called my office in a panic upon learning that information. Ovarian cancer causes more deaths than any other cancer of the female reproductive system and Susan was unwilling to settle for half a treatment. She was right, and her doctor supported her and my office supported her in securing an emergency delivery of Doxil for Susan, allowing her to complete treatment.

She has allowed me, graciously, to share this photo with you today.

I am pleased we have been able to help constituents in Connecticut again and again to secure these medicines when they have been in shortage, working with manufacturers as well as hospitals in that effort. But it should not have happened at all.

Not everyone has been this lucky. Stephen Hine of Bethel wrote to my office after he lost his wife Ann. She died of terminal ovarian cancer. Ann was also on Doxil. While the drug was not going to save her life—these drugs do not always save lives—it could have prolonged her life expectancy. But she could not get Doxil in time and she lost her battle with cancer. Stephen, her husband, understood that the drug would not have cured her but it would have helped her live longer to spend more time with her family, her daughter, who was going to graduate that spring. It would have meant so much for Ann to see her daughter graduate. We have a right to ask what kind of nation allows patients to go without these drugs and forces doctors to make decisions about who needs them the most.

I thank Senators KLOBUCHAR and CASEY particularly for championing this effort even before I arrived in the Senate and later, personally, the Chair of the Health, Education, Labor, and Pensions Committee and the Ranking Member, Senator HARKIN and Senator ENZI, for their support.

There are proven measures that will help solve these issues. More needs to be done, but the drug shortage provisions contained in the bill before this chamber, which provides for a requirement of notification in the event of a discontinuance or interruption of the production of life-supporting, life-sustaining drugs or drugs intended for use in the prevention of a debilitating disease or condition or a sterile injectable or a drug used in an emergency are critical. The reasons these drugs are in short supply was illustrated and documented by a GAO study. It showed that drugs are in short supply—not just once, but they are chronically in short supply, some of them many times—it showed definitively that these drugs are old, sterile, often injectable, and generic. The market simply is not working for these drugs. The profit margins are not sufficient to sustain the supply. The market for these drugs is broken.

If these drugs—to draw the analogy to a utility—were electricity, the lights would go out. We would not accept that situation. The lights are going out for patients in Connecticut

and across the country because the markets are not working and the government, the FDA, is failing in its responsibilities—under great pressure, perhaps with good intentions, but still not working effectively enough. The President of the United States recognized it when he issued an Executive order that required the FDA to use its current powers of notification more effectively and to refer price-gouging cases to the Department of Justice when there is evidence of them. The markets are not working so there is now a gray market that involves markups of 200, 300, 500, 800 percent, sometimes even higher, in the prices of these drugs as they are resold in secondary markets.

Beyond this requirement of notification that is contained in the bill, there are other measures that are important or necessary so that we do more to address these problems. I have refiled my amendment from the HELP Committee markup, along with Senators FRANKEN, SCHUMER, CARDIN, and KLOBUCHAR, to impose penalties, tough penalties for manufacturers who fail to notify. Notification is fine but it will be less effective if there are no penalties for failure to notify. We may try to walk a balance between enforcement and incentives, but enforcement in this area is critical, and this measure imposing penalties for failure to notify is critical as well.

The amendment is a fair one. It provides for penalties of up to $10,000 per day—up to $1.8 million per violation—for failure to notify the FDA within a reasonable time frame of known discontinuance of a lifesaving drug.

I am proposing as well an amendment that would require critical manufacturing reinvestment. I have worked with the manufacturing industry to create a public/private partnership to incentivize the development of additional manufacturing capacity. The root of the drug shortage problem is that these products are old and generic and difficult to make so that we need more capacity, we need more plants making more of these drugs. Over the long term, this kind of partnership will strengthen the markets and strengthen our capacity. It says the Secretary of Health and Human Services has authority to implement an analysis of the root causes of the drug shortage and to proactively seek these kinds of partnerships with manufacturers to produce more of the drugs that may be in shortage right now, but to predict, to forecast, what will be in short supply in the future.

Market manipulation must be addressed more effectively and I have proposed an amendment that will stop the gray market so far as it is possible to do, to prohibit market manipulation of drugs that are in shortage and prohibit the distribution of false information. It gives the FTC authority to assess penalties for these actions. I thank my colleagues on the Commerce Committee, Chairman ROCKEFELLER, and also thank Senator SCHUMER for his leadership, because he has shown a similar commitment to addressing these issues.

Our doctors and our health care providers deserve some recourse from market manipulation. The gray market must be stopped and the FTC must immediately establish a reporting mechanism for price gougers and gray-market profiteers.

These measures are a beginning. The notification provision now in the bill is a start. I thank, again, Chairman HARKIN and Ranking Member ENZI for their leadership and the FDA for its cooperation. The work cannot stop with this bill. Drug shortages are unacceptable and inexcusable, and the people of America, if they are aware of it, will demand that we heighten the fight toward a comprehensive solution.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Louisiana.

CHILD TAX CREDIT

Mr. VITTER. Mr. President, Senator SESSIONS and I come to the Senate floor today to discuss the Child Tax Credit Integrity Preservation Act, the bill I introduced last year, to address a real problem with IRS enforcement allowing illegal aliens to access the additional child tax credit.

The reality is, because of this enforcement problem and this loophole in terms of how the child tax credit is enforced, illegal aliens who pay no taxes and are not entitled to this check from the government received $4.2 billion in 2010 alone. These are checks from the government through the Child Tax Credit Act.

There have been several studies under the President Obama administration that say this is ridiculous, this is unintended, we need to stop this. I am proposing we do and that we move forward in a simple, bipartisan, commonsense way to stop it. Let me briefly note some of those studies.

In March of 2009, the Treasury Department said:

> As it now stands, the payment of Federal funds through this tax benefit appears to provide an additional incentive for aliens to enter, reside, and work in the United States without authorization, which contradicts Federal law and policy to remove such incentives.

In July 2011, the Treasury Department, through its inspector general, issued a report that was actually entitled ''Individuals Who Are Not Authorized to Work in the United States Were Paid $4.2 Billion in Refundable Credits.''

So, again, under this administration the Treasury Department and the IRS underscore that this is a huge problem to the tune of $4.2 billion every year.

I urge all of us to come together in a straightforward, commonsense, bipartisan way to fix this problem. The IRS and the Treasury Department have told us that the fix is simple, and it is clear. We simply need to mandate that folks applying for the credit use valid Social Security numbers. That will cut off the fraud, and that will cut off $4.2 billion going improperly to illegal alien families. It will not cut off the benefit going to anyone who deserves it under the law.

UNANIMOUS CONSENT REQUEST—S. 577

Mr. VITTER. Mr. President, I ask unanimous consent that the Committee on Finance be discharged from further consideration of S. 577, the Child Tax Credit Integrity Preservation Act, and the Senate proceed to its immediate consideration; that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Is there objection?

The majority leader is recognized.

Mr. REID. Mr. President, reserving the right to object, first of all, I want to express my appreciation to the Senator from Louisiana and the Senator from Alabama for their courtesy. They are going to talk a lot longer on this matter. They recognized there was a good chance I would object to their request. They have agreed to allow me to say a few words before they finish what they have to say on the Senate floor. I appreciate their courtesy very much because I do have some other things I need to work on.

Mr. President, the Vitter-Sessions legislation literally takes a sledgehammer to a problem that deserves some very fine tuning and a scalpel. There are news reports that have suggested that some have claimed the child tax credit for children who actually live outside the United States.

The Tax Code is very clear that the child tax credit is not available for children living outside the United States. It is very clear. If, in fact, someone is doing that, then those filers and tax preparers are committing a fraud on the people of this country. If they are doing that and there is a loophole that is existing, we need to close that loophole.

Chairman BAUCUS has already had his staff work with the IRS to determine if its procedures are strong enough to stop such fraud. We believe they are, but if they are not then it is up to Congress to plug any loopholes that may exist. However, the Vitter-Sessions legislation eliminates the child tax credit for filers who are fully complying with the law. That is not a good result. In fact, the legislation that is proposed fails to address the issue of the child tax credit being claimed for children not living in the United States, so the problem is not solved by this legislation. The legislation goes well beyond what is necessary to stop fraud in the Child Tax Credit Program, and therefore I object to the consent request.

The PRESIDING OFFICER. Objection is heard.

The Senator from Louisiana.

Mr. VITTER. Mr. President, before the distinguished majority leader has to leave, I would just ask, through the

Chair, if we can get some clarification and hopefully come to some consensus, is he suggesting that illegal aliens in the country should continue to receive the credit? Is he suggesting that citizens who qualify for the credit but happen to live outside the country should not get it?

It seems to me the problem is illegal aliens receiving the credit, wherever they are physically, not the people outside the country who are receiving the credit, some of whom qualify for the credit.

If I could bring that point up through the Chair.

Mr. REID. Mr. President, without fully debating the subject—and others know more about it than I do, but what I do know is that we want to make sure any children who are here and who are American citizens and entitled to this get the benefits.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. I would say, through the Chair, thank you for that clarification. We have exactly the same goal in mind, and I believe this approach of the Vitter bill—the House has already passed this approach recently, and its budget outline actually accomplishes that. By requiring a valid Social Security number, we allow everyone who truly qualifies for the credit to get it, and we stop it from going to illegal alien families who do not deserve the credit under the law.

I invite my distinguished colleague from Alabama to add to the discussion.

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SESSIONS. Mr. President, I thank the Chair, and I appreciate the insight the majority leader provided. We will look at that and see where we stand on it, but I would urge that we do not need to wait a great deal of time for this to be fixed.

The inspector general for Tax Administration of the U.S. Treasury Department started raising this formally in 2009. The issue actually came up in 2007 when individuals in the Treasury Department thought there was something wrong occurring. So the inspector general did a report, and he has called on us to fix it.

In fact, he said in his report:

> We continue to believe the legislation is needed to ensure compliance with both laws.

I would say that is what we need to do. The House has acted and we should act. Four billion dollars a year is a great deal of money. It is about $10 million a day that is going out of the country to individuals who should not be receiving it.

According to the inspector general's report, the amount of the child tax credit—and as Senator VITTER said, this is not a tax deduction. This is a $1,000-per-child tax credit that we have for people in the United States who work, who have worked lawfully, and who have children and they get a check. If they owe no income tax at all, and a substantial percentage of the people who work in America end up not paying income tax, but they still get a check from Uncle Sam for $1,000 per child.

It was a policy I supported because over the years families had not gained the kind of deductible advantage that had been done 30 years ago when people had children, and it leveled the playing field and helped working families raise children in a decent environment. It is a policy I like, but it is not for somebody here illegally and has children in some foreign country. That is not what it is about. It is for $4 billion. It has surged.

In 2005 the inspector general noted that the IRS paid out to these ITIN filers $924 million in 2005. In 2006, it was $1.3 billion. In 2007 it was $1.7 billion. In 2008 it was $2.1 billion. In 2009 it was $2.9 billion. From 2009 to 2010 it went from $2.9 billion to $4.2 billion. It has been surging every year.

As a matter of protecting the Treasury of the United States from abuse, the IG says we need legislation. The Senator from Louisiana has drafted legislation that will do the job precisely as it should. Would the Senator agree that Congress should not wait around another year? It is something that the House already passed, and if we passed it, it would become law in perhaps a matter of days.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. Mr. President, if I could respond through the Chair.

I absolutely agree with the Senator from Alabama. Too often folks in Washington want to make things overly complicated. Some issues debated in the Congress are complicated. Other issues are not complicated, but they are made a whole lot more complicated than they need to be made, and this is one of those.

All we are saying is folks who qualify for this benefit under the law should get it, but folks who don't qualify, including illegal alien families, should absolutely not get it. The law is clear on that. What we have is an enforcement problem. We also have the Obama administration, through the Treasury Department, absolutely agreeing that this is an enforcement problem and that this bill is the legitimate and proper solution.

Again, in March 2009 the Treasury said:

> As it now stands, the payment of Federal funds through this tax benefit appears to provide an additional incentive for aliens to enter, reside, and work in the United States without authorization. . . .

That means it is a magnet to draw more illegal crossings into the country.

Again, in July 2007, the Treasury inspector general had a whole report, and the title was ''Individuals Who Are Not Authorized to Work in the United States Were Paid $4.2 Billion in Refundable Credits.'' That inspector general said what we need is fixed legislation just like this.

In fact, this is what we do with regard to the earned-income tax credit. We require a valid Social Security number for that separate tax credit. We are simply applying that valid fix to this different tax credit.

Again, let's not make a pretty straightforward situation difficult. Let's fix a glaring problem. As the Senator from Alabama said, it is a $4.2 billion-a-year problem. We come to the floor every day to talk about soaring deficits and debt, to talk about impending cuts in defense and other areas, and yet we have this glaring $4.2 billion savings that we are not taking advantage of.

The House has acted. The House recently acted and passed exactly this provision. Let's act in a bipartisan, commonsense way in the Senate and tell the American people we are going to stop wasting $4.2 billion a year for this completely unauthorized purpose.

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SESSIONS. Mr. President, I would point out to my colleagues how much $4 billion is. It is a matter that we deal with on a regular basis around here. It is a number that has come up several times recently.

For example, we had a shortfall in our plans to fund the Federal highway program—a deeply disappointing event that we couldn't get that bill passed. It started out as a $4 billion shortfall. They worked that number down, but it is still not fully paid for. We would like just a few billion dollars to pay for the bill, and it hasn't been passed.

The student loan fixed rate where the interest rates would be dropped—if I am not mistaken, that was $4 billion. We need it to reduce interest rates on student loans. That is $4 billion, according to the IG, going out of our country wrongfully every year that we could save.

The President spent a lot of time traveling around the country saying we should raise taxes on the rich and we should pass the Buffett tax. He had a proposal for the Buffett tax. How much would the Buffett tax raise? It would raise $4 billion. That is how much closing this loophole would raise. Frankly, I am a little disappointed that the Treasury Department officials and the administration itself haven't immediately seized upon this loophole that is costing the taxpayers large amounts of money and responded themselves by sending legislation over and asking us to pass it. Why aren't they asking us to pass it to begin with? Well, the inspector general, who is an independent—who gets a little independence within the Department of Treasury but, in fact, is an employee of the Secretary of the Treasury—he says we need this legislation. Quoting his report:

> Clarification to the law is needed to address whether or not refundable tax credits such as ACTC may be paid to those who are not authorized to work in the United States.

Well, of course they ought not to be getting a check from the U.S. taxpayers if they are not authorized to be working here.

So as the ranking member on the Budget Committee, knowing how tight our budget is, I salute Senator VITTER for doing it this year as well as last year when he saw this problem and attempted to get it passed. I am pleased the House has passed it. I think if we keep working at it, I say to Senator VITTER, maybe we can get it done in the Senate, remembering that $10 million a day is going out of the country for every day we fail to act.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. Mr. President, I wish to thank very much my colleague from Alabama for his leadership on the Budget Committee and his leadership on issues such as this. I want to encourage the distinguished majority leader to look at the actual details of the problem and this legislation. When he does, he will see that this legislation is very finely tuned to the actual problem, and it is an outrageous problem.

There has been quite a bit of media attention on this abuse over the last several months. A lot of it came out of Indiana. A tax preparer there brought cases in Indiana and said he got no response from the IRS when he tried to report completely fraudulent returns using fake income and documents. He pointed to a number of actual tax forms in which illegal aliens were exploiting this. He said: ''I can bring out stacks and stacks. It is just so easy, it is ridiculous.''

An illegal alien who was actually interviewed admitted in another case that his address was used by four other illegal aliens who didn't even live there. All told, they claimed 20 children were living in one trailer, and they received checks from the government through this program totaling over $29,000. Only one child was ever observed at that mobile home. Twenty other children who live in Mexico have never even visited the United States.

Again, let's not make a simple fix overly complicated because it is not. This is an outrageous abuse. The Obama administration Treasury Department has said so. They have endorsed this fix. The House has passed this fix. Let us in the Senate pass this fix on a bipartisan basis and save the American taxpayer $4.2 billion each and every year.

With that, Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SESSIONS. Mr. President, to conclude, I think the American people are unhappy with their leaders. They feel as though the money they have sent here is not being well spent, is not being watched closely enough. We have a big judicial conference for the second year—since 2010, the second time—to go spend $1 million on a resort conference in Maui. We have the Solyndra loans going out to cronies that are not being paid back in any way. We have the General Services Administration having a big party out in Las Vegas with hot tubs and magicians and so forth. We have no budget for three consecutive years in the U.S. Senate. And what are we hearing from many of our leaders here in Washington? Well, we have a problem, American people. We have too big a debt. Send us more money. Send more money. We don't have enough. We are borrowing 40 cents of every dollar we spend. Send more money.

I think the American people are tired of hearing that. I think they have a right to be tired of hearing that. Until this country is willing to face up to saving $10 million a day on this kind of manipulation that has been going on since 2007, at least, and has been raised by the inspector general since 2009, until those kinds of things are stopped, I don't think they should send any more money to Washington. We need to honor the money they are sending.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

TRIBUTE TO THOMAS HUDNER

Mr. BROWN of Massachusetts. Mr. President, I rise to speak about a historic ceremony that took place in Boston Harbor—the birthplace of the American Revolution—this very morning.

This morning, the United States Navy named an *Arleigh Burke* class guided-missile destroyer for retired United States Navy Captain Thomas Jerome Hudner, Jr., of Concord, MA. The ceremony took place aboard the oldest commissioned warship in our United States Navy, the USS *Constitution*.

As the Presiding Officer knows, it is a distinct honor for any service member to have a Navy vessel commissioned in his or her name. What made the event today extremely rare is that Captain Hudner is the Navy's last living Medal of Honor recipient from the Korean War.

As the story my colleagues are about to hear shows, no one could be more worthy of this distinction than Tom Hudner.

Tom is a native of Fall River, MA. He was a student at Phillips Exeter Academy when the Japanese attacked Pearl Harbor. As a leader on his school's athletic fields and in its student government, naturally he responded to the call to arms. And although World War II ended before his commissioning at the Naval Academy in Annapolis, Hudner began a storied Navy career that would earn him our Nation's highest military honor.

During his first few years in the Navy, Hudner served as a communications officer aboard various warships before being accepted to the Navy's flight school in Corpus Christi, TX. After earning his wings of gold, Hudner became one of the ''Fighting Swordsmen'' of Strike Fighter Squadron 32 aboard the aircraft carrier USS *Leyte*.

Just a few years after the racial integration of the U.S. military, Hudner began flying alongside a young ensign named Jesse LeRoy Brown, the Navy's first black pilot. Brown was born and raised in the segregated, deep south town of Hattiesburg, MS, a world away from Hudner's home in Fall River, MA.

In the summer of 1950, less than a year after Hudner finished flight school, North Korean Communist forces invaded the Republic of Korea. Within months, President Truman ordered the *Leyte* into action off the coast of Korea where Hudner and his wingman, Jesse Brown, immediately began flying reconnaissance and attack sorties against Communist positions. Not long after their squadron joined the fight, Chinese forces invaded the Korean peninsula and threatened to overrun U.S. positions.

There are no routine missions in wartime, especially when flying close air support over enemy positions. On the afternoon of December 4, 1950, Hudner and Brown were on a mission to destroy enemy targets near the Chosin Reservoir. About an hour into the mission, Brown's Corsair was hit by enemy fire, began to lose fuel and he was forced to crash land his aircraft into a snowy mountainside.

The events that transpired over the next few hours became enshrined in the history of American Naval aviation.

Despite exposure to hostile ground fire, Hudner continued to make low passes over Brown, who was trapped in the wreckage of his destroyed aircraft. When Hudner saw that his wingman's plane was burning, he deliberately crash-landed his own aircraft, risking his life. And though injured in the violent landing, Hudner ran to try to rescue Brown.

For Tom Hudner, never leaving your wingman was more than just a phrase he learned in flight training, it was a covenant. A short time later a rescue helicopter pilot arrived, and both he and Hudner tried in vain to free Brown from the wreckage. With night falling and Ensign Brown lapsing in and out of consciousness, Hudner was finally forced to evacuate the bitter cold crash site. Brown's final words to Hudner were to tell his wife Daisy that he loved her. He would do that in person.

On April 13, 1951, Daisy Pearl Brown was in the audience when President Harry S. Truman presented Thomas Hudner with the Medal of Honor for his heroic attempt to save Ensign Brown.

Over the next two decades, Hudner continued to serve with distinction in the United States Navy. In addition to flying many of the Navy's newest jet fighters, Hudner's career would take him from various ships and air bases where he served in positions of increasing responsibility, including as executive officer of the USS *Kitty Hawk* during the Vietnam War.

Hudner and Brown's wife Daisy remained friends, their lives intertwined by the events decades earlier on a snowy mountainside on the other side of the globe. In fact, the two friends would stand together at another ceremony some 22 years later when the

U.S. Navy commissioned the first American warship in honor of an African American, the USS *Jesse L. Brown*.

Hudner retired from the U.S. Navy at the rank of captain in 1973, and while his day-to-day service in the military would end, he continued to serve his fellow veterans through the USO and a variety of veterans' organizations. In fact, for most of the 1990s, Hudner served as commissioner of the Massachusetts Department of Veterans Affairs.

Today, the newly commissioned USS *Thomas Hudner* will serve as a living legacy to heroism and service. Think about it for a moment. When a sailor or Marine is assigned to this ship, they will proudly tell their family and friends about Hudner and Brown. When the *Hudner* makes a port call, those in the communities it visits will see the ship in port and meet scores of crew members with ''USS Thomas Hudner'' stitched on their shoulder.

And when citizens around the world learn about Captain Hudner's specific act that the Navy has described as ''conspicuous gallantry and intrepidity at the risk of his life above and beyond the call of duty,'' they will begin to understand what uncommon valor truly is. Tom Hudner's story will serve as an inspiration to a future generation of Americans.

Please allow me to thank Captain Hudner for his lifetime of exceptional service to our Nation and his dedication to his fellow veterans. I ask my colleagues and our Nation to join me in wishing him and his wife Georgia all the very best in the years ahead.

Mr. President, I yield the floor.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate stands in recess until 2:15 p.m.

Thereupon, the Senate, at 12:30 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. WEBB).

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

Mr. REID. Mr. President, I ask unanimous consent that the Senate remain on the motion to proceed to S. 3187 until 4 p.m. today and that all other provisions under the previous order remain in effect at that time.

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

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, I thank the majority leader for bringing up this bill. He and the Republican leader have put on the floor a piece of legislation that affects nearly every American family. This will not have the fireworks some things we do have, because we have a lot of agreement on it, which is one reason it is on the floor. It has gone through the committee. Senator HARKIN and Senator ENZI have worked carefully with all of the Republicans, all of the Democrats on the committee, and many other people on a complex piece of legislation for a year, to bring to the floor the Food and Drug Administration Safety and Innovation Act—a bill that is likely to succeed.

We take our medicines for granted. During the Civil War, the Capitol was used as a hospital—this Capitol. Two thousand cots were set up in the House and Senate Chambers and the Rotunda. The first group of wounded arrived from the Second Battle of Bull Run and later from Antietam in September of 1862. Those soldiers did not have the benefit of antibiotics or other modern medicines that we take for granted today, and that contributed to a horrible number of deaths in the Civil War.

Still, as the 20th century dawned, disease cast a long shadow over the United States of America. A child born in 1900 could expect to live an average of 47 years. Infectious diseases took many children before they reached their teens. In 1900 pneumonia and influenza were the leading causes of death, followed by tuberculosis and diarrhea.

Physicians had few weapons to fight diseases. The medicines at the time included such things as mercury for syphilis and ringworm; digitalis and amyl nitrate for the heart; quinine for malaria; and plant-based purgatives. For most of human history, diabetes meant death, but insulin was introduced in 1923 commercially, and within a few years enough insulin was being produced to meet the needs of diabetes patients around the world.

It is hard to remember this, but vaccines began to be commercially produced only during the time of World War I. It was not until the time of World War II that we saw the introduction of widespread and effective antimicrobial therapies with the development and mass production of penicillin. Since then, the sky has seemed to be the limit.

Half of Americans take at least one prescription drug every day. One in six takes three or more. Many take over-the-counter medicines. It is a real miracle what has happened in terms of our lives with the introduction of medicines, and we rely upon the Food and Drug Administration to keep those medicines safe and effective, which is what this legislation is about.

I would like to renew my compliments to Senator HARKIN and Senator ENZI for bringing this bill to the floor in a condition where they have already worked out most of the issues. This bill is complex. It is long. It has 11 titles. It will help safe and effective drugs, medical devices, and biosimilar products get to the market and, more importantly, get them to the market more quickly so people who need help can use these medicines and devices.

We are reauthorizing two user fees. These things have absurd names. The Prescription Drug User Fee Act is called PDUFA, and the Medical Device User Fee Modernization Act is called MDUFMA. There are two new ones, which are GDUFA and BSUFA. It is really absurd. I promise to never again use those phrases for these user fee programs. But they are critically important programs that give the Food and Drug Administration needed resources to review new medically necessary products.

For example, there is the Better Pharmaceuticals for Children Act. It is a part of what we are doing this week. I cosponsored it with Senators REED of Rhode Island, MURRAY, and ROBERTS. I thank them for the ability to work with them.

This makes permanent the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. One is an incentive, and one requires pharmaceutical companies under certain circumstances, when they develop new drugs for adults, to figure out the effect that those drugs will have on children. Too often, we do not know the answer to that, and the drugs are either ineffective or can have bad results. It also reauthorizes the Pediatric Medical Device and Safety and Improvements Act to promote pediatric medical device development.

Another critical part of the bill has to do with the medical device approval process. The United States is a world leader in medical devices. In Tennessee we have lots of them, especially in Memphis. We need to improve the regulatory process. There are many who believe the FDA is over-regulating medical devices. That has a negative effect on the industry's ability to raise capital and create jobs. It does not make those devices any safer in the United States than they are in Europe. This will help address those problems. For example, it will allow customization of medical devices for small populations—that means five people or fewer—without going through a very burdensome approval process, and it changes the humanitarian device exemption to encourage and incent the development of devices to treat patients with rare diseases—that would be groups of patients of fewer than 4,000 people.

There is another problem that is addressed in this legislation. It is the generation of antibiotics dealing with antibiotic resistance. We know there is a growing problem with antibiotic resistance as bacteria continuously mutate and evolve in their resistance to the drugs and the medicines we develop. While efforts have been made to preserve existing antibiotics, drug development has not kept up with the pace. These changes will provide meaningful market incentives and reduce regulatory burdens.

In addition, I am very pleased with the results of our work in dealing with drug shortages. That is a part of this bill. It will give the FDA additional tools to help prevent drug shortages and require FDA to look internally at

regulations to see if the FDA is making the problem worse.

Senator CASEY and I worked together on a review of Federal initiatives to combat prescription drug abuse and to issue a report on those. Tennessee, my State, ranks second in the Nation for prescription drug use. Our Governor, Bill Haslam, and our legislature took action this year to deal with that. We intend to help them.

In closing, I would like to commend Senators HARKIN and ENZI. I see the Senator from Washington on the floor. I do not want to take much more time because I know she is about to speak. She has been integrally involved in the development of this legislation over the last year, especially the Better Pharmaceuticals and Devices for Children Act. I mentioned that a little earlier. It incentivizes drug manufacturers to study their products and how they affect children, and in return, they get to keep the exclusive use of those products for a little while longer. That means they do not go to generic quite as quickly. That has been tried in this legislation since it was first authorized and reauthorized and reauthorized. It has worked. It has been a very good example of an innovation in legislation that has achieved the desired result.

The Pediatric Research Equity Act gives the FDA authority to require pediatric studies in some cases and the Pediatric Medical Device Safety and Improvement Act promotes the development of pediatric medical devices.

So the importance of the legislation is it takes a big step forward in making it clear what drugs that are created for adults will do when offered or provided to children. Currently, just under half of the drugs prescribed to children have been studied and labeled for children, but that is a significant improvement over where we were when these programs started fifteen years ago. Children's bodies react very differently to medicines. Children are not just small adults. Sometimes side effects are different. Physicians have to guess what dosages are appropriate, whether a therapy that might be effective for an adult is also effective for a child. Sometimes there are examples of overdosing or previously unknown side effects. In one case in Tennessee in 1999, seven babies were prescribed an antibiotic to treat whooping cough. They became so seriously ill, they needed stomach surgery. The CDC—Centers for Disease Control—later linked their illness to the antibiotic, which had never been tested in young children. Children differ widely in sizes and growth rates, so for medical devices doctors must either 'jerry-rig' devices or be forced to use a more invasive treatment.

Prior to the passage of these laws that we are working on today, and reauthorizing, 80 percent of drugs used for children were used off-label; that is, we did not really know how they affected children. Now we can use those drugs—half of our drugs today—safely and effectively because we do know that. The Best Pharmaceuticals for Children Act is the carrot that FDA uses to encourage pediatric studies, while the Pediatric Research Equity Act is the stick to mandate studies. Together these two laws have been a success. According to the Institute of Medicine, as of October 2010, the FDA has approved 425 labeling changes as a result of studies or analyses done under these laws. In 1975, only about 20 percent of drugs prescribed to children had been studied and labeled for children, in 2007 that number had risen to about one-third, and today it is roughly half.

The Pediatric Medical Device Safety and Improvement Act was enacted in 2007 to encourage manufacturers to bring more pediatric devices to the market and strengthen FDA post-market surveillance of devices used in children. This law allows manufacturers to profit under the humanitarian device exemption for devices specifically designed to meet a pediatric need affecting fewer than 4,000 children per year. In addition to three humanitarian device exemption pediatric products, GAO reports that 15 new devices have been approved for children since 2007.

I am happy to come here today to join with Senator MURRAY, Senator HARKIN, Senator ENZI, Senator REED of Rhode Island, and Senator ROBERTS to offer what I believe is a piece of legislation that affects nearly every American family. It takes one more step in the dramatic story of how we have gone from a country with almost no medicines to a country in which almost everyone takes some medicine and a situation where the lifetime of the average American has increased from 47 years of age to 78 years—its present level today.

I see the Senator from Washington on the floor. I wish to recognize and thank her for her leadership on the legislation.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I too wish to thank the Senator from Tennessee, as he referred to how we are working together on a bipartisan basis on the Better Pharmaceuticals and Devices for Children Act—a very critical piece of this legislation that I will talk about in just a few minutes as well. But I would like to thank him for working with us, and really I want to thank all of the Senators who worked very hard on this piece of legislation, working with stakeholders and advocates for over a year on the bill that will be on the floor later this afternoon. I commend Chairman HARKIN as well as Ranking Member ENZI for working together in a bipartisan fashion to get this to the floor today.

I hope all of our colleagues really understand the critical importance of moving forward with this bill as efficiently as possible because, as many people know, if we do not make this legislation a priority, by the end of September over 2,000 employees at the Food and Drug Administration are going to be sent packing with pink slips. But what is just as important, if not more important, is that failure to pass this legislation will put drug and medical device approval at a standstill. That will not only halt innovation but it will put the lives of many Americans at risk while they wait for potentially lifesaving medicine.

No one knows the importance of that more than Seattle Genetics, a company in my home State of Washington. In August of last year, Seattle Genetics received FDA accelerated approval of a drug intended to treat Hodgkin's lymphoma, the first of its kind approved by the FDA in more than 30 years.

As a biotech company, Seattle Genetics' relationship with the FDA was really vital to the work they were doing to bring this drug to patients who were in need. Ultimately, Seattle Genetics received FDA approval 11 days earlier than expected, and that meant they were able to anticipate the timing of its approval, organize their sales teams, and ship the first business day following approval for a patient already waiting for that critical drug. That kind of collaboration would not have been possible had the FDA lacked the resources necessary to make it a reality.

I believe that Clay Siegall, who is the president and CEO of Seattle Genetics, was truly able to underscore the issue of what we are discussing here today. I want to tell you what he said.

> It is only through working with an FDA—that has the resources and dedication to achieve thorough and timely reviews—that we are able to fulfill our promise to improve the lives of people through innovation. Passage of this bill helps to provide both the resources and incentives for FDA to rapidly review and approve important therapeutic breakthroughs for patients in need.

That highlights the importance of this legislation.

I also wish to highlight another part of this bill that I have been very focused on, as the Senator from Tennessee just talked about, and that is the need to make sure drugs and medical devices are specifically tested and labeled and proven to be safe and effective for our children. This is so important for families and doctors across America.

I really want to thank Chairman HARKIN as well as Ranking Member ENZI for including my bill, the Better Pharmaceuticals and Devices for Children Act, in the broader legislation we are considering here today.

I was very proud to work with Senator ALEXANDER, along with Senators REED and ROBERTS, to put together this commonsense legislation. This bipartisan language will make sure our children are prioritized in the drug development process and that drug labels provide clear, detailed information about the proper use and dosage of medications for children. It will give parents and doctors more information, and it will make sure the key programs

we count on to protect our children do not expire. It will push to make sure children are never just an afterthought when it comes to the safety and effectiveness of our Nation's drugs and medical devices.

Mr. President, as you have heard today, this is a bill that has received bipartisan support. I commend all of the Senators who have worked on it in a bipartisan way. We don't get credit for that enough in this country. But this is certainly one where everybody came together and worked together in committee. This bill holds the livelihood of so many Americans in its balance.

I urge the Senate to move forward quickly and support the legislation and get it passed.

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. DURBIN. 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. DURBIN. Mr. President, I ask unanimous consent to speak as in morning business.

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

THE DREAM ACT

Mr. DURBIN. Mr. President, 11 years ago, I introduced the DREAM Act, which is legislation that would allow a select group of immigrant students with great potential to contribute more fully to America.

The DREAM Act is not an amnesty bill. It would give students a chance to earn legal status in America, and there are standards they would have to live up to: No. 1, they came to the United States as children; No. 2, they have been long-term U.S. residents; No. 3, they have good moral character; No. 4, they have graduated from high school; No. 5, they either serve in America's military or complete 2 years of college.

The DREAM Act also includes important restrictions to prevent abuse. Under the DREAM Act, no one would be eligible for Pell grants or any other Federal grants when they go to school. Individuals who commit fraud under the DREAM Act, who lie, misrepresent their status, would be subject to tough fines and criminal penalties, including a prison sentence of up to 2 years. It is serious. No one would be eligible for the DREAM Act unless they arrived in the United States at least 5 years before the bill becomes a law. There is no exception and no waiver for this requirement.

My colleague from Florida, Senator MARCO RUBIO, on the Republican side of the aisle, said in a recent speech that the DREAM Act is not an immigration issue, it is a humanitarian issue. I might add that I think it is an issue of justice.

Thousands of immigrant students in the United States were brought here as children. They didn't make a decision at the age of 2 to come to America. It was not their decision to come here, but they grew up here, went to school here, and they stood in classrooms across America pledging allegiance to the only flag they ever knew. They sang ''The Star-Spangled Banner'' before baseball and football games, believing they were part of America.

The fundamental premise of the DREAM Act is that we should not punish children for their parents' actions. It is not the American way. Instead, the DREAM Act says to these students that we are going to give them a chance. These Dreamers, as I have come to know them, don't want a free pass. They just want a chance to earn their place in America. That is what the DREAM Act would give them.

The DREAM Act isn't just the right thing to do, it would make America a stronger country by giving these talented young people the chance to serve in our military and contribute to our future. Tens of thousands of highly qualified, well-educated young people would enlist in the Armed Forces. That is why we end up with the support of people such as General Colin Powell, who has given his life to the military and the security of America. He says the DREAM Act is the right thing to do for the future of America.

Studies have found that DREAM Act participants would contribute literally trillions of dollars to the U.S. economy during their working lives.

One might wonder how an idea like that ends up becoming a bill and being debated not only on the floor of the Senate and the House but becoming a subject of debate in the Presidential contest now going on. It started with a phone call to my office about 11 years ago from a woman named Duffy Adelson. Duffy is the director of the Merit music program in Chicago. The Merit music program is an amazing program which offers to children in the public schools of Chicago an opportunity to learn to play a musical instrument. That program goes to the poorest schools and asks children if they are interested, if they would like to have an instrument and a chance to learn. Children sign up and amazing things happen. These kids—100 percent of them—end up in college. That is what that one life experience of learning to play music can do.

She called me about a young girl. She was a Korean who had been brought to America at the age of 2. Her mother and father became citizens. Her two siblings, a brother and a sister, were born here and were automatically citizens, but she was not. She joined the Merit music program and turned out to be an accomplished pianist, to the point where, when she was graduating high school, she was being offered scholarships to the best music academies in the United States.

When her mom sat down with her to fill out the application, there was a little box that said ''citizenship.'' She turned to her mom and said: So what do I put there? Her mom said: I brought you here at the age of 2 on a visitor's visa, and since you were a little baby, I didn't file any more papers. I don't know what you should put there. The girl said, What are we going to do? Her mom said: We are going to call DURBIN.

So they called me and my office checked the law and the law turned out to be pretty harsh. The law said this 18-year-old girl—who had never lived, to her knowledge, in any other place but America—had to leave America for 10 years and then apply to come back. That didn't seem right. She came here at the age of 2. She had done nothing wrong. So I introduced the DREAM Act.

Well, here is the rest of the story about this young lady, whose name is Teresa Lee. Teresa Lee did go to the Manhattan School of Music, and when she went there she turned out to be as good as the Merit music program thought she would be. She progressed to the point where she literally played in Carnegie Hall. She found a young man, fell in love, got married, and she became a citizen by virtue of that marriage. She is now working toward her PhD in music. She is a brilliant young woman.

There was a talent that would have been lost to us and lost to the future if we had followed the strict standards of the law at that moment. But we didn't. We gave her a chance and she proved herself. She proved she is a quality individual.

When I introduced the DREAM Act, it was a bipartisan bill. There were Republican Senators who actually debated as to who was going to be the lead sponsor of the bill because they thought it was such a good idea. The DREAM Act has had a history of broad bipartisan support. When I introduced it with Senator ORRIN HATCH of Utah, he was chairman of the Judiciary Committee and was the lead Republican sponsor. When the Republicans controlled the Senate, the DREAM Act was reported by the Judiciary Committee on a 16-to-3 bipartisan vote. And on May 25, 2006, 6 years ago this week, the DREAM Act passed the Republican-controlled Senate on a 62-to-36 vote as part of comprehensive immigration reform.

That bill, unfortunately, did not pass, and, unfortunately, the Republican support for the DREAM Act has diminished over the years. The last time the DREAM Act was considered on the floor of the Senate in 2010, the bill had already passed the House and received a strong majority vote there, but only eight Republicans supported it in the House and only three Republicans in the Senate. A bill which had been so bipartisan and so popular was now becoming, each time we called it up for a vote, more partisan. The bill hasn't changed, but politics had changed.

The vast majority of Democrats in the House and Senate continue to support the DREAM Act. But the reality is we cannot pass the bill without substantial support from my colleagues on the other side of the aisle. That is why I have always said I am open to working with anyone—Republican or Democrat—who is interested in working in good faith to solve this problem. I will never close the door on the possibility of providing assistance to these DREAM Act students.

I have come to the floor almost every week for the last several years to tell the story of another young person who would qualify under the DREAM Act. Today I want to tell you the story of Sahid Limon. Sahid was brought to the United States from Bangladesh in 1991 at the age of 9. He grew up in Durham, NC. His dream was to become a doctor. He attended Southern High School—a prestigious magnet school for young people interested in health care. He was a member of the National Honor Society and won his high school's Diamond in the Rough Scholarship award. One of Sahid's teachers said:

In the classroom, he was kind, very respectful, and responsible. He showed great interest in a career in medicine. In the medical community, through shadowing experiences, he was professional, highly motivated, and caring with patients.

Sahid didn't learn about his immigration status until his senior year in high school. He went on to graduate from East Carolina University with a bachelor's of science in biology, with a concentration in microbiology. And understand, he didn't qualify for any Federal loans or any Federal grants. It wasn't easy to get through college under those circumstances.

During college, Sahid volunteered at underserved rural areas in North Carolina and it made a big impression on him. In his application for medical school, he wrote:

I was surprised to see that so many people would line up during a cold winter morning, just to know if they were healthy or not. Seeing their dedication and patience influences me every day to work my hardest in order to meet my personal goal of becoming an exceptional physician.

That was 7 years ago—2005. Today, Sahid is 30 years old. He has been unable to attend medical school because of his immigration status. Since he graduated from college, he has volunteered with a health clinic in Raleigh that serves low-income patients, he has tutored elementary school students to help develop their interests in science, but his personal dream of becoming a doctor has not become a reality.

Some of my colleagues have criticized the DREAM Act because people under the age of 35 are eligible. They say only children should be eligible for the DREAM Act. But this ignores the obvious. Every year we wait, those children grow a year older. In order to qualify for the DREAM Act, an individual must have come to the United States as a child, as Sahid did. Today he is 30. That doesn't change the fact he was brought here when he was 9 years old. It doesn't change the fact he has lived in the United States virtually all his life. And it doesn't change the fact he should not be punished for the choices his parents made. Sahid was 19 years old when the DREAM Act was first introduced. Why should he be penalized because I can't pass the bill? I keep trying, but Congress doesn't get it done. Does that mean his life should be wasted?

Last year, Sahid was arrested by immigration agents and placed in deportation proceedings, despite the fact he has lived in the United States for 21 years, since he was 9 years old. He was held in a county jail with violent criminals. Sahid has never committed a crime in his life. Sahid sent me a letter, and here is what he said about the experience of being in jail and facing deportation:

I lived my life by the law, did everything by the books, never committed any crime, and somehow ended up in jail for something I had no control over as a child. What would I do if I was sent back [to Bangladesh]? I barely speak the language, and I don't know how to read or write. How am I supposed to start my life from scratch in such a place without the knowledge of the language or the culture?

Well, my office learned about Sahid's case. We contacted Immigration and Customs Enforcement and asked them to consider his request that his deportation be placed on hold. The Obama administration placed a stay on his deportation proceedings. However, it is only temporary. It doesn't give him permanent legal status, and he is still at risk of being deported sometime in the future. The only way for Sahid to be permitted to stay in the United States permanently is for us to do something to pass the DREAM Act—to change the law.

In his letter to me, Sahid explained what the DREAM Act meant to him:

The DREAM Act means being able to be home. Regardless of where we go . . . we all yearn to come back to our home. To me, North Carolina is that home . . . I watched live on C–SPAN [in 2010] as the bill passed the House, but failed to pass the Senate. To most of the Senators, it's just another bill that was rejected. However, to someone like me, whose life not only depends on something so crucial, but my future literally hangs in line, it's absolutely devastating to witness such a rejection. I hope this is the year that politics is set aside, and all of the representatives can work together for a solution.

Sahid is right. Those of us who are fortunate enough to serve in Congress have an obligation to set politics and party aside and do the right thing. This isn't a Democratic issue or a Republican issue. We are going to be a stronger and better country if we give Sahid a chance to earn his way to American citizenship.

This is not just one example, one person. There are literally thousands like him waiting for their chance. The DREAM Act would give Sahid and other bright, accomplished, and ambitious young people like him the opportunity to become tomorrow's doctors and engineers, teachers and soldiers. Today I ask my colleagues again, as I have so many times before, to support the DREAM Act. Let's give Sahid and so many other young people like him the chance to contribute more fully to the country they call home. It is the right thing to do, and it will make America a stronger Nation.

FINANCIAL REGULATION AND REFORM

Mr. DURBIN. Mr. President, 2 weeks ago, we were given a cautionary lesson about the need to ensure that our Nation's banks are carefully regulated. We are still learning the details about the $2 billion bad bet made by banking giant JP Morgan Chase. But what we have learned is disturbing. Apparently, the London office of this Wall Street giant crafted a credit derivative trading strategy that spun out of control over the course of 6 weeks. At the center of the strategy was one single trader who was nicknamed ''the London whale.'' One trader, 6 weeks, $2 billion gone.

It is not clear how widely the repercussions of this trading loss will extend, but this incident clearly is an important reminder to all of us that we cannot afford to take a hands-off regulatory approach to the giant financial institutions on Wall Street. These institutions drove this Nation to the brink of economic disaster just a few years ago. If they are simply left to their own devices, it could easily happen again.

We need reasonable financial regulation that will ensure transparency, competition, and choice. We need to prevent Wall Street banks from fixing the rules and setting up rigged schemes that line their own pockets and hang Main Street America out to dry.

Two years ago, Congress passed, and the President signed, the Dodd-Frank Wall Street Reform and Consumer Protection Act. This legislation took on the challenge of placing a reasonable regulatory framework on Wall Street. It is a tough challenge. Wall Street and the banking industry have enormous resources and enormous power, and they are not afraid to use it—not only on Wall Street but on Capitol Hill.

In the days to come, we are going to see important regulatory efforts proceed on issues such as the Volcker rule, which deals with the big banks' ability to make bets with their customers' money. It is important we pursue this regulatory effort diligently. We cannot let the big banks use their threats and scare tactics to water down reform and to preserve business as usual. There is too much at stake.

I want to talk today about another part of the Wall Street reform that passed 2 years ago, a provision that the big banks hate as much as any other. I am talking about the provision I wrote dealing with interchange fees, or swipe fees. The swipe fee is a fee that a bank receives from a merchant, like a restaurant or a retailer, when the merchant accepts a credit or debit card

issued by the bank. That fee is taken out of the transaction amount. If your bill is $50 at the restaurant, that includes the fee the restaurant is paying to the bank and credit card company called the swipe fee—the interchange fee.

The vast majority of bank fees are very transparent and competitive. Chase, Bank of America, Wells Fargo, and the rest set their own fee rates and compete for business based on the fees they charge. But that is not the case with these swipe fees—the interchange fees—that affect credit and debit cards. The big banks know competition and transparency help keep fees at a reasonable level, and make it harder to make big money off of fees. That is why they set up the swipe system—the interchange system—to avoid competition and transparency.

The big banks decided, rather than each of them setting their own swipe fees, they would designate two giant card companies—Visa and MasterCard—to set the fees for all of them. That way, each bank could get the same high fee on a card transaction. No competition. Then the banks buried this swipe fee under layers of complexity within debit and credit transactions. Most consumers, and even most merchants, still have no idea how much they are being charged on a swipe fee.

This system helped the card-issuing banks do very well over the last 20 years. U.S. swipe fee rates became the highest in the world, and they kept going up even as the cost of processing transactions went down. Debit swipe fees alone—just debit cards—brought the banks over $16 billion in the year 2009. That is the interchange fee paid by the merchants—and ultimately by the consumer—to the banks and credit card companies when people use a debit card.

Of course, banks don't need all this debit swipe fee money to conduct debit transactions. The actual cost of a transaction is very low, a few cents. But the banks, looking for more revenue, exploited the swipe fee system to charge far more than they could ever justify. It doesn't have to be this way. Many other countries—Canada, European countries, and others—have vibrant debit card systems with swipe fees strictly regulated or prohibited altogether. In the United States, debit swipe fees used to be tiny, until Visa took over the debit card market in the mid 1990s using tactics that I think bordered on violations of antitrust.

By 2010, the U.S. swipe fee system was growing out of control, with no end in sight. There were no market forces serving to keep fees at a reasonable level. Merchants and their customers were being forced to subsidize billions in windfalls to the big banks. That is when I introduced an amendment to the Wall Street reform bill that, for the first time, placed reasonable regulation on swipe fees on debit cards.

The reason I picked debit cards is—some of us are old enough to remember something called a checking account. Those checking accounts are still around, but checks are becoming rare. Most people do their checking transactions with a piece of plastic called a debit card. The money comes directly out of their bank accounts just as the check removed money directly from their bank accounts. That is why the debit card is a different transaction than the credit card.

My amendment said if the Nation's biggest banks are going to let Visa and MasterCard fix swipe fees for them, then the rates must be reasonable and proportional to the cost of processing the transaction. There would be no more unreasonably high debit swipe fees for big banks.

My amendment also included a nonexclusivity provision which aimed to stop Visa from taking over the debit card market entirely. This provision says there needs to be a real choice of card networks—real competition.

The regulatory steps my amendment proposed were modest. Most other countries have gone a lot further in regulating their credit and debit systems. But if you have listened to the banking industry and card companies, you would have thought my amendment would be the end of the world as we know it. They made outrageous claims, that regulation and swipe fees could kill the debit card system, devastate small and community banks, and particularly be an end to credit unions and cause banks to raise their fees on customers.

My amendment passed the Senate with 64 votes and was signed into law, and it has been 8 months since the swipe fee reform took effect. It turns out all the scary scenarios threatened by the banks have not come to pass.

First, the banks claimed it was impossible for Visa and MasterCard to establish a new tier of regulated swipe fee rates. As it turned out, creating this two-tier system was easy. There were already hundreds of rate tiers, so adding another one wasn't difficult.

The banks then claimed that small banks and credit unions would be hurt by reform—even though all institutions with assets of less than $10 billion were exempt. As it turned out, small banks, community banks, and credit unions have actually thrived since this reform took effect. Why? Because under my amendment, small banks and credit unions can continue to receive high interchange fees from Visa and MasterCard—higher than the big banks that control about 60 percent of the issuer market. And, those big banks have been so heavy-handed in their response to swipe reform that they have driven their customers—many of them—straight into the arms of the community banks and credit unions.

Credit unions in particular are flourishing after the passage of swipe fee reform—a reform which they actively opposed. Last year, 1.3 million Americans opened new credit union accounts. That was up from 600,000 the year before. More than twice as many people as before opened credit union accounts, and credit unions now have a record number of members across the Nation—almost 92 million overall. So much for the prophecy by the credit unions that this change in the law would be the end of them. It has turned out to be the best thing that has ever happened to them.

I know the Washington lobbyists for the small banks and credit unions still like to complain about this reform. These lobbyists have spent so much time fighting reform they are just not going to change their positions. But the facts are clear—if they will just be honest enough to admit it. Small institutions have thrived since this reform took effect.

How about consumers? The big banks tried last year to recoup their reduced swipe fees by charging $5 monthly debit fees on their cardholders. Do you remember that? Do you remember when Bank of America said it was going to go up to $5? Do you remember what they said all across the nation? Bye-bye, Bank of America. We will go somewhere else. Within a matter of a month or two Bank of America backed off of it.

Finally, consumers were coming alive. They were awakened to the reality that they could shop too. This is a free market—underline the word ''free.'' If you don't like the way your bank or any institution is treating you, go shopping. That is part of America. The banks had never run into that before. People just waited, unfortunately, for the latest fee increase. People don't wait around anymore. They pick up and move.

Unlike swipe fees, the big banks' $5 debit fees were transparent and customers had a range of competitors to choose from. So they moved. Transparency and competition worked.

Consumers are also benefitting from savings passed along by merchants. After swipe fee reform took effect in October, we saw a massive level of retailer discounting that extended beyond the usual holiday season discounts. According to USA Today—an article from May 11—a number of individual merchants are offering debit card discounts for items such as gas, furniture, and clothing.

USA Today also pointed out that despite the banks' threats, free checking accounts for consumers have not disappeared. USA Today reported that in the second half of 2011, 39 percent of banks offered checking accounts with no monthly maintenance fee, up from 35 percent for the first half of the year. Also, of those banks that charge checking maintenance fees, the average fee fell in the second half.

This is what is known as competition. What is wrong with that? That American families and consumers go shopping for the best bank deal. It is happening because swipe fee reform has created new competition. I think competition is a good thing.

It is important to note that the savings of swipe fee reform to merchants and consumers actually should be even greater than it is. When the Federal Reserve was writing its rule to implement my amendment, the banks lobbied them to set a swipe fee cap at a level significantly higher than the 12 cents that the Fed established in its draft rulemaking. Predictably, Visa, MasterCard, and the big banks took advantage of this watered-down regulation they had lobbied for. Visa and MasterCard promptly jacked up their swipe fees to the 24-cent ceiling set by the Fed.

Here is what has happened. Swipe fees have traditionally been charged as a percentage of the transaction amount plus a small flat fee. This meant the small dollar transactions used to incur fees of much less than 24 cents. Now, with Visa and MasterCard's rate increases, businesses that primarily deal with smaller transactions—coffee shops, fast-food restaurants—are paying far more in swipe fees than they did before.

This is not a flaw in the law we passed, which wisely required reasonable and proportional fees. Rather, it shows the danger of watering down the regulations to implement the law. The banks and card companies lobbied the Federal Reserve for a loophole which they immediately raced through. This is something we need to fix going forward. It can be fixed.

I am pleased the modest swipe fee reform we enacted in 2010 is off to a good solid start: more competition, customers and families moving across America for the best treatment they can receive from their bank or their credit union. But already the big banks and card companies are plotting to undo all these reforms and get that money back, the billions of dollars which they were taking in under the unregulated swipe fee regime. Visa, in particular, has crafted new fee schemes in its continuing effort to monopolize the debit card market. In fact, Visa recently disclosed that the U.S. Justice Department has opened a new antitrust investigation into anti-competitive aspects of Visa's newest fees.

I continue to be concerned that the giant card companies—particularly Visa—are becoming too big and too powerful. These companies have gained an enormous amount of control over the way Americans can use their money. They set up the fee systems, they dictate the security standards, and they make a fortune by taking a cut out of every transaction they handle, far beyond the cost of processing. There is no regulatory agency that directly supervises the actions of these card companies, and we can't afford to simply trust these companies to do what is in our Nation's best interest or to watch out for consumers.

That, again, is why the Consumer Financial Protection Bureau created by the Dodd-Frank law is such a critically important agency. It is virtually the only agency at the highest levels of our government that is solely devoted to consumer protection when it comes to financial products.

In the weeks and months to come, I will continue to work to ensure that the debit and credit card systems have competition, transparency, and choice, and that there is a framework for reasonable regulation. I know the big banks and card companies are going to continue to fight it. They have a lot of money on the table. But I believe reasonable regulation is the right way to move forward, and I will continue to work for it. Our economy, our small banks, our credit unions, our merchants, and our consumers are benefitting from this important change in the law.

Mr. President, I yield the floor.

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

Mr. SESSIONS. Mr. President, I am on the floor this afternoon to discuss a discovery—really, a stunning discovery for me—and that is important for all of us.

As many people know, Congress and the President struck a deal last summer to raise the debt ceiling. That deal set in place discretionary spending caps—not nearly enough to balance our budget over 10 years but a step in the right direction. That legislation said we will raise the debt ceiling $2.1 trillion but we will cut spending $2.1 trillion over 10 years—a promise to cut spending over 10 years.

That legislation also required the chairman of the Senate Budget Committee—of which I am the ranking member—by April 15 of this year to file aggregate spending levels—spending limits—based on the Congressional Budget Office's March 2012 financial baseline and to allocate the funds that could be spent under that Budget Control Act legislation to each of the Senate Appropriations Committees. In other words, these levels as submitted tell the appropriators how much they can spend, and the budget chairman has that responsibility and duty to do that. He takes the level agreement that was agreed to and sends that over.

These are real dollars that each appropriating committee is therefore allowed to spend. Yet we have learned something that is disappointing—really astounding to me. The numbers filed by Chairman CONRAD, my good friend who is a fair and able chairman, are not, in fact, the spending levels from the CBO baseline as the statute sets forward. Instead, the discretionary outlay total submitted by the chairman to the committees for fiscal year 2013 is derived from the President's budget, not from the CBO baseline.

The discretionary spending allocation for the Senate is therefore inflated by about $14 billion more than what was agreed to just last August when we told the American people we would raise the debt ceiling, continue to borrow money, but we were going to reduce spending.

So let me repeat that. These allocation levels have been inflated by $14 billion to match the President's budget—not the CBO base line that the BCA Committee was working from. It raises outlay levels over that August agreement. That, I submit, was a solemn agreement between the Members of Congress, both the Senate and the House, the American people, and the President himself who signed that agreement.

So I have sent a letter to Chairman CONRAD urging my chairman to correct and refile numbers that are proper—numbers that comply with the law.

I ask unanimous consent to have printed in the RECORD a letter that I have written Senator CONRAD today.

U.S. SENATE,
COMMITTEE ON THE BUDGET,
Washington, DC, May 22, 2012.

Hon. KENT CONRAD,
Chairman, U.S. Senate Committee on the Budget, Dirksen Senate Office Building, Washington, DC.

DEAR CHAIRMAN CONRAD: Section 106 of the Budget Control Act (BCA) requires the Chairman of the Senate Committee on the Budget to file allocations and aggregate spending levels that are consistent with the Congressional Budget Office's (CBO's) March 2012 baseline. On March 20, 2012, you filed such levels in the Senate to be printed in the Congressional Record (at pages S1832–S1833).

I was therefore surprised to find that the filed outlay aggregate for fiscal year 2013 is not consistent with CBO's baseline but, instead, appears to reflect the higher outlay level for discretionary spending in the President's budget request (as estimated by CBO). The President's blueprint was voted down unanimously by the Senate.

Specifically, the filed outlay aggregate for fiscal year 2013 is approximately $14 billion higher than CBO's baseline figure. The aggregate on-budget outlay level filed with the Senate is $2,944,872 million, but the CBO baseline for on-budget outlays is only $2,931,228 million. The filed figure, therefore, does not satisfy section 106 of the BCA.

Furthermore, section 106(b)(2)(B) of the BCA requires that the mandatory spending allocations to Senate authorizing committees be consistent with the CBO baseline. The CBO March 2012 baseline amount for the Committee on Finance for fiscal year 2013 is $1,328,395 million. But the allocation filed on March 20 ($1,328,474 million) is $79 million higher than the CBO baseline figure.

Before the Senate takes up appropriation bills for fiscal year 2013, I request that you review your allocations and re-file the enforceable levels and related committee allocations at amounts that are consistent with CBO's March 2012 baseline, as required by the BCA.

Very truly yours,

JEFF SESSIONS,
Ranking Member.

Mr. SESSIONS. It is unthinkable that we would not only spend more than Congress agreed to but would institute instead the numbers derived from President Obama's budget—which, in this Chamber, when I brought it up a few days ago, was rejected unanimously. This is another example, I am afraid I have to say, of the sleight-of-hand tactics that have been utilized in this Congress for too long that say we have an agreement and we are going to do better and we are going

to spend less. But as soon as the ink is dry—before the ink is dry, really, on the agreements, people start manipulating ways around it trying to spend more than the allowed. It seems to me, since I have been in the Senate for 15, 16 years, we have Members of Congress who take it as a personal challenge to see how they can defeat, get around, and spend more money than they are allocated.

The American people are being misled in this attempt. We are not following the Budget Control Act, and it is not a partisan matter. It is about honest accounting. It is about safeguarding the American treasury. It is about restoring faith in the Senate Chamber. The American people are right to be angry with us and to not trust us because we haven't honored their trust. We haven't managed their money well. Political elites remain totally disconnected from the financial reality that our country faces.

Game the system, spend more. The alarming discovery that the discretionary allocations filed for the Senate are a total of $14 billion higher than we agreed to and the latest in a long line of episodes, this is the latest in a long line of episodes that underscores the financial chaos that is the American Government.

These episodes include the GSA scandal in Las Vegas, with hot tubs and skits and magicians; the Solyndra loan, $500 million to cronies for an ideological vision that did not work; the IRS checks I talked about earlier this morning, with Senator VITTER, given to illegal aliens who claim dependents living abroad. These are people here illegally claiming dependents abroad while the U.S. Government is sending them checks based on children who are not in the country. The inspector general from the IRS says this is costing the taxpayers $4 billion a year.

It also includes the revelation that the Ninth Circuit Court of Appeals will spend $1 million or more of taxpayer money for a decadent getaway to a beachfront resort and spa in the Hawaiian tropics. And, of course, it includes a 3-year refusal of the Senate majority to produce a budget plan—3 years without a budget.

We are badly in need of strong Executive leadership to put our finances in order. We need a President, Cabinet heads, sub-Cabinet heads who understand from the top to the bottom that they are there every day to look for ways to save money. This immigration tax scam costs the American taxpayers $10 million a day. Divide that out, $4 billion over 365 days. The House has passed legislation that would close that gaping loophole. Meanwhile, the Senate is not acting.

This chaos cannot continue. Accountability and discipline must be achieved, and the first step to right the ship ought to be actually correcting these allocations. I call on my Senate leadership friends to do that. We need an honest accounting. We need to spend what we agreed to, what was passed by both Houses of Congress and signed by the President. These dollars do not belong to us, they belong to the American people. They must be protected. Each one of them is precious. Each one of them was extracted from some hard-working American and sent to Washington on the hope and the prayer that it would be wisely spent. And we do not have enough of them. We do not have enough money.

To stealthily increase discretionary outlays by $14 billion in one fell swoop is unacceptable. It must be corrected. I call on my colleagues to do so, else we will continue to lose the confidence of the American people.

I yield the floor.

The PRESIDING OFFICER. The Senator from Arkansas.

Mr. PRYOR. Mr. President, I would like to speak as in morning business for 15 minutes.

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

NATIONAL FLOOD INSURANCE PROGRAM

Mr. PRYOR. Mr. President, today I rise to discuss the National Flood Insurance Program, which is a program we are now trying to reauthorize in the Senate. Senators JOHNSON and SHELBY have shepherded this bill through the Banking Committee. I have a ton of respect for both of those Senators and the work of the Banking Committee because they worked very hard to get it to the floor, to get it ready. In fact, it expires on May 31. If for some reason we cannot work out something here in the next couple of days, I sincerely hope we will extend this on at least a short-term basis—for another, say, 30 days—to give us time to work this out. The National Flood Insurance Program is too important to mortgages and commercial real estate, et cetera, to let it lapse. If we cannot work it out, I hope we can get a 30-day extension. I support that effort.

We need to reauthorize this legislation, this program, but we need to do it in the right way. Several Senators over the course of the last few months have stated objections to S. 1940. Here are mine. I have listed some of mine in a letter we sent to the chairman and ranking member last month or so—November 15, 2011. We listed several objections and concerns we had with the bill. There were 13 Senators from 9 States who signed this letter going to Senators JOHNSON and SHELBY. Again, we appreciate their efforts, but we have to do this the right way.

Let me run through three or four or five of my concerns about this legislation and tell my colleagues why I cannot support it in its current form and why I do support an extension but why, in the end, if the bill stays the way it is now, I cannot support it. I hope many of my colleagues will join me in the effort of not supporting this legislation as it is currently drafted.

Let me start with the bill itself, S. 1940. The primary objection I have is in section 107 of the legislation. It is titled ''Mandatory Coverage Areas.'' Basically what it does is it redefines ''special flood hazard areas.'' This may not sound very exciting or very fun to people, but this is critically important.

I am showing a map here on the floor today. All of these counties in the dark green—there are 881 counties total that have levees in their counties. To my understanding, well over 50 percent of the U.S. population lives somewhere near a levee. They may not realize it because the levees work and they don't have floods, but if you see this map, you can see the levees all over the country. If you are a Senator representing one of those States, I strongly encourage you and your staff to look at section 107 of the legislation.

Here is part of it, 107(b):

> Residual Risk Areas—The regulations required by subsection (a) shall require the expansion of areas of special flood hazards to include areas of residual risk that are located behind levees or near dams or other flood control structures, as determined by the Administrator.

Subsection (c) says:

> Mandatory Participation in National Flood Insurance Program—
>
> (c)(1) In General—Any area described in subsection (b) [the one I just read] shall be subject to the mandatory purchase requirements. . . .

Then go down to (c)(3):

> In carrying out the mandatory purchase requirement under paragraph (1), the Administrator shall ensure that the price of flood insurance policies in areas of residual risk accurately reflects the level of flood protection provided by any levee, dam, or other flood control structure in such area, regardless of the certification status of the flood control structure.

So regardless of whether these levees and dams are certified—in many cases by the Corps of Engineers, in other cases by private engineering firms—regardless of whether they are certified, the people behind those levees are going to be required to purchase flood insurance.

Let me read that one more time:

> The regulations required by subsection (a) shall require [there is no wiggle room there] the expansion of areas of special flood hazards to include [these] areas. . . .

This is a great expansion of this program. I want to talk about the expansion in just a moment, but let me say that the folks in these areas—I know it is certainly true in my State of Arkansas—the people in these areas currently pay for flood protection. In most cases, what they do is, through some sort of local levy or local tax—it is different in different places, but somehow, someway, they pay to build and maintain these levees. They are paying out of their pockets right now to make sure they do not get flooded. What this bill does and what FEMA would do under this bill—they would be required to do it, wouldn't have any wiggle room—what they would be required to do is make them pay again; not only have to pay for their own levee, they have to pay for flood insurance for floods that will never happen in their

areas because these levees are certified. Again, this is 881 counties, 50 percent of the U.S. population.

Over half the counties in Arkansas have levees. There are over 1,200 dams in our State. I don't have the number of dams for everybody all over the country, but it is over 1,200 in my State, so you can multiply that over how many dams you might think there are in the United States. It is a huge number, and it will affect over half the people in the United States.

I mentioned that these folks are already paying for their own flood protection through local levies. Now, also, according to this law, they are going to have to pay for insurance. In addition to that, to rub salt in the wounds, what they are going to have to do is their local counties are going to have to pass an ordinance that FEMA has written and it is going to restrict the land use. In many cases, that ordinance will diminish the property values, diminish the ability for them to do economic development in their communities.

If we can just take one example of something that happened last year, last year we had terrible flooding in the midsection of the country. Many of you remember that. The Corps of Engineers ended up having to blow the levee at Bird's Point. That is part of the Corps of Engineers' Mississippi River and tributary system.

By the way, we have to thank the Corps of Engineers and praise them for the engineering they have done on the river. I know there have been a few problems over the years. Some obviously happened in Katrina. But overall the Corps of Engineers designed things that work. Certainly when you look at last year, the 2011 flood of last year, in the Mississippi River, one of the longest rivers in the world, certainly the longest in North America, there was more water that flowed through the gauging stations from Cairo, IL, to Natchez, MS, than in any flood in recorded history. The flow at Cairo, IL—the confluence of the Mississippi and the Ohio—was over 2 million cubic feet per second. That was running through the Mississippi River right there. At Helena, AR, it was running at 2.3 million cubic feet per second.

In some locations—the Corps of Engineers is in the process of determining this; they are not ready to say it yet—in some locations up and down the Mississippi River system, they are considering whether this actually was not a 100-year flood or 250-year flood, this was actually a 500-year flood, the largest flood in history.

All of this Mississippi River—MR&T, we call it, Mississippi River and tributary system—all that has cost our taxpayers $32 billion since its inception, but just in the flood last year, it saved taxpayers $110 billion in damages. That is a great return on investment. We need to honor that return on investment. We need to not charge people additional flood insurance for areas that do not flood. They maybe had the 500-year flood up and down the Mississippi or maybe in certain parts of it, and there was not 1 acre of ground that went underwater. It was a new flood of record. Ten million acres of land were protected, 1 million structures were protected, and, again, it prevented $110 billion of property damage. There were no lives lost, and not 1 acre was flooded. The system worked exactly according to plan.

Now this bill comes in and says: Well, even though we just had the 250-year or the 500-year flood, still we want to make all these people up and down the Mississippi in all these counties—not all the people but in certain parts of these counties, depending on what the flood maps say—we want to require them to pay for flood insurance when it is never going to flood there.

I want my colleagues to know that this provision, section 107 in the Senate bill, is not in the House bill. I think the reason it is not—I can't speak for the House, of course, but I think the reason it is not is for the reasons I am saying right here. We know it is not going to flood in these areas. This is the Corps of Engineers. This is the best levee system in the world, and it is keeping these folks safe and dry when the floods come.

Also, I wanted to say the House does not have section 107 in their bill. It never did. There is a House amendment offered by Congressman CARDOZA who took out a requirement to show these areas are on their maps, and that vote passed 261 to 163. So not only can we get consistent with the House because we can get rid of section 107, but we can also get rid of other specific parts of this legislation that will be more consistent with the House.

Here is a map of the Mississippi River, the area I am talking about. We can see the States of Louisiana, Mississippi, Arkansas, Tennessee, Missouri, and a little bit of Kentucky and Illinois is in there as well. But this large blue area is what they call the historic floodplain. Before man came, before people started building levees, before they started draining swamps and trying to manage the land, this is the area that would flood.

One thing important to know about this is that a lot of this area in light blue has some of the richest farmland in the world. The reason it is so rich is that for centuries or eons or however long it was, this river would flood periodically and put this very rich soil out there. That is one reason why in this part of the country they can grow almost anything. That soil is great.

This is a huge industry for the area, and it is important we keep it going. It is also critically important for U.S. trade and the U.S. economy. This is the breadbasket, so to speak, of the United States right here. We have that area growing food and fiber for everyone. It is critical we keep that going.

Once the Corps of Engineers gets control of the Mississippi River—this is what it looks like now when it floods. This is now the floodplain. If you go back to last year when it flooded so badly, this is what it looked like, with one exception; they blew out this one little area in Birds Point to give a little bit of relief. Again, that was by design and that worked.

The first problem I have with the bill is section 107. Another problem is the general expansion of what this bill does to the National Flood Insurance Program. One of the things buried in the bill that a lot of people may not see is in section 118. Section 118 talks about how the Administrator needs to establish an ongoing program under which they review and update and maintain National Flood Insurance Program rate maps in accordance with this section, et cetera, et cetera. Then they go down their criteria of what they need to look at.

It says here ''all populated areas and areas of possible population growth located not within''—not the 100-year floodplain. The current law is the 100-year floodplain. What this plan says is the 500-year floodplain. We don't have a map of that because the Corps of Engineers has not finished mapping and FEMA has not accepted all the maps yet. We don't know exactly what that is going to look like, but I am going to say it is going to look something like this here. It is a good bet that a lot of people in this light blue area are going to have flood insurance.

Based on the flood we had last year, they are never going to get flooded, not in 100 years, and certainly not in 500 years. They are not going to get flooded, but this says they must purchase flood insurance. This is a huge expansion of the program. It has a big impact not just on homeowners, which is obviously very important. They are not going to be able to get a mortgage if they are in a floodplain.

What this law says in the committee report is that notice will be provided to property owners in the 500-year floodplain to inform them of their flood risks, which may lead to more owners protecting their property through flood insurance.

The PRESIDING OFFICER. The Senator has used his 15 minutes.

Mr. PRYOR. Mr. President, I would ask to have 5 more minutes to wrap up.

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

Mr. PRYOR. Mr. President, what this says in the committee report is that the 500-year flood notation should be sent out to everyone so everyone knows this property is in a 500-year floodplain. The problem is folks are not going to be able to get mortgage insurance, they are not going to be able to do real estate development; commercial real estate is going to hurt from that. They are not going to be able to have economic development projects in these areas because of the floodplain notation.

Also on page 8 of the committee report it talks about how they are going to spend about $400 million annually in

doing this mapping. Well, if they are going to map out the 500-year floodplain, that is a lot more map than the 100-year floodplain. They can save quite a bit of money by doing that.

The bottom line is these levees are designed correctly, they are built correctly, they are maintained correctly, and they are certified that they are safe. What is the point of people having to get flood insurance in that area when it is not required right now?

I also think this legislation requires a huge conflict of interest for FEMA. It is not FEMA's fault; they are not asking for this. It is what the Congress is trying to do. Basically under this law FEMA would write the regs, they will draw the lines, they will control the timing, they will set the standards, they will update the maps, they will maintain the maps. If there is an appeal, they would have to go to FEMA. They also set the rates, they collect the money, and they spend the money. Everything is done by FEMA.

Obviously FEMA is going to have an interest to make sure this program is adequately solvent and funded, and obviously they should. They have control of every aspect of this, with no checks and balances in the system. There are going to be millions of people who will pay in to make this solvent, I guess, but it will never need flood insurance.

With that, I wish to say I hope my colleagues who represent these States, when they look at section 107, will see what I see and we can all work together to either take out section 107 completely or get the 30-day extension so we can have time to take it out in the next few days.

ORDER OF PROCEDURE

Mr. PRYOR. Mr. President, I ask unanimous consent that the majority leader be recognized at 4 p.m.

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

Mr. PRYOR. Thank you, Mr. President.

I yield the floor.

Mr. HATCH. Mr. President, I ask unanimous consent that my remarks be placed in the appropriate place in the RECORD and that I be permitted to finish my remarks.

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

FISCAL POLICY

Mr. HATCH. Mr. President, we find ourselves in the midst of a Presidential election. In years past it might be expected that during a Presidential election, politics would take precedent over policy. That is not right then and it is certainly not right now. Our Nation faces serious problems—immediate problems—and we cannot wait to tackle them until after the election.

We are over $15.7 trillion in debt, and before the end of the year it will be over $16 trillion. We have a Tax Code that is unmanageable and a burden on conscientious taxpayers. If the Congress and the President fail to act, we have a tax increase coming next year that will dwarf any in our Nation's history. We cannot afford to wait another 7 months to get our fiscal house in order, and we need to act now.

President Obama at least claims to understand that we cannot wait to address this fiscal crisis. He remarked recently that the fact this is an election year is not an excuse for inaction. Unfortunately, other than talk, the President and his liberal allies have done nothing to address either our rising debt or the fiscal cliff we are quickly approaching, both of which are significantly hindering our economic recovery and job growth.

Last week President Obama's budget received zero votes in the Senate. For the second year in a row every Republican and every Democrat who voted on the President's budget voted against it. Remarkably, not one Democrat voted for the serious Republican budgets offered by my friend Chairman PAUL RYAN, and my friends and colleagues Senators TOOMEY, PAUL, and LEE.

While he talks a big game, President Obama has shown little interest in lighting a meaningful path toward balancing the budget, reforming the Tax Code, and reducing the tax burden on working families and small businesses.

Instead, President Obama seems to have a single-minded focus on his reelection. While he attempts to scare up votes in swing States, Americans across the country are suffering due to President Obama's failed economic policies. The people of Utah and the people across the country are naturally growing restless. They look to Europe and see the consequences of out-of-control spending and taxes. Yet even with the example of Europe, the President and his friends resist meaningful spending cuts at every turn, and his liberal allies have done everything they can to mislead the public about the responsible intentions of Republicans to reduce wasteful government spending.

Just as critical for our economy is the President's failure to do anything to address the tax relief that will expire at the end of this year. If the President allows current tax relief to expire, the result will be at least a $4 trillion tax increase on the American people. We can call this a fiscal cliff; we can call it ''taxmageddon,'' as others have done. Whatever you call it, it will be a disaster for the middle class. It will be a disaster for small businesses that will be the engine of our economic recovery. One thing we hear time and time again from businesses is that uncertainty holds them back from investing, expanding, and hiring. A robust recovery will require permanent progrowth tax policy.

Given the continued jobs recession and weak economic growth, we need those policies now. Economic growth slowed to 2.2 percent last quarter. For 39 consecutive months the unemployment rate has remained above 8 percent, but that only tells part of the story. There are 12.5 million Americans unemployed, and of those more than 5.1 million workers have been looking for work for 27 weeks or more. There are 7.9 million Americans who are working part time for economic reasons, and another 2.4 million have only a marginal attachment to the labor force. Close to 2 million college graduates are unemployed.

Growth slowed to a tepid 2.2-percent rate in the first quarter, and we already saw business cut back investment as business investment spending declined 2.1 percent in the quarter. Yet the President and his Democratic allies seem content even in this environment to sit on the sidelines as ''taxmageddon'' approaches and threatens even greater harm to our economy.

The coming tax increases will be, without any exaggeration, the largest tax increases in American history, and the possibility of these tax increases is creating enormous uncertainty. The so-called business tax extenders expired at the end of 2011. Will there be an R&D tax credit in 2012? Will there be an exception from subpart F for active financing income after 2011? Families and businesses do not know if the 2001 and 2003 tax relief will be extended beyond 2012. That creates tremendous uncertainty for anyone planning on buying a home, saving for college, investing in a new business, or hiring a new worker. Will passthrough organizations be taxed at 35 percent or 39.6 percent? Will dividends be taxed at 15 percent or will dividends be taxed at 39.6 percent, as President Obama has proposed? Will there be a death tax that hits family businesses and farms with a maximum rate of 55 percent, or of 35 percent, or something else? What will happen to the alternative minimum tax? Will it be patched? Will it be reformed? Will it be repealed? Will it be replaced with higher taxes somewhere else?

The President and the Senate Democratic leadership have shown no willingness to answer these questions and provide the certainty our economy craves. The adverse impact of these tax increases on economic growth is unquestioned. But don't take my word for it. It has been reported that Federal Reserve Chairman Ben Bernanke recently discussed with Senate Democrats the significance of ''taxmageddon.''

In short, the coming tax increases will be so large that Chairman Bernanke apparently warned that monetary policy would not be capable of offsetting the resulting decline in economic growth.

Last month the Fed's policy-setting committee repeatedly warned in minutes of their meeting that fiscal uncertainty has negative effects on consumer and business sentiment, on household spending, durable goods, business capital expenditures, and on hiring.

The former Director of President Obama's Office of Management and Budget concluded that what he estimates to be a $500 billion tax increase

would be so large that ''the economy could be thrown back into a recession.''

According to Barclay's Capital, this fiscal cliff could reduce our GDP by 3 percent.

In addition to these looming tax hikes, budget cuts from the sequester that followed from the administration's failure to arrive at a budget are set to hit as well. According to the magazine ''The Economist,'' the Congressional Budget Office has found that the combined effects of the sequester and the expiring tax relief would add up to 3.6 percent of GDP in fiscal year 2013. Federal Reserve Governor Duke has reportedly indicated that the combined impact of the expiring fiscal policies at the end of the year could amount to around 4 percent of the Nation's economy.

No economy can sustain such a hit without being hurled into recession. Yet instead of addressing this fiscal cliff—tax increases that will harm all of America's families—the President seems content to pursue misguided micropolicies that target the so-called rich in the name of so-called fairness.

I wish to make two points about the President's obsession with redistribution of wealth. First, the American people do not care. The American people do not want government bureaucrats in Washington figuring out who gets what. They don't want politicians spreading the wealth around. They don't want self-anointed arbiters of how much income is fair. What they want is the opportunity that comes with economic growth. They don't want a handout. They don't want their industries vilified for engaging in free enterprise. They want a job. And nothing is more fair than giving every American the chance to make something of himself or herself. That requires Washington getting out of the way, not getting more involved.

Second, the American people seem to understand that the President's promise that he will only tax the rich is a sucker's bet. With his health care law, he already repeatedly broke his campaign promise not to raise taxes on families making less than $250,000 a year. The people of Utah, my home State, and the rest of the other States know that the Democrats' thirst for more spending will require much more than taxes on the wealthy. If President Obama and his Democratic allies get their way, all taxpayers are going to be looking at bigger tax bills.

President Clinton was honest on this point recently. He rejected President Obama's politically convenient claim that he would only tax the rich, and called for across-the-board tax increases: This is just me now; I'm not speaking for the White House. I think you could tax me at 100 percent and you wouldn't balance the budget. We are all going to have to contribute to this, and if middle-class people's wages were going up again, and we had some growth in the economy, I don't think they would object to going back to tax rates from when I was President.

There we have it. Tax increases on everybody. President Clinton can claim that he does not speak for the White House, but the American people are not fooled. They see where the President's policies are leading. Our debt and deficits are unsustainable, but the President has shown no inclination to address them through spending reductions.

There is only one other option available to President Obama and it is one that he and his party have shown to be their preferred policy for decades: higher taxes to pay for more spending. Utahns and Americans all over the country know that the failure to address ''taxmageddon'' is a very real threat. We cannot put this discussion off any longer. It is time for our President to lead.

To that end, last week I, along with 40 of my Republican colleagues, sent a letter to our colleague and friend from Nevada, the Democratic leader, asking for him to address this fiscal cliff in short order. Today we received a response. I have to say I am disappointed. While there is a great deal of political posturing about evil millionaires and big corporations as well as repeated attacks on the tea party and the citizens who support its goals of smaller constitutional government, there is no acknowledgment of the fiscal cliff we are fast approaching. This response seems to confirm what we already know: President Obama and his liberal allies would prefer to put off the discussion of this fiscal cliff. They do not want to address ''taxmageddon.'' I am fairly certain their preference would be to get to the other side of the election and then have tax hikes set in not only for their caricatured evil corporations and individuals but for the middle class as well.

But I am confident that the markets and the American people are not going to allow this to happen. We cannot afford to delay action that will prevent ''taxmageddon'' and steer us away from the coming fiscal cliff.

The likelihood of ''taxmageddon'' and the uncertainty it creates is an anchor around our economy. Americans young and old, unemployed and underemployed, want this anchor thrown off now. We cannot wait until next year or even a lameduck session. The economy is slowing, job growth is lagging, and businesses are cutting back investments. The uncertainty caused by ''taxmageddon'' is contributing to the lackluster economic recovery. American families and businesses are not going to invest in the future if the future holds a $310 billion tax increase next year alone. The best thing we can do to jumpstart our economy is to turn the wheel away from the fiscal cliff sooner rather than later.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. I note the majority leader has appeared on the floor and I believe he has a procedural motion. I yield to him.

ORDER OF PROCEDURE

Mr. REID. Mr. President, if my friend would complete his remarks.

Mr. REED. I would be happy to.

Mr. REID. Following the remarks of the Senator from Rhode Island, we will go into a quorum call.

I ask unanimous consent that immediately following the statement of my friend, the Senator from Rhode Island, a quorum call will be initiated, and then I will be recognized for such time as we decide to come out of the quorum call.

I see people shaking their heads. Here is the deal. Senator REED is going to talk and put us into a quorum call, and when we come out of that, I will be recognized. I ask unanimous consent to that effect.

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

The Senator from Rhode Island.

Mr. REED. Mr. President, I rise today in support of the Food and Drug Administration Safety and Innovation Act, which is pending before the Senate this week.

This legislation will give the FDA, through five agreements made between the agency and industry, the resources to approve additional drugs and devices every year for their safe and effective use. Without these agreements, the FDA, starting in October, would lack these resources which are necessary to approve new drugs and devices, and they would also lack resources to monitor the safety and efficacy of those drugs already on the market. This would result in a reversal of decades of work modernizing our drug and device approval and safety programs.

I am particularly pleased that for the first time, the generic pharmaceutical industry will provide the agency with $1.5 billion over 5 years for faster product reviews. In fact, the essence of the legislation is that the industry is actually providing resources for the monitoring and for the approval of drugs. Getting generic drugs onto the market sooner will help lower costs for individuals and families as well as for the Federal and State governments.

This measure would also significantly improve FDA's regulatory authority, including its ability to help prevent drug shortages and to partner with the private sector to develop new medications to treat life-threatening diseases that have become resistant to antibiotics, which is a very important measure included within this legislation.

I wish to recognize especially Chairman HARKIN and Senator ENZI for their very thoughtful, very deliberative, and extremely important work. They have represented through their committee work the model of what we should be doing here collaboratively and on a bipartisan basis to advance important measures for the American people. Both of them deserve great accolades for their work today. I hope we can follow through and bring their work to conclusion.

I wish to particularly thank both of them, Chairman HARKIN and Senator ENZI, for including provisions pertaining to pediatric drugs and devices that I authored along with my colleagues Senator ALEXANDER, Senator MURRAY, and Senator ROBERTS, another bipartisan effort to improve the health of children throughout this country.

Until 1997—15 years ago—80 percent of drugs were used off-label to treat children. Doctors were treating children without fully understanding the appropriate dosage requirements or the potential for any dangerous side effects. This frustrated pediatricians and angered many families, but those sentiments were largely ignored by the industry until Congress stepped in.

With the passage of the Best Pharmaceuticals for Children Act in 1997 and the Pediatric Research Equity Act in 2003, 427 drugs have been relabeled with important pediatric information. Now 46 percent, rather than 80 percent, of drugs are being used off-label in children, but that number is still too high. The legislation before the Senate makes critical improvements to these laws so we can further lower this percentage. It would make these two acts—BPCA and PREA—permanent, like the laws that govern the approval of drugs for adults. It would also provide the certainty that the pharmaceutical companies believe is necessary to continue to wisely invest in the appropriate use of drugs in children.

The legislation will also help ensure pediatric studies are planned earlier in the drug development process and completed sooner. Currently, a disappointing 78 percent of studies that were scheduled to be completed by September 2007 are either late or were submitted late. While Congress, the FDA, advocates, and the industry agree that a pediatric study should not hold up the approval for a drug for use in adults, drug companies should not be allowed to get away with submitting unrealistic study plans to the FDA for approval or failing to complete a required study once they are profiting from these drugs on the market.

The legislation that is before us would also require pharmaceutical companies to work with the FDA early in the process of developing these drugs to create a reasonable and sensible plan for studying the products in children. It would also, for the first time, provide FDA with an enforcement tool that will deter companies from neglecting their obligation to complete these studies on time.

Our bill also responds to the need for pediatric medical devices—not just pharmaceuticals, but devices—in children, which can lag 5 to 10 years behind those manufactured for adults. The pediatric profit allowance for Humanitarian Use Devices has proven to be a very effective incentive. Three new devices have been approved for their use in children in the last 3 years. This is an incredible increase as a result of this incentive.

This policy has shown much promise and I am pleased to see it continue in this bill, along with the Pediatric Device Consortia Grant Program, which has assisted the development of 135 proposed pediatric medical devices in just over 2 years.

The Food and Drug Administration Safety and Innovation Act would also extend this Humanitarian Use Device incentive to manufacturers of devices for use in adults with rare conditions. While it is my hope this policy is equally effective in spurring developmental devices for use in adults as it is for children, I am concerned that it could impact the development and the marketing of devices for use in children. I plan to monitor this policy closely should it become law, but I have full expectations that both noble objectives can be achieved.

There are some children, however, who do not receive the full benefits of BPCA and PREA.

I am pleased the Senate bill begins to address this problem for pediatric cancer patients and children with other rare diseases. It calls on the FDA to hold a public meeting to discuss ways to encourage the development of new treatments for this population. Indeed, for some pediatric cancers, the treatment has not changed in many decades. For other rare diseases, an effective treatment has yet to be found. I look forward to receiving a recommendation that might stem from this important meeting, as well as working with my colleagues to respond to their needs with reasonable and sensible policy.

I am truly pleased these pediatric provisions have drawn the support of 24 organizations, including the American Academy of Pediatrics, also including the Pharmaceutical Researchers and Manufacturers of America. I think this stakeholder support is very important not only to the ultimate passage of the legislation, but for its effective implementation.

There is another provision I would like to talk about; that is, this bill contains provisions which would require the FDA to decide whether to update the labeling requirements for tanning beds.

Every day 2 million Americans visit a tanning salon. Seventy percent of these are women. According to the World Health Organization, the risk of deadly melanoma increases by 75 percent when the use of tanning devices begins before the age of 30.

So this is a particular concern with young women beginning to use—and younger men—beginning to use these tanning devices. Yet the warning labels on tanning beds have not been updated in over three decades and are often placed far from view.

In 2007 my colleague, Senator ISAKSON of Georgia, joined me in requiring the FDA to study the labeling standards for tanning beds and make recommendations about how these standards could be improved. In its report, the FDA found that tanning bed labels could be clarified and located in a more prominent location. But the agency has yet to act. It is my hope the FDA will heed its own advice and update the labeling requirements for tanning beds.

Similar to the outdated labeling requirements for tanning beds, sunscreen testing and labeling standards have also been over three decades in the making—three decades. Last year I was pleased when the FDA finally took action. However, just last week the agency announced it would be extending the implementation of these new standards by 6 months, until December. Consumers will have to go another summer without knowing whether they are truly protected from the Sun's harmful UVA and UVB rays.

I have filed an amendment to make sure there are no future delays. I look forward to working with my colleagues to see that this amendment is accepted as part of the final FDA legislation which I hope is passed very quickly by the Senate.

I again want to thank Chairman HARKIN and Senator ENZI for their extraordinarily effective and collaborative work on the Better Pharmaceuticals and Devices for Children Act, which is included in this bill.

STUDENT LOAN INTEREST RATES

Mr. REED. Just for a moment, let me raise another pending issue which is of critical importance. In 40 days, as I think many of us recognize, student borrowing rates for college will double unless we act. We have seen both sides of the aisle—colleagues from both sides—come down and say we cannot let this happen. Well, we cannot let it happen. That means we have to take action to prevent the doubling of interest rates on Stafford loans.

Unfortunately, last week we had a series of budget votes, which most of my Republican colleagues supported, which would have, if they had passed, mandated the doubling of the student loan interest rate. So I think we have to move away from this debate and actually pass legislation which would prevent the doubling of student loans by July 1. I hope we can do it promptly, certainly before July 1.

Also, I hope we find an effective offset. What the Republicans have suggested is using the Prevention Fund. The President made it clear he would veto the legislation if it included that offset. Also, what should be clear that using resources to prevent disease is not only helpful to the American public, but it is also probably one of the most practical ways we are going to be able to begin to bend that very important cost curve going forward.

This Prevention Fund is going to help everyone, but it is going to particularly help middle-income families who are struggling with medical bills, who are struggling to find insurance, the same families who are struggling to pay the cost of college for their children. It makes no sense to me to take from one program that will largely

benefit working families to pay for another program that will benefit working families.

We have an offset which is an egregious tax loophole that allows lobbyists, financiers, et cetera, to create subchapter S corporations to essentially avoid their payroll and Medicare taxes. I think that is an appropriate way to pay for this support for students' education. If there are other ways beyond the prevention fund, I certainly am happy to listen to them. If there are other principled ways to avoid doubling the interest rate for student loans, let's talk about them. Let's get them on the Senate floor and let's debate them.

I yield the floor

The ACTING PRESIDENT pro tempore. The majority leader.

Mr. REID. Madam President, I ask unanimous consent that execution of the previous order with respect to S. 3187 occur at 11 a.m. on Wednesday, May 24, and that all other 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, as I sit here this afternoon, I hope I am not disappointed, and I hope the Senate is not disappointed in not being able to finish this FDA bill. We are on the bill. I hope we can work out some finite list of amendments. That would be the best thing to do for this bill.

So I just say to everyone, I hope we can do that. I do not want to have to come here tomorrow and file cloture on the bill. But that is the choice I will have. Or I can do this: Maybe what I might do is move to reconsider the student loan legislation. I have the ability to do that at any time. So I might do that. We need to get this done.

Today is Tuesday. I just think it is unfortunate. There is an event tomorrow night that we cannot get out of. It has been longstanding for the Senate and their spouses. So we do not have a lot of time.

So tomorrow morning, if we do not have something worked out, I think we will have to do some other things and recognize that all the happy talk on this bill may not come to be.

The ACTING PRESIDENT pro tempore. The Senator from New Mexico.

Mr. BINGAMAN. Madam President, I wanted to speak about an amendment which I intend to offer once we do get on this Food and Drug Administration Safety and Innovation Act. This is an important amendment. I want to advise my colleagues and all who are listening about it so they can, hopefully, look into it and wind up supporting it.

This is an amendment that Senator VITTER has worked with me on, as well as Senators FRANKEN, SHAHEEN, KOHL, TOM UDALL, TIM JOHNSON, KLOBUCHAR, MERKLEY, SANDERS, and SHERROD BROWN. The amendment has the strong support of many organizations that are focused on the cost of prescription drugs.

Here is a list: AARP, AFL–CIO, Walmart, Families USA, Consumer Federation of America, U.S. PIRG, Consumers Union, Center for Medicare Advocacy, AFSME, National Legislative Association on Prescription Drug Prices, the Alliance for Retired Americans, various other companies and organizations—the New Mexico Pharmacy Association strongly supports this legislation.

This amendment addresses the root cause of anticompetitive, anticonsumer settlements that are entered into between brand-name and generic pharmaceutical manufacturing companies. The effect of these settlements they enter into is to delay timely access that consumers would have to generic drugs. This practice is commonly referred to as pay for delay. It costs American consumers and it costs the Federal Government billions of dollars each year in higher drug costs.

According to the Federal Trade Commission, in 2010, pay-for-delay agreements, limiting access to affordable generic drugs, protected $20 billion in sales from brand-name pharmaceutical companies. That was at the expense of consumers who would have been able to pay much less for those same drugs.

Ensuring access to affordable medication is an essential aspect of addressing the growth in health care spending. Prices for brand-name prescription drugs have continued to outpace inflation, and overall spending on prescription drugs has also increased sharply. These statistics are amazing to me. The Kaiser Family Foundation found that in 2008, spending in the United States for prescription drugs was $234.1 billion. That is nearly six times what it was in 1990.

Since generic drugs are, on average, one-fourth of the price of their brand-name alternatives, they can be an important source of affordable prescription drugs for many Americans. But to actually achieve the savings for consumers, those generics have to reach market in a timely manner.

In 1984, Congress passed the bipartisan Hatch-Waxman Act to create market-based incentives for generic pharmaceutical companies to bring their drugs to market as quickly as possible. The express purpose of that law was to incentivize early generic drug competition while preserving incentives for pioneer companies to develop innovative new medicines. Instead, the pay-for-delay settlements that our amendment tries to address—these pay-for-delay settlements between brand-name and generic pharmaceutical manufacturers have become commonplace.

These settlements stifle competition. They delay access to generic drugs at significant costs to consumers and to the Federal Government. In these settlements, the first filer generic drug company agrees to delay market entry in exchange for monetary or other rewards. This has the effect of blocking all subsequent generic filers in coming to market.

This is a complicated issue. I would like to take a few minutes to explain how these agreements work under existing law and also how our amendment would solve this problem as we see it.

Under current law, first-to-file generic drug applicants are rewarded with 180 days of market exclusivity. Exclusivity is awarded only to generic companies that are the first to file. It is not available to subsequent filers even if they successfully invalidate a patent and are ready to come to market immediately. So subsequent generic filers can only enter the market after the first generic filer has enjoyed its 180 days of market exclusivity.

So under the pay-for-delay settlements, the first filer generic company essentially parks its exclusivity; that is, it blocks all other generic manufacturers from coming to market until 6 months after the market entry date. This is true regardless of the strength of the patent or the readiness of subsequent generic filers to come to market.

So this means under pay-for-delay settlements, first filer generic companies receive a reward from brand-name companies for delaying market entry, usually a cash reward, a very substantial amount. They also get a reward from the current statute, this 180-day exclusivity period, and brand-name companies get to extend their monopolies beyond what was originally intended under the Hatch-Waxman legislation.

Consumers are left footing the bill and left with no option but to buy the more expensive drugs and to keep buying it, even after the generic should have come to market.

''Pay for delay'' settlements also typically include an agreement that the first-filer generic company can accelerate its entry into the market in the event that a subsequent filer invalidates the patent in question. In such cases, the subsequent filer triggers the first filer's exclusivity. Put simply, there is no incentive for subsequent generic filers to fight to invalidate weak patents and come to market as soon as possible, even when they believe strongly that they would win their case in court. In other words, whereas the original intent of Hatch-Waxman was to reward companies that were the first to file and actually bring their drugs to market, currently the reward goes to the first company to submit the necessary paperwork. Bringing the generic drug to market immediately has become an option that can be negotiated away.

To fix the ''pay for delay'' problem, the law needs to be changed so that first filers who enter into ''pay for delay'' settlements can no longer block generic subsequent filers who successfully challenge patents from entering the market and bringing affordable drugs to consumers. The amendment we are offering provides this solution or this fix in the following three ways:

First of all, the amendment grants the right to share exclusivity to any

generic filer who wins a patent challenge in the district court. This means that if a subsequent filer successfully challenges a patent, even after a first filer has entered into a ''pay for delay'' settlement with a brand-name company, that subsequent filer has a right to share exclusivity with the first filer. This provision provides an incentive for subsequent filers to challenge patents and stimulates competition.

Second, the amendment we are offering maximizes the incentive for all generic challengers to bring products to market at the earliest possible time by holding generic settlers to the deferred entry date agreed to in the settlements they have signed.

Third, our amendment creates more clarity regarding litigation risks by requiring brand-name companies to make a decision to litigate a patent challenge within the 45-day window provided for in the Hatch-Waxman Act. This ''use it or lose it'' provision enhances market certainty by eliminating the option for brand names to litigate patent challenges well after a generic has come to market.

Finally, I think it is important to point out that the amendment we are offering does not interfere with the rights of the parties to settle their patent litigation if they choose to do so.

There have been numerous antitrust experts and consumer groups that have identified the Hatch-Waxman Act's structural flaw—the one I have been describing here—as the source of the ''pay for delay'' problem and have called for a legislative solution. In addition, in 2003 Senator HATCH himself expressed concern that the flaw remained despite an attempt to fix it by including a ''use it or lose it'' provision in the Medicaid Modernization Act of 2003. Senator HATCH emphasized that the law should be changed to reward, and not penalize, generic companies that successfully invalidate a patent and are ready to come to market.

Let me further underscore the need for this amendment with some concrete examples.

I have a chart here that I think will make the point I am trying to make. This table shows three drugs included in ''pay for delay'' settlements. And this is just three; there are many of these settlements entered into each year. The delay to market in years for each of the three drugs—the three drugs are Altace, Lipitor, and Provigil—the delay period the settlements called for in one case is 2 years; in another case 1½ years; and in the other 6 years. The estimated lost savings to consumers is here.

Let me describe each of these a little bit. The first drug is King Pharmaceutical's Altace. A generic version of Altace was delayed for 2 years at an estimated cost of $637 million to consumers under a ''pay for delay'' settlement. In 2007, Lupin invalidated a patent covering Altace. Lupin could not launch, or bring their generic to market, despite being the party responsible for invalidating the patent and opening the market early. Instead, the first filer, Cobalt, accelerated its entry into the market and benefited from 180 days of exclusivity. Lupin was left with no reward despite the fact that they had been the one that succeeded in the litigation to invalidate the patent.

The second is a cholesterol-lowering drug familiar to most of us. It is the best-selling pharmaceutical drug in the history of the world, Lipitor. According to a 2008 New York Times report, Pfizer and generic manufacturer Randbaxy Laboratories agreed to a settlement delaying generic entry into the market by 20 months. The same report stated that the generic version of the drug was estimated to sell for less than one-third of the cost of the brand-name Lipitor, which had earned $12.7 billion in sales the year before. A letter sent to FDA Director Hamburg last year by some of my colleagues in the Senate indicated that the Federal Government was spending $2.4 billion a year on Lipitor and that a generic version was expected to generate $3.97 billion to $6.7 billion in savings annually.

The final example on the chart here is Provigil, which is a sleep-disorder drug, a generic version of which could have come to market as early as December of 2006. However, due to ''pay for delay'' settlements, a generic version of Provigil just entered the market this year instead of in 2006.

In addition, in October 2011, a subsequent generic filer, Apotex, invalidated a patent covering Provigil. Because the first filers in this case settled their patent litigation with the brand company 6 years prior, Apotex could not begin selling generic Provigil despite its court victory. Even the CEO of Cephalon, which is the brand-name manufacturer of Provigil, is quoted as saying—this is the CEO of the brand-name company—this:

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

In other words, the Provigil case represents 6 years and tens of millions of dollars in lost savings to consumers. One of the largest of those consumers is the U.S. military. As this chart illustrates, this is an estimate of the effect of this settlement—the so-called ''pay for delay'' settlement—related to Provigil on the Department of Defense. Assuming that a generic version of Provigil would have been released in 2006 with expiration of exclusivity, the DOD would have saved $159 million for this drug accessed by almost half a million soldiers between the years 2006 and 2011. Had our amendment, the Fair Generics Act, been the law—and we have introduced it as a stand-alone bill—had the Fair Generics Act been the law, generic versions of Provigil would very likely have been available 6 years ago. The first filers, knowing that the patent was weak and that subsequent filers could invalidate it and come to market themselves, would have fully prosecuted the patent fight instead of just settling it as they did.

As these examples illustrate, by granting shared exclusivity rights to any generic challenger that wins its patent case or is not sued by the brand company, our amendment will end the ''pay for delay'' problem and move us closer to the original intent of Hatch-Waxman. That original intent was more competition, greater access to affordable drugs, and substantial savings to the U.S. Government and American consumers.

I hope that when we get the opportunity to offer this amendment and consider it on the Senate floor and have a vote on it, my colleagues will support this amendment. It will be a substantial step forward for American consumers and will help us greatly in our effort to reduce the cost of prescription drugs for Americans.

I yield the floor.

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

Mr. BROWN of Massachusetts. Madam President, I am pleased that the Senate is moving this week to consider the FDA Safety and Innovation Act, which is a very important piece of legislation that will help ensure Americans have access to save, innovative medical treatments by giving the FDA the resources it needs to review new products as safely and quickly as possible, while also giving the industry that certainty it needs to continue investing in new research. As I travel around Massachusetts, the No. 1 issue I find is that lack of regulatory certainty and sometimes tax certainty. This is a step in the right direction.

I am pleased that this legislation takes many steps to strengthen the medical innovation industry in the United States. I have championed one such provision with Senators MCCAIN and CASEY that will smooth the regulatory path that I referenced earlier for new, moderate-risk medical devices.

The underlying bill before us needs to be passed as quickly as possible to guarantee regulatory certainty at the FDA for the industry and its stakeholders.

However, I am disappointed the Senate has not yet taken time to address a key area of concern related to this bill; that is, the new medical device excise tax. The new 2.3 percent tax on medical device sales that was imposed in the Federal health care law will cost our economy thousands of jobs and limit Americans' access to the most groundbreaking, state-of-the-art medical devices which people need.

For the past 18 months, I have been pushing for the Senate to consider a medical device tax repeal bill that I introduced in February of 2011—one of the first bills I introduced. Today I, along with others, will be introducing an amendment to repeal this job-killing tax—a tax that will, in fact, drive up the cost of health care for patients and make our workers and our companies less competitive.

I can tell you that in Massachusetts we have over 400 medical device companies. We are an innovative State. We have the ability to have companies like these in Massachusetts, and they are employing nearly 25,000 workers and contributing over $4 billion to our economy. That is obviously a substantial industry in Massachusetts. And it affects every person throughout this country indirectly. If it goes into effect next year, this harmful tax will put American workers at a competitive disadvantage and chase jobs overseas. There are already companies, over the last year and a half, that have been looking overseas and already shifting their strategy.

Where is that 2.3 percent tax coming from? It represents, in some instances, the entire net profit for some young companies in Massachusetts and throughout the country. It will potentially cost 43,000 jobs across the country, with a loss of $3.5 billion in wages. I am not quite sure how that makes sense in anybody's book. Massachusetts alone is expected to lose over 2,600 jobs as a direct result of this tax, and up to about 10 percent of our entire medical device manufacturing workforce will be affected. The bottom line is that we cannot have this kind of job loss in any sector of our economy when we are still struggling. In Massachusetts, we have over 400 medical device companies. We do generate a tremendous amount of revenue—in the billions of dollars. So where is this tax going to come from? Is it from R&D, from growth and expansion, hiring, firing? Where? Nobody seems to know.

I can tell you that the Massachusetts companies and companies throughout the United States are deeply concerned about this. I find it surprising and disappointing that there is not a consensus to repeal the medical device excise tax which will affect States across this country. Whether it is on another bill or a stand-alone bill, we need to get it done the way we did, in a truly bipartisan, bicameral manner, on the 3-percent withholding, the 1099 fix, the hire a veteran bill or the insider trading bill. We have worked together in a bipartisan manner to get things done. It matters a great deal to Massachusetts, and it should concern every Member of this body.

Madam President, I yield the floor, and 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. 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, dietary supplements have become a common health aid in medicine cabinets all across America. More than half of us in America use dietary supplements, including this Senator, who, for a variety of reasons, takes a multivitamin tablet every morning. In spite of their popularity, many people would be surprised to learn the Food and Drug Administration doesn't know how many dietary supplements are actually being sold in the United States. Most people don't know if a dietary supplement ingredient presented serious health concerns, the Food and Drug Administration doesn't have the information to track down products containing the harmful ingredient. We assume if it is for sale in America, some government agency has taken a close look to make sure that product is safe and that we know what is inside it and that it wouldn't harm an innocent customer. It turns out that may be true when it comes to prescription drugs and over-the-counter drugs, but the dietary supplement world is a much different world, with minimal regulation.

I have an amendment which I will be offering to ensure the Food and Drug Administration has the information it needs to respond quickly and efficiently when safety concerns arise concerning dietary supplements. This amendment would require dietary supplement manufacturers to give the Food and Drug Administration the name of each supplement they produce, along with a description, a list of ingredients, and a copy of the label. It is not an onerous requirement, but for the first time the Food and Drug Administration would literally have a catalogue of all the dietary supplements being sold to Americans all across the Nation. With this information, the FDA would be better equipped to protect consumers' health and to work with manufacturers to address any problems should they arise.

A 2009 report by the Government Accountability Office found the Food and Drug Administration is limited in its ability to respond to safety concerns because dietary supplement manufacturers don't always provide basic information, such as product names or lists of ingredients. This commonsense amendment I am offering is supported by the Consumers Union, and it would provide the Food and Drug Administration the basic information it needs to protect the public.

Trust me. It will be opposed by certain interest groups. But I heard opposition almost 10 years ago when I introduced a bill to require dietary supplement manufacturers to report serious adverse events, such as hospitalizations or deaths, to the FDA. The need for mandatory reporting of adverse events was demonstrated by injuries and deaths across the country caused by the popular and dangerous dietary ingredient ephedra before it was banned in the United States in 2004. One of the victims was 16-year-old Sean Riggins from Lincoln, IL—30 miles from where I live in downstate Illinois. He died in September 2002. Sean was a high school student, and he died from a heart attack after he took something called Yellow Jackets. It was supposed to be an energy boost, and he was headed off to play football. It contained ephedra and it killed him.

Shortly before his death, Metabolife—the largest manufacturer of supplements containing ephedra—claimed to the public they had no ephedra-related adverse event reports, period. However, a lawsuit was filed, and they were required under that lawsuit to disclose their records.

In October of 2002, under pressure, Metabolife gave FDA over 13,000 ephedra-related adverse event reports. People had taken their substances with ephedra and had gotten sick or worse.

In 2006 I worked with Senator ORRIN HATCH of Utah and TOM HARKIN of Iowa to pass the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which mandates reporting of adverse events to the Food and Drug Administration. It stands to reason if there is a drug for sale in the United States—a dietary supplement in this case—that causes a problem, we should know about it. If it is causing a problem in a lot of different places, the Food and Drug Administration, through these reports, will discover it.

Since the law took effect in 2007, dietary supplement adverse event reports submitted to the FDA have increased sevenfold, from 368 in 2007 to 2,473 in 2011. The FDA is using these reports as part of a surveillance system to signal potential safety issues and, in some cases, to take regulatory action. Mandatory reporting of adverse events was an important step to help protect consumer safety, but we need to do more to ensure the FDA and consumers have the information they need.

Madam President, the sad reality of this amendment and this issue is that it takes a tragedy to catch our attention. Someone has to be seriously hurt or worse before Members of Congress and others will take notice and do something.

I recently learned about the tragic death of this beautiful young 14-year-old girl. Her name was Anais Fournier from Maryland. Anais was an honor student. She liked to read vampire novels. She watched chick flicks with her mom, and she had a passion for writing. Last December her life was cut short when she went into cardiac arrest. What caused it? Caffeine toxicity. She drank two 24-ounce Monster Energy Drinks in less than 24 hours, and it took her life.

The American Academy of Pediatrics recommends that adolescents, such as 14-year-old Anais, consume no more than 100 milligrams of caffeine every day. But in less than 24 hours, Anais had consumed 480 milligrams of caffeine. That is the equivalent of 14 12-ounce sodas with ordinary caffeine content. Of course, she did it with two drinks—Monster Energy Drinks.

A recent report by SAMHSA shows energy drinks pose potentially serious health risks. I might just say that in the Senate today, as I am speaking, are members of Anais' family. We want to

join them in mourning her loss and hope that her life will at least give us notice there are things we can do to spare other families the grief their family has gone through. Wendy Crossland is her mom, her sister Jade is here, her grandfather Dick and grandmother Faith. They have come here today because they are hoping the Senate will hear about this amendment and that we can take it up and pass it.

Anais' case is not the only one. Emergency room visits due to energy drinks have increased tenfold between 2005 and 2009 from 1,128 in 2005 to 13,114 ER visits in 2009. Energy drinks target kids with flashy ads and names like Monster and Rockstar and Five Hour Energy Drink, but there are serious concerns about the high level of caffeine in these beverages and the herbal ingredients that act as stimulants and contain additional caffeine.

But here is an interesting thing. If you walk in—as I have—to an ordinary gas station—whether it is in New Hampshire or in Illinois—and you see the cooler with the drinks in it, and then you see others on counters, you might assume, well, they are all subject to the same level of regulation. But that is not true. If we are talking about ordinary beverages—sodas—they are characterized as food, and they are subject to certain limits by the FDA. However, if you look at the fine print—and you better look closely, because it is very tiny—you may find this is being characterized and described as a dietary supplement.

By putting those two words on the label, the product escapes regulation. So we limit the caffeine in an ordinary soda pop, for example—a cola—but when it comes to the dietary supplement side of the story, there are no limitations. That is why this poor young girl was a victim because of the huge amount of caffeine that was consumed in the name of a dietary supplement.

The FDA has the authority to regulate caffeine levels in beverages and to require beverage manufacturers to prove the additives they put inside that can or bottle are safe. But most energy drinks avoid FDA oversight by calling their products dietary supplements.

I defy anyone to walk into a store and look at all the things they can buy and pick out the ones that are regulated by the FDA and those that are not. They are going to have to study long and hard and look closely at the labels to figure it out.

Is that fair to consumers? Is it fair to families and parents that we don't have even basic oversight and regulation of products that can literally harm or take the life of a beautiful young girl? The amendment I am offering would ensure the FDA knows about all of the energy drinks being sold in the United States and can provide information about ingredients that could help the agency address potential safety concerns.

Most dietary supplements available today for sale are safe, and they are used by millions of Americans as part of a healthy lifestyle. Some ingredients may be safe for the general population but may be risky for kids, pregnant women, or people with a heart condition or who are taking certain prescription drugs.

Furthermore, in spite of the many responsible dietary supplement companies, sadly, there is a murky market space out there where some bad actors are selling potentially dangerous products—some of them imported into the United States—which literally do not even disclose their ingredients in an accurate way. This amendment will take an important step in protecting public health by requiring dietary supplement manufacturers to submit basic information to the FDA that would help the agency identify safety issues and respond more quickly.

No one wants to hear of the death of another 16-year-old who loved to play football or a young girl such as this wonderful young 14-year-old girl who loved watching movies with her mom. We can help prevent these tragedies by requiring that better information is reported to the FDA when these dietary supplements go on the market.

Madam President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Georgia.

Mr. ISAKSON. Madam President, as a member of the Health, Education, Labor and Pension Committee, I rise for a brief speech. But I want to begin that speech by thanking Chairman HARKIN, Ranking Member ENZI, and the entire staff of the HELP Committee, and my staff—Francie Pastor—who have helped so much on this legislation which is so important to the American people. There is a chance where we have a bipartisan effort in the Senate to do something constructive and meaningful, and I commend both Senators on their work.

There are component parts of this legislation I want to illuminate for a few seconds because I had a lot to do with them, and they are very important. One deals with third-party logistics providers. As the Chair is aware, and as the Senate is aware, we have a placeholder in the managers' amendment for a third-party provider and logistical providers with track and trace.

Track and trace is the mechanism of tracking the drug from its origin and tracing it all through the system to the individual using the drug to ensure we have safety and security. But there are third-party logistics carriers who deliver an awful lot of content in the United States, such as FedEx and UPS, that operate in all 50 States, and we ought to have a 50-State seamless standard in terms of third-party delivery rather than 50 individual States all having regulatory authority.

So my first message today is to the conferees, that when the conference committee is ultimately reporting, it should take this placeholder on these third-party logistics providers and make sure in the track-and-trace legislation we provide a seamless national policy for the delivery of pharmaceuticals. That is very important to our country and very important to the pharmaceutical industry, but mostly it is very important to those who consume those pharmaceuticals.

Secondly, there is another provision called the Medical Gas Safety Act, which was included in this legislation, and I am very grateful the managers of the legislation agreed to put it in the bill because it is equally important for the people of this country. I want to make sure one thing is underlined. Medical gases are critically important to sustain life, gases such as oxygen. A gas such as nitrous oxide, which is sometimes called laughing gas by some, is sometimes used to sedate individuals. I want to make sure as we go through this process we have a system under which medical gases—that have stood the test of time—remain available through medical use and that brandnew medical products that have never been through the testing of time go through an appropriate FDA review, which is what the original act—the Medical Gas Safety Act—included and which we want to be included in this legislation.

Madam President, I also wish to further speak for a moment about an important section of this legislation—the Medical Gas Safety Act. I want to thank the Chairman and the Ranking Member, and Senator BLUMENTHAL, for working with me to include this in the bill. The Medical Gas Safety Act has a number of important benefits for patients, health care providers, FDA and medical gas providers, it will ensure a continued supply of quality medical gases that patients can depend on, and it will provide regulatory certainty for FDA and providers.

The intent of the Medical Gas Safety Act is to create a process for those medical gases and medical gas mixtures that have a history of safe and effective use to become approved drugs. This will ensure that medical gases that have a long history of use, like oxygen, become approved drugs. The legislation provides FDA with the authority to ensure that any mixture of medical gases be ''medically appropriate.'' Congress urges FDA to work with industry to develop a guidance over the next year to better define the term ''medically appropriate'' so that those mixtures that have been on the market for a long period of time can continue to be available to the patients that need them.

I think we have a finished product that everyone can support—it is a matter of fine tuning at this point, which can be accomplished through FDA guidance. We need to have a system under which medical gases that have stood the test of time remain available for medical use; and brand new medical

gas products that have never been tested go through an appropriate FDA review—which is what the original bill envisioned.

I once again thank the chairman and ranking member for all of the hard work they have done to move this entire bill forward in such a bipartisan manner. The way the Committee has approached this important legislation has resulted in a good bill that deserves everyone's support. I also want to express my appreciation for the inclusion of the Medical Gas Safety Act in this bill. Senator BLUMENTHAL deserves credit for the work he has done in this area.

Madam President, I applaud my colleagues, Senators BENNET and BURR, for their efforts to enhance the safety of America's pharmaceutical supply chain. While we are fortunate in America not to have a widespread problem with counterfeit drugs, the potential that they could pose a serious health risk to consumers is significant.

Supply chain compliance and safety is currently a patchwork of inconsistent State requirements and licensing which potentially jeopardizes the safety and welfare of millions of Americans. Unless a uniform Federal policy covering all pharmaceutical supply chain stakeholders is enacted, the United States will fail to provide the best tools needed for regulators and law enforcement to do a more effective job. Additionally, the U.S. would be missing an opportunity to leverage technology that will provide superior, cost effective consumer protection.

Third Party Logistics Providers, or 3PLs, are playing a growing and important role in making sure medicines reach their destination safely and securely. The term ''third party logistics provider'' refers to an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, wholesaler, or dispenser, but does not buy, sell, or direct the sales of those products.

Currently, Federal law does not recognize the role of a 3PL. Only one State even offers a license for 3PLs. Other States require a 3PL to apply for a wholesale distributor license, even though 3PLs do not buy or sell drugs. The varying patchwork of inconsistent State requirements makes law enforcement more difficult and there is added cost without a safety benefit.

Failure to include and define 3PLs in Federal language is simply wrong. Recognizing the role of 3PLs is a strong first step towards the development of uniform Federal standards for a 3PL license. Ensuring that all entities are properly licensed within the pharmaceutical supply chain not only makes sense, but it is one of the most effective deterrents to dangerous counterfeit drugs entering the supply chain.

I thank my colleagues Senators BENNET and BURR, and their staff, for their leadership to enhance supply chain safety by working with all industry stakeholders. I also express my gratitude to Ranking Member ENZI, Chairman HARKIN and Senate leadership for their support.

Through a constructive conference process, I am confident we can enhance supply chain safety in a reasonable and cost effective manner. By properly defining 3PLs, and ensuring that properly licensed entities handle our medicines, we can help to ensure they safely and securely reach patients in need. My constituents in Georgia expect nothing less.

Once again, Madam President, I commend the chairman and ranking member on their service and their fine work on the FDA bill.

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

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

The assistant bill 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 (Mr. CASEY). Without objection, it is so ordered.

Mr. HARKIN. Mr. President, I ask unanimous consent that the statement I am about to give appear as in morning business and not connected to the motion at hand.

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

REMEMBERING KATIE BECKETT

Mr. HARKIN. Mr. President, last week our Nation lost one of its most determined and courageous advocates for the rights of people with disabilities, Katie Beckett.

I am proud to say that Katie was a native Iowan. She was born in March of 1978 and 5 months later contracted viral encephalitis. She subsequently had a seizure and went into a coma for 10 days. This illness caused nerve damage to her brain and left her paralyzed and unable to breathe on her own. She received a tracheotomy, was placed on a ventilator, and was fed using a tube.

Initially, after coming out of the coma, she could not move at all. Slowly, much of the paralysis receded, but she was not able to breathe on her own until she was 2 years of age. During that time, she lived in a pediatric intensive care unit. Naturally her family wanted her out of the hospital and home where they could care, support, and love her.

By her third birthday, Katie's private insurance reached its $1 million cap, and she began to receive Medicaid for her health care. Doctors determined that she could leave the hospital with proper supports at home. However—and here is the catch—Medicaid refused to pay for such care even though it would cost one-sixth as much as hospital care. Medicaid would pay for institutional care but not for care in her own home. She could only receive care in a hospital or nursing home in order to be covered.

Katie's predicament began to receive attention thanks to the intervention of many people, including then-Congressman Tom Tauke, who was Katie's Congressman at the time. He began to speak out about this and brought it to the attention of then-President Ronald Reagan and many in Congress. Because of that, President Reagan spoke out about this and a new home- and community-based waiver was created to allow children in Katie's situation to receive their care at home rather than in hospitals. This new program is called the Katie Beckett Waiver. At the time, it was thought the program would benefit only a few hundred children. However, since 1982 over half a million children have benefited from the Katie Beckett Waiver, including 11,000 in Iowa. Katie and her family were true pioneers in changing the institutional bias in Medicaid and permitting children with significant disabilities to receive their support and services in their own homes rather than in a hospital, nursing home, or other institutional setting.

Under the new program, Katie went home almost 3 full years after she was admitted. At that time she was able to be off her ventilator for 6 hours a day. What happened after her discharge? Well, she attended school. While her fellow students considered her different because of her medical condition, she never needed special education services. At an early age she became a passionate advocate for home- and community-based care.

While in middle and high school, she testified before Congress, met with Governors, and, as I said, even met with the President of the United States. She served as an intern at Exceptional Parent magazine while living in Boston. That summer between her junior and senior year of high school, Katie learned to manage her own medical care, directing nurses who provided her treatment and managed her ventilator.

Katie considered advocacy to be her vocation and chosen path—in particular, to raise the consciousness of other young people about disability issues. Even though she found this work rewarding, she sometimes felt uncomfortable in those pre-ADA days—the pre-Americans with Disabilities Act days—and being singled out because of her disability. All she really wanted, as she put it, was ''to fit in and just be normal.''

Katie's first job was at a music store in a local mall. She got the job, as any young person would, by virtue of her knowledge and interest in music. Katie said, ''Advocacy is in my blood and in my soul,'' so she looked for work that would allow her to help other people. She volunteered at the local YWCA in the secondhand shop that supported the only homeless shelter for women and children in eastern Iowa and was then hired as the receptionist at the Y. The job title ''receptionist'' did not begin to describe her true job responsibilities. Katie was the first responder to sexual assault and domestic violence

victims. She helped with the neutral exchange program, where divorced or separated parents could drop off their children without having to encounter each other. She learned to quickly assess the needs of others and to help connect them to appropriate services and supports. She also helped with the supervised visitation program and was soon promoted to be the assistant to the supervisor of that program.

Later, Katie worked with her mother, Julie Beckett, to help establish the Kids As Self-Advocates Network, a group designed to help children and youth with significant medical needs to speak up for their own care and support. Working through Family Voices, another organization spearheaded by Julie Beckett, Katie helped to teach hundreds of young people how to advocate for their own health care. In addition, she served as a Senate appointee on the Ticket to Work and the Work Incentives Advisory Panel, which provided advice to the Social Security Administration, the President, and Congress on work incentives, employment, and other issues facing people with disabilities.

Katie Beckett graduated from Mount Mercy College in Cedar Rapids, IA, in 2001. She later took writing courses at nearby Kirkwood Community College. She was close to completing a novel. A series of illnesses obliged her to put off returning to college to take the classes necessary to become a teacher.

Katie treasured the freedom to engage in the kinds of activities that so many of us take for granted, including eating at Red Lobster, going to the shopping mall, and recently moving into her own apartment.

Katie will be greatly missed by so many people all across America. She will be remembered for her determined advocacy and that of her family, which has changed countless families forever. She inspired a host of young people with disabilities by showing that an ordinary person can accomplish extraordinary goals through great spirit, determination, and persistence.

Dr. Martin Luther King, Jr., once said, ''Life's most urgent and persistent question is: What are you doing for others?'' During her memorable but very short lifetime, Katie answered that question in powerful ways as an agent for change and as a determined advocate. Her living legacy is the program that bears her name, the Katie Beckett Waiver, which will continue to improve the lives of children and young people with disabilities far into the future.

I see my colleague from Iowa, who has also been a friend of the Becketts and has been very supportive of Katie and all of her work and of Julie Beckett. This has truly been bipartisan, bicameral support for this wonderful family.

Katie's funeral is this Friday. We are all going to miss her. As I said, when you met Katie Beckett, you were inspired to do more than you thought you could do. She was a wonderful person, and it is tragic that her life came to such a short close, just last week. She is going to be remembered. As I said, she changed so many lives in this country for the better.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I thank my colleague from Iowa for his very nice remarks about Katie Beckett. I come to the floor for the same reason—to celebrate the life of Katie Beckett.

Never has the word ''inspiration'' been used more appropriately in describing somebody, and today I am grateful to be able to recognize the inspirational life of Katie Beckett.

Mary Katherine Beckett—nicknamed ''Katie''—was born in Cedar Rapids, IA, on March 9, 1978. Five months after she was born, Katie contracted viral encephalitis, followed by grand mal seizures. The encephalitis caused damage to her central nervous system, her respiratory system, and she was attached to a ventilator. She would be almost 2 years old before she could breathe on her own.

As Senator HARKIN said, under Medicaid law at the time, Katie could only receive care through Medicaid if she remained in the hospital even though she was able to receive the care at home.

Iowa Congressman Tom Tauke heard of Katie's situation and realized that it made no sense to keep a child in the hospital who could be at home with her family living a better quality of life as well as saving the taxpayers money. Congressman Tauke worked to convince the administration that the system should be changed to allow States to provide Medicaid to children receiving care in their homes.

Ultimately, President Reagan took up Katie's cause, intervening so that Katie could receive treatment at home and still be covered under Medicaid. This change in policy became known as the Katie Beckett Waiver, and to date more than half a million disabled children have been able to receive care in their homes with their families rather than being forced into hospitals and institutions.

But Katie's story doesn't end there. As Katie grew up, as she battled to establish her own place in society as a young American with disabilities, she realized she had an opportunity to serve others who faced similar challenges.

In her own words—and this is from a piece Katie wrote in the year 2002 entitled: ''Whatever Happened to Katie Beckett?''

I started my advocacy career at age ten. It was not my choice, but rather a path chosen for me. It was not until I was twelve or thirteen that I realized the important work I was able to do because I was who I was and how much this work helped other kids.

Katie graduated with a degree in English from Mount Mercy College in Cedar rapids. She lived in the community. She wanted to be a teacher and write novels for young people. She was fiercely independent, sometimes to the consternation of her mother Julie. She was quick-witted and funny and loved a good cup of coffee. She lived her life as a tireless advocate for the disabled. She testified before Congress several times and was a contributing voice on numerous groups dedicated to disability policy.

When we took up policy proposals such as the Family Opportunity Act and Money Follows the Person, we wanted Katie's perspective and we depended upon her advocacy in the community to get those laws passed. Katie was the living embodiment of a person with disabilities participating and contributing in society.

On Friday, May 18, Katie went home to be with the Lord. She leaves behind thousands of lives touched by her presence. A light may go out, but a light lives on in those of us fortunate enough to have known Katie Beckett.

We remain inspired to work every day to create opportunities for the disabled to participate and contribute and live the life of service and dedication that Katie did. So, obviously, even though not alive today, Katie will remain that inspiration for many people for a long time to come.

Thank you very much. I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. Mr. President, I ask unanimous consent to speak as in morning business.

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

Mr. BURR. Mr. President, I think I can say I was blessed to be here right before the tribute to Katie that our colleagues from Iowa gave. What an inspiring life of a young lady. Although cut short, her impact is felt by many.

VISN REORGANIZATION ACT OF 2012

I rise today to speak on a bill that I introduced last week, S. 3084, the Veterans Integrated Service Network Reorganization Act of 2012. This legislation would significantly reorganize the structure of the Department of Veterans Affairs, or VA, Veterans Integrated Service Networks, or VISNs, to make these networks more efficient and to allow resources to be moved to direct patient care.

The veterans' health care system in our country was originally established to treat combat-related injuries and to assist in the recovery of veterans with service-connected disabilities. Since its start, the scope of the Veterans Health Administration, or VHA, has expanded and now treats all veterans enrolled in the health care system through hundreds of medical facilities located around the country. Prior to 1995, VHA was organized into four regional offices. These regional offices simply channeled information between the medical centers and the VA's Washington, DC, headquarters office. Since the regional offices' duties were to pass

on information to the facilities, they had little ability to exercise independence in implementing policies based on the needs of the veterans in their region.

In March 1995, based upon the recommendations of former Under Secretary of Health, Dr. Kenneth Kizer, VHA underwent a significant reorganization of its Washington, DC, and regional offices. Basically, the VHA health care system was divided up into 22 geographic areas—now 21—with each region having its own headquarters with a limited management structure to support the medical facilities in that region. The goal of the reorganization was to improve access to, quality and the efficiency of care to veterans through a patients-first focus. This structure would improve care by empowering VISNs with the independence to decide how to best provide for the veterans in their region. This change also would have made the most of spending for patient care by suggesting that VISN management be located on a VA medical center campus.

The aim was to provide a better organized system that would have oversight management responsibilities of the medical facilities through a new structure called the Veterans Integrated Service Network. This new system intended to offer a clearer picture of what the duties were of both the VHA central office in Washington, DC, and the VISN headquarters offices. Going forward, VHA central office's responsibilities included changes to VA policies and medical procedures and monitoring the facilities' performance in providing care. Each VISN headquarters' primary function was to be the basic budgetary management and planning unit for its network of medical facilities. Because the scope of their tasks was limited, it was expected that a VISN headquarters could be operated with 7 to 10 full-time employees, for a total of 220 staff for all VISN headquarters nationally. Any additional expertise needed was to be called up from the medical centers on an informal basis.

I believe VHA has significantly strayed from the initial concept behind the 1995 reorganization. While some growth and an increase in VISN management staff over 17 years is expected, the growth and duplication of duties we have seen at VISN headquarters offices and medical facilities quite simply is troubling. Examples of such duplication are coordinators for homeless veterans, OIF–OEF–OND veterans, women veterans who are present at both the medical facilities and the VISN headquarters.

This duplication has not only redirected spending away from medical centers, it has caused a bloating of the numbers of staff across the 21 VISN headquarters. VISN headquarters have grown well beyond the 220 staff proposed by the 1995 reorganization to a total of 1,340 staff for the 21 VISNs headquarters today—an increase from 220 to 1,340 employees today. These staff are performing functions that have little to do with budget, management, and oversight, let alone direct health care for our veterans. It appears that VHA has allowed VISN headquarters staff to increase without the necessary oversight or an assessment of the impact on the original purpose for VISN. Also left unchecked are the changes in the veterans' population and how veterans have moved between States to determine if there is a need to adjust the VISN boundaries to best serve the veterans seeking care.

This bill—my bill—would bring about a much-needed change to the VISN structure. It would, No. 1, consolidate the boundaries of 9 VISNs; No. 2, move some jobs back to the VHA central office; No. 3, reduce the number of employees to 65 per VISN headquarters; and No. 4, require VHA to review the VISN staff and structure every 3 years. What a novel suggestion, that we would actually review the progress we make.

My colleagues may find it a bit odd that we could reduce the staff of VISN headquarters while also increasing the size of the veterans' population and facilities from some VISN headquarters, but because we are reducing the tasks that the VISN headquarters perform while transferring several jobs to new Regional Support Centers—or RSCs—VISN headquarters staff would be more productive in carrying out the simple budget, management, and planning duties that they were originally tasked with in the 1995 original reorganization.

While the consolidation of VISNs would result in the closure of nine VISN headquarters, no staff would lose their job as a result of this legislation. Staff whose jobs would be eliminated because of the consolidation would have a chance to be transferred to other positions within the VA. Staff who perform the oversight functions that would be moved to the newly created RSCs would be given the opportunity to continue that work at the RSC. This legislation also returns the idea that VISN headquarters should be located on VA campuses by directing that VISN headquarters, if possible, be located on a VA medical center campus. Relocating to vacant space on the VA medical center campus hopefully would reduce the cost to the VA in the long run but, more importantly, it would bring the headquarters staff closer to the facilities they oversee.

I realize this would be an enormous change in the way VHA does business, and yet I believe this can be accomplished without any changes to how VA provides treatment and care to our Nation's veterans. In fact, I believe it will improve how VA cares for veterans by increasing the resources directly available for patient care.

It is important that VA not lose sight of its primary mission, as stated by Abraham Lincoln: '' . . . to care for him who shall have borne the battle'' and, to that end, VA should redirect spending away from bureaucrats and back to the direct care of veterans.

I believe the VISN Reorganization Act of 2012 would provide a more efficient and effective health care system to our veterans, and I hope my colleagues will see it in that light and support this effort at reorganization that is way past due.

I thank the Chair, and I note the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BENNET. 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. BENNET. Mr. President, I came to the floor tonight to talk about the FDA reauthorization bill that is before the Senate. I was sorry we could not get it to a vote today. I am hopeful that tomorrow we will be able to because from my perspective, as someone who has only been here for a few years, the process, the committee process that led to the creation of this bill, is a model for how this town ought to be working.

The conversation we have had for so many months and even years has felt decoupled from the conversations I have been having in my townhall meetings and across the country about the challenges we need to address. This gap has been miles apart. But in this piece of legislation, I think we have actually found something responsive to patients, responsive to consumers, and responsive to the bioscience industry that is so important to my State and so many States across the country.

Chairman HARKIN and Ranking Member ENZI deserve enormous credit for running an excellent process that has enabled this Senator and others on the committee to be responsive to what our constituents say they want, which is a modern FDA with improved patient safety and innovation. We have also had committee members who were interested in rolling up their sleeves and doing hard work together irrespective of which party they were in. We have been able to work through a markup with virtually no partisanship.

This has been a uniquely fine process, which is why we have had such great momentum toward a full extension in what I call the Land of Flickering Lights. The standard of success around here has become: Keep the government running for 1 more month, keep this extension in place for 2 more months. We actually have on the Senate floor a rational and responsible bill that is a 5-year extension of the Food and Drug Administration authority.

Tonight I only want to talk about two aspects of the bill. There are a number we worked on, but tonight I spare you with the rest. In 2010 I introduced a bill called the Drug Safety and Accountability Act. Chairman HARKIN

and Ranking Member ENZI took notice, and we were able to form a working group to address serious problems in the FDA's statutory authority.

FDA laws that are supposed to protect our domestic drug supply were created in 1938 and desperately needed to be updated for the 21st century. Back then the lines of commerce were based on 48 States. Now we live in an era where over 80 percent of the active ingredients in our pharmaceuticals and our drug supply are being manufactured abroad. Couple that with the FDA laws that force them to inspect American facilities every 2 years but they have no mandates on how often they inspect facilities overseas. The GAO has found that FDA can only keep pace with inspecting the most high-risk overseas facilities, the places where our moms and dads are getting their pharmaceuticals for our children, once every 9 years.

So patients taking their pills have no idea whether the ingredients in their drugs were made in China or India or if they were ever inspected. Our American manufacturers are operating on an uneven playing field. They have to expect a surprise FDA inspection every 2 years on average here and make sure they are following all of their good manufacturing practices, when their foreign counterparts do not have to worry about FDA visiting them for a decade, if ever, because they can delay or refuse FDA inspection because they are overseas.

Patient groups and the industry came together to try to change that, and this bill does change all of that. It would implement a risk-based inspection schedule for both foreign and domestic manufacturing sites. It would make sure that drug manufacturers know who is in their supply chain every step of the way. And for the first time, if you are abroad and you refuse or delay inspection without a fair reason, the FDA can refuse to let your product into this country.

These are all the steps American families already think we have in place to protect them. I cannot tell you how many townhalls I have had where people have been shocked to learn that the products they have in their medicine cabinets have never been inspected by anyone. This will change that. It is a thoughtful, commonsense approach I think all of the constituents to this debate support.

So we need to make sure that happens. I also want to talk about something called track and trace. American families also want to know what happens to their pills, pills that can mean the difference between life and death, once they leave the manufacturer, enter the country and change hands several times. Right now we can know a lot more from a bar code on a gallon of milk than from a bar code on medication. That seems absurd to people at home.

I take a moment again to thank the Chair and ranking member for their commitment to working together to meet the challenge of developing a uniform traceability system. This is something that has been worked on for over a decade in this town, and we are finally this close to making it the law of the land.

I thank, in particular, my colleague, RICHARD BURR, a Republican from North Carolina, for being such a great partner in this work. FDA, the HELP Committee staff, Pew, and other stakeholders across the supply chain have been meeting for weeks with my staff and with Senator BURR's staff, all in good faith. Our goal is to finalize a plan after we wrap up this Senate bill.

Let me talk about another very exciting part of this bill. If we pass this bill, for the first time the FDA is going to be able to apply 21st-century science to the approval of drugs, particularly drugs that are breakthrough medications, drugs that we know will work in one subset of populations even if they might not work so well in another.

This is very important to cancer patients all across the United States who are looking to access these breakthrough therapies. So from the standpoint of driving an industry in this country that in my own State has a median salary of roughly $74,000, and from the point of view of patient health and protecting our supply chain, this FDA reauthorization is a must pass.

I thank the members of the committee and especially the chairman and the ranking member for establishing a model for how this Senate should operate.

I yield the floor.

The PRESIDING OFFICER (Mr. BENNET.) The Senator from New Hampshire.

Mrs. SHAHEEN. I applaud my colleague from Colorado, Senator BENNET, for the work he has done on the FDA legislation—as he pointed out, the good work that has been done by our colleagues on both sides of the aisle to get to this bill, to move it forward and to have a responsible and reasonable amendment process. So I hope we can move it forward this week and actually see its passage on the floor because it is so important to so many people who are dependent on what the Food and Drug Administration does in this country.

(The remarks of Mrs. SHAHEEN pertaining to the introduction of S. 3218 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mrs. SHAHEEN. I yield the floor.

AMENDMENT NO. 2149

Mr. KOHL. Mr. President, the inappropriate overuse of antipsychotics—which are associated with a higher risk of death in frail elders—is a well-recognized problem that warrants new policy to ensure that these drugs are targeted to people suffering from serious mental illness, and not to curb behavioral symptoms of Alzheimer's or other dementias.

Addressing these concerns requires additional transparency and accountability on how antipsychotics are being used today in older adults with dementia. I am pleased to be joined by Senators GRASSLEY and BLUMENTHAL in filing an amendment to S. 3187, the Food and Drug Administration Safety and Innovation Act S. 3187, which would require the HHS Secretary to develop standardized protocols for obtaining informed consent, or authorization, before administering an antipsychotic for a use not approved by the Food and Drug Administration. Authorizations would be provided by patients or, as appropriate, their designated health care agents or legal representatives. These informed consent protocols would provide valuable information to patients and their families, including possible risks and known side effects associated with the antipsychotic, as well as alternative treatment options that may be available.

This bipartisan amendment also calls for a new prescriber education program to promote high-quality, evidence-based treatments, including non-pharmacological interventions. The prescriber education programs would be funded through settlements, penalties and damages recovered in cases related to off-label marketing of prescription drugs.

While the Food and Drug Administration—FDA—has approved antipsychotic drugs to treat an array of psychiatric conditions, numerous studies conducted during the last decade have concluded that these medications can be harmful when used by frail elders with dementia who do not have a diagnosis of serious mental illness. In fact, the FDA issued two ''black box'' warnings citing increased risk of death when these drugs are used to treat elderly patients with dementia.

Last year, the Health and Human Services Office of the Inspector General—HHS OIG—issued a report showing that over a 6-month period, 305,000, or 14 percent, of the Nation's 2.1 million elderly nursing home residents had at least one Medicare or Medicaid claim for atypical antipsychotics.

The HHS OIG also found that 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions and that 88 percent were associated with a condition specified in the FDA box warning. Further, it showed that more than half of the 1.4 million claims for atypical antipsychotic drugs, totaling $116.5 million, failed to comply with Medicare reimbursement criteria.

I hope this policy will send a strong signal that Congress is committed to improving the quality of treatment provided to millions of our most vulnerable Americans—older adults with dementia and the families who support them.

Ms. COLLINS. Mr. President, I rise in support of the Food and Drug Administration Safety and Innovation Act,

which will help speed safe and effective drugs and medical devices to the patients who need them. This bipartisan, consensus bill was developed through a long and collaborative process involving the FDA, stakeholders, and Senators from both sides of the aisle. I commend the chair and ranking member of the HELP Committee for their tremendous leadership and hard work on this very important bill.

The legislation we are considering today reauthorizes existing user fee programs for prescription drugs and medical devices and creates new user fee programs for generic drugs and biosimilar biological products. In addition, the bill reauthorizes programs that have helped make medicines safer for children, upgrades the FDA's tools to police the global supply chain, increases incentives for the development of new antibiotics, and expedites the development and review of certain drugs for the treatment of serious or life-threatening diseases and conditions.

I particularly want to commend my colleagues for including provisions based on legislation I sponsored with Senator KLOBUCHAR to address the shortages of drugs that are causing significant disruptions in care and putting patients at risk.

I continue to hear from doctors, emergency medical personnel, and other medical professionals in Maine who are extremely concerned about this issue. Many of the drugs in short supply are vital, used in hospitals and cancer centers for anesthesia, chemotherapy, and treatment of infections. There are also continuing shortages of drugs used in emergency rooms and intensive-care units.

These shortages are causing serious problems around the country, including forcing some medical centers to ration drugs or postpone elective surgeries. Oncologists have told me of situations where they were forced to change a patient's chemotherapy regime midcourse because they suddenly encountered a shortage of a particular drug. Moreover, for some drugs, there are no effective substitutes.

This crisis is widespread, with more than 80 percent of hospitals reporting that they have had to delay treatment due to shortages. That is why I joined my colleague from Minnesota in sponsoring the Preserving Access to Life Saving Medications Act to give the FDA tools to better manage, and hopefully prevent, shortages of life-saving medications, including requiring manufacturers to provide an ''early warning'' when a drug will not be available.

Providing early warning when a drug will not be available will help both doctors and patients. It builds on the successful model of the FDA's Drug Shortage Program which encourages manufacturers to report potential or existing shortages so that problems can be addressed or other manufacturers can ramp up production. Through this voluntary approach, the FDA was able to avert almost 200 shortages last year.

The legislation we are considering today will give the FDA the information and tools it needs to help address and prevent drug shortages. It will also promote innovation, improve safety, and increase access to the drugs and devices that are critical to our health. Again, I commend Senators HARKIN and ENZI for their leadership and encourage all of my colleagues to join me in supporting this important legislation.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. BROWN of Ohio. 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. BROWN of Ohio. Mr. President, I ask unanimous consent to address the Senate as in morning business for no more than 10 minutes.

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

MANUFACTURING

Mr. BROWN of Ohio. Mr. President, last week the Vice President was in my State in the Mahoning Valley, in the Youngstown area, northeast Ohio. He saw what I have been seeing in my State for the last several months, and he heard what I have been hearing from so many Ohioans in the last several months. He went to the Lordstown auto assembly plant, which assembles the Chevy Cruze. He saw what we have been seeing in my State, where manufacturing finally is coming back.

From early 2000 to January 2010, about a 10-year period, the manufacturing sector in this country lost a huge number of jobs—more than 5 million jobs. In the 35 years before that, manufacturing jobs in this country were pretty constant, up and down. In 1997 or 1998, we had about the same number of manufacturing jobs in America that we had in 1965—a smaller percentage of the workforce, or smaller percentage of GDP, perhaps, but roughly the same number of jobs. From January of 2000 to January of 2010, some estimates were as high as one-third of our manufacturing jobs. We know there were at least 5 million jobs and some 60,000 plant closings in that 10-year period, from 2000 to 2010. It is almost impossible not to ascribe at least part of that to trade policy and tax policy—a tax policy that far too often has given manufacturing companies an incentive to shut down and move overseas. If you shut down a plant in Warren, OH, or Mansfield, OH, or Springfield, OH, and move to Wuhan or Zihan or Shanghai, you can deduct the moving expenses and save on your Federal taxes. It is hard to do anything but to ascribe at least a part of that to some of the trade agreements we have signed, such as NAFTA, which the President pushed through Congress. And it was both parties. I was just as critical of President Clinton for NAFTA as I was President Bush on CAFTA.

We know what the Central American Free Trade Agreement and the North American Free Trade Agreement have meant, and we know what PNTR with China did, where we went from not much more than a $10 billion trade deficit in 2000 to trade deficits that were, I believe, $10 billion to $15 billion a month with China later in the decade. And we know from the policy of tax cuts that went overwhelmingly to the wealthiest Americans that passed in 2001 and 2003, going into two wars and not paying for those, a Medicare drug law that in the name of privatization basically gave away huge incentives to the drug and insurance companies—all that played into an economic policy that didn't work for the American people. We lost more than 5 million manufacturing jobs, with 60,000 plant closings between 2000 and 2010.

What happened in 2009 and 2010 to finally turn that around? The House and Senate and the President of the United States rescued the auto industry. We know the kind of job loss we were seeing and now look at what we have. It is not great yet. We are not seeing a huge growth in manufacturing, but almost every single month since early 2010, in Ohio and across the country, we are seeing job growth in manufacturing. So far, since early 2010, after that 5 million jobs lost in manufacturing—from early 2000 to early 2010—we have seen a 400,000-plus net job increase in these 2-plus years. Again, that is too anemic—it is not enough—but it is the direction we need to go.

Let me give a couple of examples as to why this auto rescue meant so much to my State and the rest of America. The Jeep Wrangler and the Jeep Liberty are assembled in Toledo, OH. Prior to the auto rescue, these workers assembled the Wrangler and the Liberty with only 50 percent American-made components. After the auto rescue—today—about 75 percent of the components that go into the Wrangler and the Jeep Liberty—assembled in Toledo, OH—come from components made in the United States.

Look at what has happened in Lordstown, OH. The engine is made in Defiance, OH, the bumper comes from Northwood, OH, the transmission comes from Toledo, the speaker system comes from Springboro, OH, the steel comes from Cleveland and Middletown, OH, the aluminum comes from Cleveland, OH, the stamping is done in Parma, OH, and this is put together—all these parts come together in Lordstown, OH, near Youngstown, assembled by 5,000 workers on three shifts. Almost none of that would have happened without the auto rescue.

Do you know what else the auto rescue was all about? It didn't just help Chrysler and GM, which had, in fact, gone into bankruptcy. The auto rescue was also supported by Ford and Honda in my State. We have huge Ford and Honda investments in my State. Why

would they have supported the auto rescue when the support from the government—the loans from the government, if you will—went to Chrysler and GM, not to Ford and Honda? Because they knew the importance of the supply chain. Because the supply chain for Chrysler and GM had collapsed, as it would have if those two companies had gone into bankruptcy and not been restructured and financed so they could come out of bankruptcy. If that had happened, the supply chain for Ford and Honda also would have partially collapsed. We see evidence of that in what happened with the tsunami in Japan, where Honda and others had to shut down for a period of time because they couldn't get the supply components they needed—some of them—from Japan.

So the point is that we stepped in with the auto rescue not just for Chrysler and GM, not just for Honda and Ford in my State—where 800,000 jobs, it is officially estimated, are affiliated with the auto industry—but also because it was important for these jobs at our tier 1 suppliers. Some of these tier 1 suppliers were about to collapse. So the rescue of the auto industry also directly helped to rescue some of those tier 1 suppliers. I have seen those tier 1 suppliers—Magnum in a suburb of Toledo. I have been there; Johnson Controls, which makes seats in Warren, OH—they make seats for the Chevy Cruze. I left that one out. All those tier 1 suppliers were in trouble.

We also knew the tier 2, 3, and 4 suppliers for the auto industry—making components you might not know what they were for or recognize them if you held them in your hands but that go into the Chrysler and the Ford and the GM and the Honda—were not able to get financing many times, and so we helped them through that with the auto rescue.

So the point is that what Vice President BIDEN saw in Youngstown and in Lordstown, OH, and what I hear in Dayton and Columbus and Mansfield and in Toledo and Rossford and Parma and all over my State is these workers saying they understand this auto rescue, where the government invested because nobody else would have—these companies are paying these investments, and that rescue saved all these jobs. It is why manufacturing is beginning to turn around.

There are other factors, of course, and one of them is the President of the United States enforcing trade law. We see a new steel mill in Youngstown in part because the President stood up to the Chinese and enforced trade law when the Chinese were gaming the system on something called oil country tubular steel, used in drilling for oil and for natural gas. All of that has mattered to this manufacturing job growth.

We are not there yet. We need the administration to step up on a real policy for manufacturing, a real strategy. I think they are starting to do that on better tax law, better trade law, and better enforcement of trade laws. We want to assist manufacturing when we can partner with them—not picking winners and losers but understanding that to create wealth, you either grow it, you mine it, or you make it. My State does all three and does it very well and will continue to do so with this kind of partnership as we move forward.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. BROWN of Ohio. 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. BROWN of Ohio. Mr. President, I ask unanimous consent that the Senate proceed to a period of morning business, with Senators permitted to speak therein for up to 10 minutes each.

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

ENHANCED ISRAELI MISSILE DEFENSE

Mr. NELSON of Florida. Mr. President, on April 19, 2012, I introduced S. 2325, the Iron Dome Support Act, along with my colleagues Senators BOXER and KIRK. This bipartisan bill authorizes further assistance to Israel for the Iron Dome anti-missile defense system. As of today, 17 of our colleagues have also joined us on this bill, because we all recognize that an investment in the Iron Dome is an investment in peace and security in the region.

The Iron Dome system uses small radar-guided missiles to blow up Katyusha rockets and mortar bombs in midair coming from 3 to 45 miles away—and can do so in any weather condition. The Israeli Defense Force reports that Iron Dome has already proven itself to be 90 percent successful intercepting rockets well before they could potentially hit residential neighborhoods, busy highways, shopping centers, or crowded streets in southern Israel.

This is an incredible piece of technology. Right now, there are 3 Iron Dome batteries in the south of the country. But Israel remains vulnerable to attacks on other fronts from terrorist groups. That is why I encourage my colleagues to join me in supporting S. 2325. Increased support for this legislation will send a strong message to include additional funding for Iron Dome batteries in order to protect all of Israel.

The Iron Dome is just one of the ways the United States supports Israeli missile defense. The Arrow Weapons System and David Sling protect Israel from medium and long distance threats to the country's existence.

We are developing these systems in cooperation with the Israeli government, so we can harvest the technology for future American systems. Our backing is important to keep the deployment of these systems on track as they must keep pace with the aggressive development of threat missiles.

As the markup of the various defense bills moves ahead this month and next, I urge my colleagues to fully support the accelerated deployment of anti-missile systems vital to the survival of our Israeli allies.

TAIWAN'S PRESIDENTIAL INAUGURATION

Mr. WICKER. Mr. President, I congratulate President Ma Ying-jeou on his inauguration as President of Taiwan. From his education at Harvard University, to becoming the youngest cabinet minister in the history of Taiwan, to his election to the Presidency of Taiwan in 2008, President Ma has faced difficult challenges. As Justice Minister he took on the task of rooting out political corruption. As President he has faced the daunting charge of navigating Taiwan through the economic downturn, and after just a few years Taiwan has seen successful economic growth. In addition, President Ma has made notable progress in improving cross-strait relations. During his first term, he successfully negotiated 16 trade agreements with the People's Republic of China, increasing economic cooperation between these two countries.

For all of his hard work and success, I congratulate President Ma and wish him well on his second term in office. I hope the U.S. and Taiwan can continue to advance our shared interests and goals and to strengthen our valued relationship.

ADDITIONAL STATEMENTS

GOLDEN GATE BRIDGE

• Mrs. BOXER. Later this month, California residents and visitors from around the world will gather to celebrate the 75th anniversary of a beloved California landmark: the Golden Gate Bridge.

The Golden Gate Bridge is without doubt one of the greatest structures of the 20th century. This seamless stretch of cables and steel beams was the vision of renowned bridge architect and engineer Joseph Strauss, whose prior experience prepared him to design the longest suspension bridge of its day, which many said could never be built.

But built it was, even in the middle of the Great Depression. After more than 4 years of construction, the Bridge opened on May 27, 1937. Hailed as an architectural masterpiece for its complex construction and structural elegance, it soon became a cornerstone

of ground transportation in the Bay Area, carrying passengers and commerce between San Francisco and its neighbors to the north.

The Golden Gate Bridge is much more than a transportation corridor or engineering marvel. With its breathtaking setting and dazzling golden-orange color, the Bridge is the iconic symbol of the San Francisco Bay Area, holding a unique place in the hearts and minds of residents and visitors alike. It is the gateway not just to the Bay Area but to the western United States.

During World War II, the Bridge gained fame as the last site our troops saw as they shipped off to fight in the Pacific and the first structure they saw when they arrived back home. In dozens of movies shot in San Francisco, the Bridge appears in the opening scenes to let you know immediately where you are: in one of the most beautiful places on earth.

This year the Golden Gate Bridge, Highway and Transportation District and the Golden Gate National Parks Conservancy—in cooperation with the National Park Service, the Presidio Trust, and the City and County of San Francisco—have launched a 75th anniversary program, with 75 tributes to celebrate the countless ways in which the Bridge connects people and places.

On May 27th, the anniversary season will culminate in a Golden Gate Festival, with events along the San Francisco waterfront from Fort Point to Pier 39. With the theme of ''Bridging Us All,'' this community celebration will honor a beloved landmark that represents and reflects the ingenuity, inclusiveness, and creativity of the San Francisco Bay Area.●

TRIBUTE TO SISTER JEANNETTE MURRAY

● Mr. CARDIN. Mr. President, today I wish to honor the life and legacy of Sister Jeannette Murray, Order of Saint Benedict, who cofounded the Benedictine School in Ridgely, MD. According to Sister Jeannette, it has always been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has more than accomplished that goal. The Sisters of St. Benedict recognized the need for a school that would educate children and young adults with developmental disabilities and established the Benedictine School in 1959 with 19 students. Since that time, the school has provided comprehensive services for more than 1,000 individuals, including those with no meaningful family support. In 2009, the Benedictine School celebrated 50 years as a nationally recognized, accredited, and cost-effective living and learning environment for children and adults with developmental disabilities. Most recently, Sister Jeannette led the charge for the school's therapeutic aquatic center, spearheaded a $10 million campaign for capital projects and endowments, and challenged the community to realize her dream of providing 24/7 care for aging loved ones. In April 2012, the Benedictine School broke ground for Senior Homes, ''universal design'' homes for seniors with disabilities that will offer around-the-clock care.

Earlier this year, Sister Jeannette retired as executive director of Benedictine School, and on June 24 she is being honored by the community—donors, students, residents, civic and community leaders—for her work on behalf of the developmentally disabled. Sister Jeannette has made a tremendous difference in the lives of her students and their families and to all who hear and believe in her work. Her dream has benefitted not only her students and their families but also the larger community.

I hope my colleagues will join me in thanking Sister Jeannette Murray—the ''little woman with the huge heart'' as the parents of her students call her—for her vision, dedication, and service and in wishing her well in her retirement as she continues to inspire others to share her vision ''to see people with developmental disabilities living meaningful, personally satisfying and well supported lives in the community of their choice.''●

REMEMBERING GARY LUKASIEWICZ

● Mr. CASEY. Mr. President, today I wish to honor Gary Lukasiewicz, an 18 year old senior at Riverside High School in Taylor, PA, who passed away Saturday, May 19, 2012 after a courageous battle against cancer.

Born on November 15, 1993 to Chester and Cheryl Lukasiewicz, Gary excelled in everything he did. He was a varsity athlete in multiple sports, a member of the National Honor Society, and the President of his class. After being diagnosed with cancer, Gary bravely waged a two-year fight against the disease and inspired Northeastern Pennsylvania and the Nation. A Twitter hashtag ''Keep Fighting Gary'' was spread by tens of thousands of Twitter users and seen by countless more.

The day before Gary passed, he was able to find the strength to attend his senior prom, where he was crowned ''Prom King.'' As Gary's family and friends mourn his loss, we offer our condolences and we pray that they find comfort in their love for Gary and memories of him. May we all remember Gary's grit and determination as we struggle to understand his loss.

May God bless the Lukasiewicz family, Gary's friends, and the entire Riverside High School community and let them never forget how Gary and his strength affected their lives.●

RECOGNIZING THE HARTFORD FOUNDATION

● Mr. LIEBERMAN. Mr. President, today I wish to congratulate the Hartford Foundation for Public Giving on having been named the Bronze Award winner for excellence in communications by the 2012 Wilmer Shields Rich Awards Program. This award, which is given out by the National Council on Foundations, recognizes those organizations that develop top-notch communications plans to increase attention and support for nonprofit foundations and corporate giving programs. Increasing public awareness of these organizations helps them to better serve the community.

The Harford Foundation for Public Giving received this honor for its 2010 annual report, ''Creating Brighter Futures.'' This report focused on the foundation's 25-year, $30 million initiative to improve school readiness and success in early grades for Hartford children. The award—one of 12 awarded out of 140 entries in 4 categories—was presented during the Council on Foundations Annual Conference, April 29 to May 1, in Los Angeles.

Of course, this award did not come as a surprise to me, considering all the great work the foundation has done in the Hartford region. Founded in 1925, the Hartford Foundation for Public Giving is the community foundation for Hartford and 28 other towns in Connecticut's capital region. Devoted to enhancing the quality of life in the region, the foundation provides grants and other support to a broad range of nonprofit organizations, helps donors make effective charitable giving decisions, and brings people together to discuss important community issues. The foundation has awarded $532 million since opening its doors in 1925 in grants in the areas of arts and culture, children and youth, education, health, housing and economic development, and family and social services.

I am proud to honor the Hartford Foundation for Public Giving on having been named the Bronze Award winner for excellence in communications by the 2012 Wilmer Shields Rich Awards Program. I thank Linda Kelly, the foundation's president and CEO, and everyone else involved in the foundation for all they have done for the people of the Hartford region.●

RECOGNIZING HAMILTON COLLEGE

● Mrs. GILLIBRAND. Mr. President, today I wish to honor one of New York's finer institutions of higher education, Hamilton College in Clinton, NY. On Saturday, May 26, 2012, Hamilton College will celebrate its 200th anniversary as a chartered institution of higher education in the State of New York.

Founded in 1793, by the Reverend Samuel Kirkland, missionary to the Oneida Indians, the college was originally called the Hamilton-Oneida Academy. Samuel Kirkland presented his proposal for the academy to President George Washington who expressed approbation and to Secretary of the

Treasury Alexander Hamilton who consented to be a trustee of the new school, to which he also lent his name.

On May 26, 1812, Hamilton College received its charter from the Regents of the University of the State of New York ''for the instruction and education of youth, in the learned languages and liberal arts and Sciences.'' The third college to be established in New York State, it is today among the oldest in the Nation. Originally an all-male institution, Hamilton taught a traditional classical curriculum focusing on Greek, Latin, philosophy, religion, history, mathematics, and stressing the importance of public speaking.

In 1978, Hamilton College merged with all-female Kirkland College to form one coeducational institution of higher learning dedicated to academic freedom and the pursuit of truth. Alumni of Hamilton College are some of the most distinguished individuals and include public servants at every level. Among them are a former Vice President, numerous U.S. Senators and Representatives, U.S. district and appellate court justices, Cabinet members, ambassadors, Governors and State, county and local officials.

Hamilton College also boasts alumni recipients of the Noble Prize, the Presidential Medal of Freedom, and the Pulitzer Prize; and its graduates are among the Nation's most prominent business leaders, scientists, artists, teachers, lawyers, entrepreneurs, entertainers, writers, journalists as well as my brother.

Hamilton College is known for teaching its students to express their ideas with clarity and precision, to think creatively and analytically, and to act ethically and with conviction.

Mr. President, today, I ask all Members of this esteemed body to join me in celebrating Hamilton College's 200th anniversary. Here is to another 200 years.●

CONGRATULATING LINCOLN HIGH SCHOOL

● Mr. MERKLEY. Mr. President, I rise today to congratulate the Lincoln High School Constitution team of Portland, OR for winning the ''We the People: The Citizen and the Constitution'' national finals. The ''We the People'' competition requires high school students to illustrate their knowledge of the U.S. Constitution through a rigorous set of simulated congressional hearings.

These amazing students had the drive and commitment to master the U.S. Constitution. Lincoln High students, their teachers, and coaches put in hundreds of hours on weekdays, weeknights, and weekends to reach this point. The team, made up of 36 students and 9 teachers and volunteers, continues to exemplify excellence and is part of a storied history. Lincoln High School has now won the national competition 4 times, the Oregon State championship 16 times, and finished in the top 10 at nationals 9 times in its 25 year history.

I wish to again, congratulate the students on the Lincoln High School Constitution team, their teachers, and their supporters on their victory at the ''We the People'' national finals.●

RECOGNIZING WALNUT HILLS HIGH SCHOOL

● Mr. PORTMAN. Mr. President, today I wish to honor Walnut Hills High School of Cincinnati, OH, for being named the No. 1 high school in Ohio by U.S. News and World Report and the American Institutes for Research. This achievement highlights the hard work and dedication of the staff, students, and parents of Walnut Hills.

Walnut Hills High School first opened its doors in 1895. By 1918, the school had dedicated itself to preparing students for college admission in the liberal arts. The Walnut Hills High School program became so popular that the school was expanded in 1931 to accommodate more students. My dad was a proud graduate.

Walnut Hills High School prides itself on a diverse faculty and student body striving for excellence in education. The school's motto best reflects its attitude toward education: Sursum ad Summum, ''Rise to the Highest.''

Mr. President, I recognize Walnut Hills High School for the honorable achievement of being named the No. 1 high school in Ohio.●

MEASURES READ THE FIRST TIME

The following bills were read the first time:

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.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. JOHNSON, of South Dakota, from the Committee on Appropriations, without amendment:

S. 3215. An original bill making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2013, and for other purposes (Rept. No. 112–168).

By Ms. LANDRIEU, from the Committee on Appropriations, without amendment:

S. 3216. An original bill making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2013, and for other purposes (Rept. No. 112–169).

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 Mrs. GILLIBRAND:

S. 3212. A bill to require the Secretary of Health and Human Services to promulgate regulations regarding the authorship, content, format, and dissemination of Patient Medication Information to ensure patients receive consistent and high-quality information about their prescription medications and are aware of the potential risks and benefits of prescription medications; to the Committee on Health, Education, Labor, and Pensions.

By Mr. CARDIN (for himself and Ms. LANDRIEU):

S. 3213. A bill to amend the Small Business Act with respect to goals for procurement contracts awarded to small business concerns, and for other purposes; to the Committee on Small Business and Entrepreneurship.

By Ms. LANDRIEU (for herself, Mr. LIEBERMAN, Mr. KERRY, and Mr. HARKIN):

S. 3214. A bill to strengthen entrepreneurial education, and for other purposes; to the Committee on Small Business and Entrepreneurship.

By Mr. JOHNSON of South Dakota:

S. 3215. An original bill making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2013, and for other purposes; from the Committee on Appropriations; placed on the calendar.

By Ms. LANDRIEU:

S. 3216. An original bill making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2013, and for other purposes; from the Committee on Appropriations; placed on the calendar.

By Mr. MORAN (for himself, Mr. WARNER, Mr. COONS, Mr. RUBIO, and Mr. BLUNT):

S. 3217. A bill to jump-start the economic recovery through the formation and growth of new businesses, and for other purposes; to the Committee on Finance.

By Mrs. SHAHEEN (for herself and Ms. AYOTTE):

S. 3218. A bill to improve the coordination of export promotion programs and to facilitate export opportunities for small businesses, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. SANDERS (for himself, Mrs. BOXER, and Mr. BEGICH):

S. 3219. A bill to restrict conflicts of interest on the boards of directors of Federal reserve banks, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Ms. MIKULSKI (for herself, Mr. AKAKA, Mr. BLUMENTHAL, Mrs. BOXER, Mr. BROWN of Ohio, Mr. CARDIN, Mr. CASEY, Mr. DURBIN, Mrs. FEINSTEIN, Mrs. GILLIBRAND, Mrs. HAGAN, Mr. HARKIN, Mr. LEAHY, Mr. LEVIN, Mrs. MCCASKILL, Mr. MERKLEY, Mrs. MURRAY, Mr. REED, Mr. REID, Mr. SANDERS, Mrs. SHAHEEN, Mr. UDALL of New Mexico, Mr. WHITEHOUSE, Mr. KERRY, Ms. LANDRIEU, Mr. BENNET, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. COONS, Mr. LAUTENBERG, Ms. CANTWELL, and Mr. INOUYE):

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; read the first time.

By Mr. RUBIO (for himself, Mr. ENZI, Mr. DEMINT, Mr. RISCH, Mr. THUNE,

Mr. LEE, Mr. VITTER, Mr. HATCH, Mr. ISAKSON, and Mr. COBURN):

S. 3221. A bill to amend the National Labor Relations Act to permit employers to pay higher wages to their employees; read the first time.

By Ms. LANDRIEU:

S. 3222. A bill to establish a pilot program to accelerate entrepreneurship and innovation by partnering world-class entrepreneurs with Federal agencies; to the Committee on Homeland Security and Governmental Affairs.

ADDITIONAL COSPONSORS

S. 543

At the request of Mr. WYDEN, the name of the Senator from Missouri (Mr. BLUNT) was added as a cosponsor of S. 543, a bill to restrict any State or local jurisdiction from imposing a new discriminatory tax on cell phone services, providers, or property.

S. 557

At the request of Mr. SCHUMER, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 557, a bill to amend the Internal Revenue Code of 1986 to expand tax-free distributions from individual retirement accounts for charitable purposes.

S. 577

At the request of Mr. VITTER, the name of the Senator from Arkansas (Mr. BOOZMAN) was added as a cosponsor of S. 577, a bill to amend the Internal Revenue Code of 1986 to clarify eligibility for the child tax credit.

S. 847

At the request of Mr. LAUTENBERG, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 847, a bill to amend the Toxic Substances Control Act to ensure that risks from chemicals are adequately understood and managed, and for other purposes.

S. 865

At the request of Mrs. MURRAY, the name of the Senator from Minnesota (Mr. FRANKEN) was added as a cosponsor of S. 865, a bill to provide grants to promote financial literacy.

S. 1281

At the request of Mrs. FEINSTEIN, her name was added as a cosponsor of S. 1281, a bill to amend title 49, United States Code, to prohibit the transportation of horses in interstate transportation in a motor vehicle containing two or more levels stacked on top of one another.

S. 1299

At the request of Mr. MORAN, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. 1299, a bill to require the Secretary of the Treasury to mint coins in commemoration of the centennial of the establishment of Lions Clubs International.

S. 1454

At the request of Mr. DURBIN, the name of the Senator from Virginia (Mr. WEBB) was added as a cosponsor of S. 1454, a bill to amend title XVIII of the Social Security Act to provide for extended months of Medicare coverage of immunosuppressive drugs for kidney transplant patients and other renal dialysis provisions.

S. 1512

At the request of Mr. CARDIN, the name of the Senator from Washington (Ms. CANTWELL) 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. 1591

At the request of Mrs. GILLIBRAND, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 1591, a bill to award a Congressional Gold Medal to Raoul Wallenberg, in recognition of his achievements and heroic actions during the Holocaust.

S. 1734

At the request of Mr. CORKER, the name of the Senator from New Hampshire (Ms. AYOTTE) was added as a cosponsor of S. 1734, a bill to provide incentives for the development of qualified infectious disease products.

S. 1880

At the request of Mr. BARRASSO, the name of the Senator from Alaska (Ms. MURKOWSKI) was added as a cosponsor of S. 1880, a bill to repeal the health care law's job-killing health insurance tax.

S. 1904

At the request of Mr. DEMINT, the name of the Senator from Pennsylvania (Mr. TOOMEY) was added as a cosponsor of S. 1904, a bill to provide information on total spending on means-tested welfare programs, to provide additional work requirements, and to provide an overall spending limit on means-tested welfare programs.

S. 1935

At the request of Mrs. HAGAN, the name of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of S. 1935, a bill to require the Secretary of the Treasury to mint coins in recognition and celebration of the 75th anniversary of the establishment of the March of Dimes Foundation.

S. 1963

At the request of Mr. ISAKSON, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 1963, a bill to revoke the charters for the Federal National Mortgage Corporation and the Federal Home Loan Mortgage Corporation upon resolution of their obligations, to create a new Mortgage Finance Agency for the securitization of single family and multifamily mortgages, and for other purposes.

S. 1979

At the request of Mr. CONRAD, the name of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of S. 1979, a bill to provide incentives to physicians to practice in rural and medically underserved communities and for other purposes.

S. 2032

At the request of Mr. DURBIN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 2032, a bill to amend the Higher Education Act of 1965 regarding proprietary institutions of higher education in order to protect students and taxpayers.

S. 2076

At the request of Mr. FRANKEN, the name of the Senator from Delaware (Mr. COONS) was added as a cosponsor of S. 2076, a bill to improve security at State and local courthouses.

S. 2112

At the request of Mr. BEGICH, the name of the Senator from New Hampshire (Mrs. SHAHEEN) was added as a cosponsor of S. 2112, a bill to amend title 10, United States Code, to authorize space-available travel on military aircraft for members of the reserve components, a member or former member of a reserve component who is eligible for retired pay but for age, widows and widowers of retired members, and dependents.

S. 2134

At the request of Mr. BLUMENTHAL, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor 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. 2148

At the request of Mr. INHOFE, the name of the Senator from Kansas (Mr. ROBERTS) was added as a cosponsor of S. 2148, a bill to amend the Toxic Substance Control Act relating to lead-based paint renovation and remodeling activities.

S. 2156

At the request of Mr. BEGICH, the name of the Senator from Delaware (Mr. COONS) was added as a cosponsor of S. 2156, a bill to amend the Migratory Bird Hunting and Conservation Stamp Act to permit the Secretary of the Interior, in consultation with the Migratory Bird Conservation Commission, to set prices for Federal Migratory Bird Hunting and Conservation Stamps and make limited waivers of stamp requirements for certain users.

S. 2160

At the request of Mr. MORAN, the name of the Senator from Kansas (Mr. ROBERTS) was added as a cosponsor of S. 2160, a bill to improve the examination of depository institutions, and for other purposes.

S. 2165

At the request of Mrs. BOXER, the name of the Senator from Texas (Mrs. HUTCHISON) was added as a cosponsor of S. 2165, a bill to enhance strategic cooperation between the United States and Israel, and for other purposes.

S. 2194

At the request of Mr. COONS, the name of the Senator from Alaska (Mr.

BEGICH) was added as a cosponsor of S. 2194, a bill to award grants in order to establish longitudinal personal college readiness and savings online platforms for low-income students.

S. 2205

At the request of Mr. MORAN, the name of the Senator from New Hampshire (Ms. AYOTTE) was added as a cosponsor of S. 2205, a bill to prohibit funding to negotiate a United Nations Arms Trade Treaty that restricts the Second Amendment rights of United States citizens.

S. 2239

At the request of Mr. NELSON of Florida, the name of the Senator from Nevada (Mr. HELLER) was added as a cosponsor of S. 2239, a bill to direct the head of each agency to treat relevant military training as sufficient to satisfy training or certification requirements for Federal licenses.

S. 2282

At the request of Mr. INHOFE, the name of the Senator from Delaware (Mr. COONS) was added as a cosponsor of S. 2282, a bill to extend the authorization of appropriations to carry out approved wetlands conservation projects under the North American Wetlands Conservation Act through fiscal year 2017.

S. 2296

At the request of Mrs. HAGAN, the name of the Senator from Minnesota (Mr. FRANKEN) was added as a cosponsor of S. 2296, a bill to amend the Higher Education Opportunity Act to restrict institutions of higher education from using revenues derived from Federal educational assistance funds for advertising, marketing, or recruiting purposes.

S. 2347

At the request of Mr. CARDIN, the name of the Senator from Missouri (Mr. BLUNT) was added as a cosponsor of S. 2347, a bill to amend title XVIII of the Social Security Act to ensure the continued access of Medicare beneficiaries to diagnostic imaging services.

S. 2371

At the request of Mr. RUBIO, the names of the Senator from Utah (Mr. HATCH), the Senator from Georgia (Mr. ISAKSON), and the Senator from Oklahoma (Mr. COBURN) were added as cosponsors of S. 2371, a bill to amend the National Labor Relations Act to permit employers to pay higher wages to their employees.

S. 2620

At the request of Mr. SCHUMER, the name of the Senator from Minnesota (Ms. KLOBUCHAR) 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. 3053

At the request of Mr. INHOFE, the names of the Senator from Florida (Mr. RUBIO) and the Senator from Nebraska (Mr. JOHANNS) were added as cosponsors of S. 3053, a bill to require Regional Administrators of the Environmental Protection Agency to be appointed by and with the advice and consent of the Senate.

S. 3078

At the request of Mr. PORTMAN, the name of the Senator from Connecticut (Mr. LIEBERMAN) was added as a cosponsor of S. 3078, a bill to direct the Secretary of the Interior to install in the area of the World War II Memorial in the District of Columbia a suitable plaque or an inscription with the words that President Franklin D. Roosevelt prayed with the United States on June 6, 1944, the morning of D-Day.

S. 3210

At the request of Mr. BROWN of Massachusetts, the name of the Senator from Nevada (Mr. HELLER) was added as a cosponsor of S. 3210, a bill to amend title 38, United States Code, to modify the treatment under contracting goals and preferences of the Department of Veterans Affairs for small businesses owned by veterans of small businesses after the death of a disabled veteran owner, and for other purposes.

S.J. RES. 40

At the request of Mr. RUBIO, the name of the Senator from Georgia (Mr. CHAMBLISS) 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.

S. RES. 455

At the request of Mr. CONRAD, the name of the Senator from Minnesota (Mr. FRANKEN) was added as a cosponsor of S. Res. 455, a resolution designating June 27, 2012, as ''National Post-Traumatic Stress Disorder Awareness Day''.

AMENDMENT NO. 2107

At the request of Mr. MCCAIN, the name of the Senator from New Hampshire (Mrs. SHAHEEN) was added as a cosponsor of amendment No. 2107 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2108

At the request of Ms. MURKOWSKI, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of amendment No. 2108 intended to be proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2118

At the request of Mr. ROCKEFELLER, the name of the Senator from Illinois (Mr. DURBIN) 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.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Ms. LANDRIEU (for herself, Mr. LIEBERMAN, Mr. KERRY, and Mr. HARKIN):

S. 3214. A bill to strengthen entrepreneurial education, and for other purposes; to the Committee on Small Business and Entrepreneurship.

Ms. LANDRIEU. Mr. President, I come to the floor today during National Small Business Week to discuss a strong, widely-supported bill that I filed today with the help of Senators LIEBERMAN, KERRY, and HARKIN. Over the past several months, as Chair of the Committee on Small Business and Entrepreneurship, I have held three roundtables focused on strengthening the entrepreneurial ecosystem in the United States. We heard from entrepreneurs, small business owners, academics, local and Federal officials, and regulators, and we built quite a long list of strong ideas that we can implement or facilitate legislatively. I have converted many of these ideas into legislative proposals that I will file this week and markup soon in my Committee.

We have included several of such proposals in Today's Entrepreneurs are America's Mentors Act, or what I refer to as the TEAM Act. The TEAM Act addresses the domain of ''Mentorship'' in our entrepreneurial ecosystem. Its four provisions aim to nurture young Americans' innate entrepreneurial skills from the elementary school classroom through postgraduate business school and onward. We want to create jobs, and for posterity's sake we must begin with our young entrepreneurs. This bill will strengthen America's entrepreneurial ecosystem by empowering the Small Business Administration's, SBA, Office of Entrepreneurial Education, OEE, and invigorating students of all ages, entrepreneurs and mentors throughout the country. We want you to join the TEAM.

President Bush created the SBA OEE administratively in 2008. Currently, the OEE receives $131,000 in annual funding. This OEE funding sustains its oversight of the successful SCORE nonprofit association, comprised of 11,500 volunteer business counselors throughout the United States. The TEAM Act will formally authorize the SBA OEE

and create a program, aside from overseeing SCORE, to conduct entrepreneurial education outreach and mentorship in K–12 schools and will be required to work with existing groups in the entrepreneurial education space. These groups are not-for-profit organizations, for-profit companies, community civic organizations, and SBA resource partners. We do not want to reinvent the wheel or allow for some bureaucratic intrusion. We simply want the SBA OEE to act on what its title suggests and coordinate among these already successful groups and facilitate and sustain the great momentum they have built in entrepreneurial education.

Second, the OEE will administer a scholarship program for MBA students to counsel local startup companies and small businesses. With a $1,500 scholarship, 100 MBA students from around the country could share what they are learning in business school with small business owners near the school. The selected applicants would offer free technical assistance, TA, financial planning, and sustainable business practices. This scholarship program would scale up on the national level a successful program pioneered by the Idea Village in New Orleans. We know something about innovative entrepreneurship in Louisiana: Forbes magazine named New Orleans the ''Biggest Brain Magnet'' of 2011 and the second ''Best City for Jobs;'' in 2010, the Brookings Institute reported that the entrepreneurial activity in New Orleans is 40 percent above the national average; and Inc. Magazine called New Orleans the ''Coolest Startup City in America.'' With all that said, I do not mind borrowing a few good ideas from the innovators in my hometown.

Third, the OEE would, in consultation with the Secretary of Education, give Congress a report on a possible correlation between record high student debt and record high youth unemployment and whether or not student debt deters someone from starting a business. If the OEE does find a correlation, the study should provide Congress some recommendations for legislation to address it in a manner that assists entrepreneurship.

Finally, the TEAM Act also requires the SBA to sponsor competitions, through its ten Regional Offices, in which local entrepreneurs, inventors, and small businesses compete to solve local public-private challenges. There would be a $50,000 grant for each region's winning idea. The idea for these ten competitions is modeled after both the ''Water Challenge'' sponsored by New Orleans's Idea Village and the national mobile app competition for college students run by the Department of Health and Human Services.

Now that you understand the provisions in the TEAM Act, let me read out a long list of supporters. These organizations have been instrumental in providing my Committee with their ideas and perspectives on how best to help young entrepreneurs with this legislation. Most are national groups that have worked for decades on teaching young Americans entrepreneurship and the importance of financial literacy and good business practices. Others are local, but nationally recognized groups with a national impact on jobs creation.

The TEAM Act has also received endorsements from Girl Scouts of America, Venture for America, and Mayor's Office, City of New Orleans.

We urge all of my colleagues here in the Senate to join us on the TEAM to promote entrepreneurial education and nurture the entrepreneurial spirit inside all young Americans. The TEAM Act will help students, entrepreneurs, and small business owners in all 50 States.

Mr. President, I ask unanimous consent that the text and letters of support be printed in the RECORD.

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

S. 3214

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 ''Today's Entrepreneurs are America's Mentors Act'' or the ''TEAM Act''.

SEC. 2. DEFINITIONS.

In this Act—

(1) the terms ''Administration'' and ''Administrator'' mean the Small Business Administration and the Administrator thereof, respectively; and

(2) the term ''small business concern'' has the meaning given that term under section 3 of the Small Business Act (15 U.S.C. 632).

SEC. 3. OFFICE OF ENTREPRENEURIAL EDUCATION.

(a) IN GENERAL.—The Small Business Act (15 U.S.C. 631 et seq.) is amended—

(1) by redesignating section 45 (15 U.S.C. 631 note) as section 46; and

(2) by inserting after section 44 (15 U.S.C. 657q) the following:

''SEC. 45. ENTREPRENEURIAL EDUCATION.

''(a) OFFICE OF ENTREPRENEURIAL EDUCATION.—

''(1) IN GENERAL.—There is in the Administration an Office of Entrepreneurial Education, which shall develop and provide innovative entrepreneurial information, education, and resources, to promote prospective entrepreneurs and successful small business concerns.

''(2) DIRECTOR.—The head of the Office of Entrepreneurial Education is the Director of the Office of Entrepreneurial Education, who shall report to the Associate Administrator for Entrepreneurial Development.

''(3) DUTIES.—The Director of the Office of Entrepreneurial Education shall—

''(A) manage the online courses, online publications, and other online resources provided by the Administration to entrepreneurs and small business concerns;

''(B) manage the youth entrepreneurship programs of the Administration, including—

''(i) online resources for youth entrepreneurs; and

''(ii) coordination and outreach with entrepreneurial development service providers that provide counseling and training to youth entrepreneurs desiring to start or expand small business concerns;

''(C) coordinate with nonprofit and other private sector partners to share educational materials on money management and financial literacy for entrepreneurs and small business concerns; and

''(D) provide assistance and courtesy services to individuals and foreign dignitaries visiting the United States who are interested in issues relating to entrepreneurs and small business concerns.

''(b) NATIONAL PRIMARY AND SECONDARY SCHOOL ENTREPRENEURIAL EDUCATION PROGRAM.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Today's Entrepreneurs are America's Mentors Act, the Associate Administrator for Entrepreneurial Development (referred to in this subsection as the 'Associate Administrator') shall establish a program under which the Associate Administrator may make grants to nonprofit organizations, including small business development centers, SCORE chapters, women's business centers, and other resource partners of the Administration, to provide technical assistance to primary and secondary schools for the development and implementation of curricula and mentoring programs designed to promote entrepreneurship.

''(2) APPLICATION.—A nonprofit organization desiring a grant under this subsection shall submit to the Associate Administrator an application that contains—

''(A) a description of the goals of the project to be funded using the grant;

''(B) a list of any partners that plan to participate in the project to be funded using the grant; and

''(C) any other information that the Associate Administrator determines is necessary.

''(3) REPORT.—Not later than 1 year after the date on which a nonprofit organization receives a grant under this subsection, the nonprofit organization shall submit to the Associate Administrator a report that describes—

''(A) the individuals assisted using the grant;

''(B) the number of jobs created or saved through the use of the grant; and

''(C) any other information concerning the use of the grant that the Associate Administrator may require.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $3,000,000 for each of fiscal years 2013, 2014, and 2015.''.

(b) REPORT ON BEST PRACTICES OF ENTREPRENEURIAL EDUCATION AND TRAINING PROGRAMS.—

(1) REPORT REQUIRED.—Not later than 180 days after the date of enactment of this Act, the Director of the Office of Entrepreneurial Education shall submit to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives a report that describes best practices of entrepreneurial education and training programs throughout the United States.

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

(A) a description of any programs that the Director of the Office of Entrepreneurial Education determines are exemplary, including national programs, regional programs, State programs, and local programs; and

(B) a summary of entrepreneurial education and training programs carried out by—

(i) the Federal Government;

(ii) State and local governments; and

(iii) as nonprofit organizations and private sector groups.

SEC. 4. MASTER OF BUSINESS ADMINISTRATION SCHOLARSHIP PILOT PROGRAM.

(a) IN GENERAL.—The Administrator may award not more than 100 scholarships of not

more than $1,500 on a merit-reviewed, competitive basis to students who are pursuing a Masters of Business Administration degree.

(b) REQUIREMENTS.—

(1) AGREEMENT TO PROVIDE ASSISTANCE.—A student receiving a scholarship under subsection (a) shall enter into an agreement with the Administrator under which the student shall, during the fiscal year during which the student receives the scholarship, provide free technical assistance, counseling, and other assistance to small business concerns and entrepreneurs on a full-time basis for a period of 1 or 2 weeks.

(2) REQUIREMENTS.—The Administrator shall ensure that—

(A) not less than 50 percent of the students receiving a scholarship under subsection (a) are students at an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)) where entrepreneurship opportunities are limited;

(B) the activities carried out under agreements under paragraph (1) support a variety of small business concerns and entrepreneurial projects, including independent investigator-led projects, interdisciplinary projects, and multi-institutional projects (including virtual projects); and

(C) each student receiving a scholarship under subsection (a) has a mentor to help the student relate the academic course of study of the student to the assistance to be provided under the agreement under paragraph (1).

(3) DATA COLLECTION.—A student receiving a scholarship under subsection (a) and a small business concern or entrepreneur receiving assistance under an agreement under paragraph (1) shall agree to provide to the Administrator information relating to the use and result of the assistance provided and employment status until the end of the 3-year period beginning on the expected graduation date of the student.

(c) FAILURE TO COMPLY WITH AGREEMENT.—If a student receiving a scholarship under subsection (a) fails to comply with the agreement entered under subsection (b)(1), the amount of the scholarship received by the student shall, upon a determination of such a failure, be treated as a Federal Direct Unsubsidized Stafford Loan under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), and shall be subject to repayment, together with interest thereon accruing from the date of the award, in accordance with terms and conditions specified by the Administrator (in consultation with the Secretary of Education) in regulations under this section.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Administrator $200,000 for each of fiscal years 2013 through 2015 to carry out this section.

(e) SUNSET.—The Administrator may not award a scholarship under this section after September 30, 2015.

SEC. 5. REGIONAL ENTREPRENEURIAL COMPETITIONS.

(a) IN GENERAL.—The Administrator, acting through the Associate Administrator for Field Operations, shall establish a program to host regional competitions and a national conference to address regional challenges through entrepreneurial research and business planning.

(b) PROGRAM REQUIREMENTS.—

(1) REGIONAL OFFICES.—The regional administrator of each regional office of the Administration shall—

(A) identify a prominent public-private issue that challenges a broad range of individuals in the region;

(B) sponsor a single regional competition among local small business concerns, inventors, and entrepreneurs under which persons or groups of persons submit research and business plans to address the issue identified under subparagraph (A);

(C) provide outreach to universities, colleges, business communities, industry leaders and organizations, and nonprofit organizations to promote the competition and to request proposals for research and business plans;

(D) in coordination with the Director of the Office of Entrepreneurship Education, select the 3 research or business plans that best address the issue identified under subparagraph (A); and

(E) submit to the Administrator a report that contains the research or business plans selected under subparagraph (D).

(2) CONFERENCE.—

(A) IN GENERAL.—The Administrator, acting through the Associate Administrator for Field Operations, shall organize a single national conference for the presentation of the research and business plans selected under paragraph (1)(D) by the regional administrators.

(B) PANEL.—

(i) IN GENERAL.—The Administrator shall designate 11 employees of the Administration to serve on a panel that shall select, from among the research and business plans presented at the conference, 1 plan from each region that best addresses the issue identified under paragraph (1)(A) for that region.

(ii) MEMBERS.—The Administrator shall designate as a member of the panel under clause (i)—

(I) 1 employee of the principal office of the Administration; and

(II) 1 employee from each of the regional offices of the Administration.

(3) GRANT.—

(A) IN GENERAL.—The Administrator shall award a grant of $50,000 to each person or group of persons who submitted a plan selected under paragraph (2)(B).

(B) REPORT.—Not later than 1 year after the date on which the Administrator awards a grant under subparagraph (A), the recipient of the grant shall submit to the Administrator a report on the use of the grant.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Administrator $750,000 to carry out this section.

SEC. 6. STUDY ON ENTREPRENEURIAL DEFERMENT OF STUDENT LOANS.

Not later than 180 days after the date of enactment of this Act, the Administrator, in consultation with the Secretary of Education, shall submit to Congress a report that includes detailed recommendations for legislation—

(1) establishing a program to forgive student loans in a manner that assists youth entrepreneurship by making available capital for business formation; and

(2) establishing a program to defer student loan repayments in a manner that assists youth entrepreneurship by making available capital for business formation.

MAY 18, 2012.

DEAR SENATOR LANDRIEU: It is with great enthusiasm that I submit this letter of support for Today's Entrepreneurs are America's Mentors (TEAM) Act.

Over a decade ago New Orleans was in a downward spiral, failing in all relevant areas of community vitality: education, jobs, health and crime. As a result, there was an exodus of talent; from 1990–2000 over 41,000 23–35 year olds left the State of Louisiana. This ''brain drain'' created a vacuum of innovative thinking needed to redirect the economy and to address critical social issues.

The Idea Village formalized as an independent 501c (3) nonprofit in 2002 to address the ''brain drain'' with a mission to identify, support and retain entrepreneurial talent in New Orleans. What began as a small group of local entrepreneurs has evolved into an engaged global entrepreneurial ecosystem of over 2,028 CEOs, professionals, investors, MBA and high school students, corporations, entrepreneurs and civic leaders who have invested over 56,949 hours of mentorship and $3.3 million in seed capital in 1798 New Orleans entrepreneurs. This network has helped create over 1,006 jobs and $83 million in annual revenue.

Today New Orleans is at a tipping point and the movement that started in 2000 is showing measurable results. The August 2009 issue of Entrepreneur Magazine described New Orleans as a blueprint of economic recovery through entrepreneurship, and in April 2011, an article in Inc.com called New Orleans the ''coolest startup city in America.'' A 2011 Forbes article named New Orleans the ''#1 brain magnet in the country'' and the ''#2 best big city for jobs.'' During the second annual New Orleans Entrepreneur Week in March 2010, noted author and historian Walter Isaacson said, ''New Orleans is a brain magnet instead of a place that will suffer a never-ending brain drain.''

Two of The Idea Village's most impactful programs that can be duplicated nationally are IDEAcorps and Entrepreneur Challenge Competitions:

1. IDEAcorps is an MBA service learning program started in the wake of Hurricane Katrina as bright MBA students around the nation descended on New Orleans to utilize their business skills to help local entrepreneurs execute high impact projects. Since 2008, 15 national business schools and 596 MBA students have participated in IDEAcorps. Participating universities include: Stanford, Harvard, Yale, Dartmouth, Cornell, Duke, Berkeley, DePaul, MIT, Columbia, Tulane, Loyola, University of Pennsylvania, University of Chicago and Xavier Labour Relations Institute in India.

2. Entrepreneur Challenge Competitions have become an impactful way to provide entrepreneurs with much-needed resources while also galvanizing the community to develop for-profit solutions to regional problems. The Idea Village began this program by working with local partners to launch the Water Challenge in 2011, a six month intensive start up accelerator for entrepreneurs solving serious water management issues. The Water Challenge culminates in a $50,000 pitch competition during the annual New Orleans Entrepreneur Week in March, bringing together entrepreneurs, industry experts, investors, students and civic leaders to support innovative solutions to local challenges. In addition, The Idea Village has executed an Education Challenge to encourage entrepreneurs to find innovative solutions to closing the education gap.

Entrepreneurial ecosystems require consistent support and nurture from the entire community. The Today's Entrepreneurs are America's Mentors (TEAM) Act is an excellent step towards infusing entrepreneurship throughout our communities and nation and I urge the Senate to give all due consideration to this legislation.

Sincerely,

TIM WILLIAMSON,
Cofounder & CEO,
The Idea Village.

EMPACT,
New York, NY, May 21, 2012.

Senator MARY L. LANDRIEU,
Chair, Committee on Small Business & Entrepreneurship, Washington, DC.

DEAR CHAIR LANDRIEU: My name is Michael Simmons, and I'm the Co-Founder and CEO of Empact, one of the leading youth entrepreneurship education organizations in the U.S.

Over the last six years, we've held entrepreneurship conferences on over 500 college campuses and high schools featuring the country's top young entrepreneurs. In addition, we've held a 300-person, invite-only, annual Summit for the entrepreneurship education industry at the U.S. Chamber of Commerce, White House, and Capitol Hill featuring the field's top leaders. Our work with Chair Landrieu and the Committee on Small Business and Entrepreneurship began at the Capitol Hill portion of our Summit in 2011.

Through our work in these areas, our company has seen the large unmet need in exposing today's youth to entrepreneurship as a viable career path. We are in full support of the Today's Entrepreneurs are Mentors (TEAM) Act, as we believe it will have a large, positive impact on the entrepreneurship education field and help fill this unmet need.

Specifically, I believe the TEAM Act will help lead to a new generation of young people who look at problems as opportunities rather than stopping points. I am particularly in favor of the recreation of a program within the Office of Entrepreneurial Education that would conduct outreach and mentorship in K–12 schools.

Sincerely,

MICHAEL SIMMONS,
Co-Founder and CEO.

MAY 21, 2011.

Hon. MARY LANDRIEU,
Chair of the Committee on Small Business and Entrepreneurship, Russell Senate Office Bldg., Washington, DC.

DEAR SENATOR LANDRIEU: We are writing to commend your work to reduce barriers to youth entrepreneurship in America and express our strong support for the TEAM Act. The ''Today's Entrepreneurs are America's Mentors'' Act contains a number of strong provisions that can provide that vital boost young adults need to start a business and find new economic opportunity. The TEAM Act reflects an important investment in the future of our country, and in the potential of this younger generation to be drivers of innovation and job creation.

In particular, the TEAM Act contains some of the key priorities that Young Invincibles and our partners in the entrepreneurship space have advocated for as part of the Youth Entrepreneurship Act (www.YouthEntrepreneurshipAct.com). The TEAM Act helps to increase the SBA's focus on young entrepreneurs by providing badly needed support for the Office of Entrepreneurial Education. This office has tremendous potential to support and expand some of the strong entrepreneurship education models that have already sprung up in high schools, community colleges, and universities across the country. The TEAM Act also strengthens support for entrepreneurship competitions, which have been a great and cost-efficient way to introduce young adults to the challenge of starting a successful business.

Finally, the TEAM Act requires the SBA to study and issue detailed recommendations to Congress on the feasibility of a student loan forgiveness and deferment program for people who start businesses. Young Invincibles has outlined this innovative policy idea in our Youth Entrepreneurship Act, and it has found considerable support among young adults as a way to address a major hurdle for young adults trying to start a business: the tens of thousands in student loans that are all too common for recent graduates. During our recent 20-state bus tour, we heard directly from young entrepreneurs struggling to pay back student loans and stand-up a new business simultaneously. We look forward to working with the SBA and Congress to advance and study this promising idea.

Thank you again for your support of America's young innovators.

Sincerely,

AARON SMITH,
Co-Founder & Executive Director, Young Invincibles.

Re Support for TEAM Act.

MARY LANDRIEU,
U.S. Senator, Dirksen Senate Office Bldg., Washington, DC.

DEAR SENATOR LANDRIEU: Thank you for your support of entrepreneurship as a critical tool in economic development. I'm excited to endorse your efforts to authorize the Small Business Administration's Office of Entrepreneurial Education (OEE). Entrepreneurship Education is essential to DECA's mission to develop emerging leaders and entrepreneurs.

The Office of Entrepreneurial Education will strengthen small businesses, the backbone of our economy through partnerships with DECA and other entrepreneurship education organizations. It will provide new avenues to reach high school and college students with the exciting opportunities they have to create their own future through entrepreneurship.

Thank you again for your leadership in this effort.

Sincerely,

EDWARD L. DAVIS,
Executive Director, DECA Inc.

MAY 18, 2012.

CHAIR LANDRIEU AND THE SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP: As founder of the Young Entrepreneur Council, an invite-only nonprofit organization comprised of several hundred of America's top young entrepreneurs, I write today to express how proud we are to support your efforts to strengthen the youth entrepreneurship ecosystem with proposals included in the TEAM Act.

Since its inception in 2010, the YEC has promoted entrepreneurship as a means to overcome unemployment and underemployment by providing students and aspiring entrepreneurs with access to tools, peer-to-peer mentorship and resources to support each stage of a business' development and growth. Provisions of the TEAM Act will go a long way toward helping the thousands of young people we mentor each year achieve their goals—and spur new job creation.

Specifically, empowering the Small Business Administration's Office of Entrepreneurial Education (OEE) to conduct outreach and mentorship in K–12 schools will significantly impact the way we teach opportunity recognition to our youth, and regional SBA-sponsored entrepreneurial competitions will spur youth-led innovation at a relatively low cost to the government (but with the potential to lead to great gains in new jobs and businesses). The SBA Pilot MBA Scholarship program will change many lives, as has already been demonstrated in New Orleans, and we support the Senate Committee's vision for scaling the program nationally. Finally, a study on the effect of student loan deferment on youth entrepreneurship is timely and much-needed. Based on the obstacles facing young entrepreneurs that we've documented throughout our #FixYoungAmerica campaign, we believe that the results of this SBA-led study are the first step toward empowering young entrepreneurs burdened with student loan debt to create new businesses and jobs at a time when America needs it most.

With policy reforms such as the TEAM Act, the YEC can continue to speak out, educate, empower and improve our youth's ability to sustain themselves in today's challenging economy, and we are proud to voice our support for these importantly and timely efforts.

Sincerely,

SCOTT GERBER,
Founder, Young Entrepreneur Council.

MAY 21, 2012.

CHAIR LANDRIEU AND THE SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP: As Chief Executive Officer and President of the Network for Teaching Entrepreneurship (NFTE), I am happy to extend our organization's support to the TEAM Act and your efforts to strengthen the resources available to expand entrepreneurship education to all young people in our country.

For nearly 25 years NFTE has partnered with schools and local business leaders to bring entrepreneurship education to youth in some our most challenged and under-resourced communities across the nation, and we've seen firsthand how this type of intensive, experiential programming can demonstrate the relevance of school, invest students in academic pursuits and unlock in young people their potential as entrepreneurs, scholars and leaders in their communities.

The provisions outlined in the TEAM Act will serve as powerful catalysts to grow the impact of the work NFTE and other like-minded organizations do, in particular, by further empowering the Small Business Administration's Office of Entrepreneurial Education (OEE) and creating a network of regional entrepreneurial competitions.

The young people we work with each day face many obstacles and the policy reforms contained in the TEAM Act will create a powerful platform of solutions and tools to support the achievement of their personal and professional goals. We are proud to support these important efforts.

Sincerely,

AMY ROSEN,
President and Chief Executive Officer, NFTE.

NATIONAL FFA CENTER,
Indianapolis, IN, May 21, 2012.

Hon. MARY LANDRIEU,
Chair, Committee on Small Business and Entrepreneurship, U.S. Senate, Dirksen Senate Office Building, Washington, DC.

DEAR CHAIRWOMAN LANDRIEU: Today there are over 540,000 student members of FFA in nearly 7,500 high school programs across the United States studying agriculture, developing their leadership skills and preparing for career success through agricultural education. A key part of agricultural education is experiential learning experiences that provide a hands-on way for students to learn, develop their skills and apply the knowledge learned in the classroom to serve real-world problems. We have always put a high degree of focus on developing our students' knowledge and application of entrepreneurship education as away of helping them achieve their career goals.

As a Senator from Louisiana I am sure you have a special appreciation for the role of small business and the critical role entrepreneurs play in starting businesses and creating jobs in rural communities. Entrepreneurship is a critical part of agriculture and is particularly important to the development and sustainability of rural communities. It is vitally important that young people learn and develop these skills in their earliest years to help them achieve success.

We support the expansion and increased focus of Entrepreneurship Education by the Small Business and Entrepreneurship Committee. We also encourage the committee to

consider language in the bill that would direct, incentivize and enable the Small Business Administration to work with other agencies such as USDA, Department of Education and others in developing an interagency working group that can develop a more comprehensive plan and approach to k–12 Entrepreneurship Education. To the degree that we can participate in supporting that collaboration and planning we would be happy to do so.

Thank you for your leadership in recognizing the importance of this issue and for putting forward legislation that will increase the visibility and effectiveness of Entrepreneurship Education. It is important to young people, our communities, our nation and the world.

Sincerely,

KENT SCHESCKE,
Director of Strategic Partnerships.

COUNCIL OF GRADUATE SCHOOLS,
Washington, DC, May 21, 2012.

Hon. MARY LANDRIEU,
Chair, Committee on Small Business and Entrepreneurship, U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR LANDRIEU, I am writing in support of Today's Entrepreneurs are America's Mentors (TEAM) Act, legislation that is intended to strengthen the U.S. entrepreneurial ecosystem by empowering the Small Business Administration's Office of Entrepreneurial Education and invigorating students of all ages, entrepreneurs and mentors throughout the country.

We are particularly supportive of the SBA Pilot MBA Scholarship program that would provide a scholarship/fellowship to MBA students. Scholarship recipients would provide free technical assistance, financial planning and sustainable business practices to local small businesses and start-up companies. This provision recognizes the increasing importance of graduate education in providing the highly skilled talent the nation needs to be successful in the 21st century global economy. The role of graduate education in preparing a highly skilled workforce was addressed in the landmark report, The Path Forward: The Future of Graduate Education in the United States. That report reviewed trends and vulnerabilities in our nation's system of graduate education and proposed a set of recommendations to strengthen the enterprise. The report and executive summary are available at http://www.fgereport.org/

A recent report, Pathways Through Graduate School and Into Careers, proposed increased collaboration among business leaders and university leaders to develop and support the next generation of entrepreneurs and innovators and is available at http://pathwaysreport.org/. Both reports were produced by the Council of Graduate Schools and ETS under the guidance of commissions of business leaders and university leaders.

We would welcome the opportunity to work with you and your colleagues on exploring additional ways that U.S. graduate education, a strategic national asset, can support our nation's entrepreneurial enterprise. Thank you for your leadership in introducing this important legislation.

Regards,

DEBRA W. STEWART,
President.

JUNIOR ACHIEVEMENT USA,
Colorado Springs, CO, May 21, 2012.

Chairwoman MARY LANDRIEU,
Senate Small Business and Entrepreneurship Committee, Russell Senate Office Building, Washington, DC.

DEAR CHAIRWOMAN LANDRIEU, on behalf of Junior Achievement USA, I am writing in support of the proposed Today's Entrepreneurs are Mentoring (TEAM) act. This legislation would strengthen the federal entrepreneurship education outreach to our nation's schools and further empower groups like Junior Achievement to inspire students, entrepreneurs, and mentors throughout the United States.

With the job landscape of the 21st century continuously changing, an increased emphasis on entrepreneurial education for our nation's students is needed more than ever. The TEAM act appears to do just that. By encouraging the SBA Office of Entrepreneurial Education (OEE) to work with existing entrepreneurial outreach organizations, I believe more students will be inspired to take the innovative action needed to successfully compete in the world's marketplace.

As you may know, Junior Achievement (JA) annually prepares more than 4 million K–12 students across the United States. For close to 100 years, educating and training youth on entrepreneurship has been a vital component of JA's purpose as an organization. Along with financial literacy and work readiness, teaching students about entrepreneurship through hands on activities that promote an entrepreneurial spirit is woven into JA's programs. Since 1919, the JA Company Program has taught millions of students about the skills and responsibilities needed to start and run a business.

Given JA's history and scope of impact in the entrepreneurial education space, we stand ready to assist the OEE were your bill to become law. Thank you for introducing this important piece of legislation and we look forward to possibly working with you and your staff in the weeks and months ahead.

Sincerely,

JACK E. KOSAKOWSKI,
President and CEO.

By Mrs. SHAHEEN (for herself and Ms. AYOTTE):

S. 3218. A bill to improve the coordination of export promotion programs and to facilitate export opportunities for small businesses, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

Mrs. SHAHEEN. Mr. President, this week we celebrate National Small Business Week. Small businesses are so important to job creation in this country. So much of the innovation that takes place in this country happens as the result of the work of small businesses. Two-thirds of the jobs we expect to be created to lead us out of the recession and through this recovery are going to be created by small businesses.

It is important that in this Chamber we do everything we can to support small businesses. I am pleased that I have been able to be a member of the Small Business Committee. I applaud the leadership of Senator LANDRIEU and Senator SNOWE, the chair and ranking member, for all of the good work they have done for small business.

I can tell you from my own personal experience just how important small businesses are. My husband and I started our married life and for 8 years ran a family business. It put us both through graduate school and gave us a downpayment on a house. It employed a number of young people for 8 years. It taught me a lot about meeting a payroll and making sure we could take care of our employees, help make sure they had good jobs. So I have had that personal experience to make me understand just how critical small businesses are to our economy.

I am here on the floor also to talk about bipartisan legislation that my colleague from New Hampshire, Ms. AYOTTE, and I are introducing today to boost small business exporting.

Just as small businesses are the backbone of so much of this country's economy, they are clearly the backbone of New Hampshire's economy. It should come as no surprise to all of our constituents in New Hampshire that both Senator AYOTTE and I serve on the Small Business Committee because we know how important those businesses are to our State. We both recognize how critical it is for us as a delegation to work across the aisle and across Chambers when possible to help the small businesses in New Hampshire provide the good jobs the residents of New Hampshire need.

So I am glad Senator AYOTTE and I are working together to introduce legislation to help remove barriers to exporting for small businesses in New Hampshire and across the United States. The bill we are introducing today, the Small Business Export Growth Act, is the result of a Small Business Committee field hearing that we hosted together in Manchester, NH, last August. We held that hearing because we recognized that exports offer a tremendous opportunity for small businesses.

Unfortunately, for so many small businesses, those foreign markets have remained an untapped resource for most of them. Over 95 percent of the world's customers live outside of the United States, but only 1 percent of our small businesses export. That is a particularly shocking number when we compare to it large businesses because over 40 percent of large businesses sell their products overseas. So we have to do more to help our small businesses get into those international markets.

At our field hearing we heard about some of the barriers our small businesses face when they try to go global. Our legislation is an attempt to remove some of those barriers so that small businesses can access new sources of revenue and create jobs. One of the problems we heard about is that navigating the Federal bureaucracy can be a special challenge for small businesses that wish to export. I know the Presiding Officer and I can both appreciate that because we know how hard it is for us to navigate the Federal bureaucracy.

Senator AYOTTE and I heard from two such New Hampshire companies that rely on State and Federal offices to help them export. I want to talk about one of those companies specifically. It is a company that is called Secure Care. Secure Care has developed a technology that protects Alzheimer's patients who may wander away from

their home or their place of residence. It also protects newborns who are still in the maternity ward.

Grace Preston, who is the international sales manager for Secure Care, told us that the company has significantly expanded its growth by selling overseas. Grace also told us that Secure Care could not have done that without Federal and State export programs working together. In New Hampshire, we are very fortunate because our State and Federal export services work seamlessly, and that has been important in helping our businesses grow their exports.

In 2010 New Hampshire's exports grew about 40 percent. That was almost twice the national average and the most of any State in the country. So it has been very critical to our small businesses.

But we also heard that State and Federal agencies don't always have that same collaborative relationship in other places across the country. According to our former New Hampshire trade director, Dawn Wivell, these services sometimes, in some places, can overlap or, even worse, sometimes there are agencies that refuse to work together. Our bill attempts to require better coordination to make more successes like Secure Care a reality across the country.

Our bill also encourages the Federal Government to do more to promote the opportunity of exporting and to get the word out about Federal export programs.

Foreign markets can be daunting for small businesses, but that should not stop our innovators from trying to compete. Our small businesses must be assured that the Federal Government will help them when considering exporting. Part of our responsibility is to try to do everything we can to put into place policies that help small businesses when they want to try to export.

I thank Senator AYOTTE for her cooperation and for the work we have done together. I thank both Senator AYOTTE and her staff, along with mine, for working on this issue. I look forward to advancing this legislation in the Senate and to continue to recognize the important role that small business plays in our economy.

Ms. AYOTTE. Mr. President, I am pleased today to join my colleague from New Hampshire, Senator SHAHEEN, in introducing the Small Business Export Growth Act, which would help small businesses better navigate the complex process of promoting and selling their goods abroad.

Senator SHAHEEN and I serve together on the Small Business Committee, and as she mentioned, we held a field hearing in Manchester, New Hampshire, last August to examine the role of exports in small business growth and job creation. We heard testimony from key national and New Hampshire-based stakeholders about ways to improve coordination among regulatory agencies, and how to ease the burdens faced by small business owners seeking to grow and export their products to foreign markets. The Small Business Export Growth Act represents a commonsense, bipartisan response to the issues identified at that hearing.

This legislation makes improvements to the operational efficiency of the Trade Promotion Coordinating Committee, TPCC, and improves Congressional oversight of the TPCC's activities. The bill also gives the Small Business Administration a larger voice in developing export policy and facilitates more networking opportunities for small businesses.

New Hampshire companies export to 160 countries and our exports are increasing at the fourth highest rate of any State. In fact, New Hampshire is leading the ten northeastern states in exports. Since 2003, New Hampshire exports have risen three times faster than the State's economy. Small businesses comprise over 96 percent of all New Hampshire firms, and it is imperative that we empower them with the tools they need to grow and hire. Opening markets around the world for our small businesses is an area in which we can find bipartisan agreement.

During the Manchester Small Business Week Forum I attended yesterday, I heard first-hand about the challenges small business owners are facing as they try to grow and create jobs in this tough economic climate. Exporting represents an enormous opportunity, not only for New Hampshire small businesses, but for small businesses across the country. The Small Business Export Growth Act will help smaller firms to compete in the global marketplace.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2127. Mr. DURBIN (for himself and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2128. Mrs. GILLIBRAND (for herself and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by her to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2129. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2130. Mr. BURR (for himself and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2131. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2132. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2133. Mr. DEMINT (for himself and Mr. VITTER) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2134. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2135. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2136. Mr. BLUMENTHAL (for himself, Mr. FRANKEN, Mr. SCHUMER, Mr. CARDIN, and Ms. KLOBUCHAR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2137. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2138. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2139. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2140. Mr. SCHUMER (for himself, Mr. MERKLEY, and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2141. Mr. CARDIN (for himself and Ms. LANDRIEU) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2142. Mr. LEAHY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2143. Mr. PAUL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2144. Mr. HATCH (for himself, Mr. BURR, Mr. ALEXANDER, and Mr. ROBERTS) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2145. 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.

SA 2146. 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.

SA 2147. Mr. HATCH (for himself, Mr. BROWN of Massachusetts, Mr. BURR, Mr. COBURN, Mr. CORNYN, Mr. LUGAR, Mr. ROBERTS, Mr. HOEVEN, Mrs. HUTCHISON, Mr. LEE, Mr. WICKER, Mr. COATS, Mr. BARRASSO, Mr. TOOMEY, Mr. MORAN, Ms. COLLINS, Mr. INHOFE, Mr. BLUNT, Mr. PORTMAN, Mr. ALEXANDER, Ms. AYOTTE, and Mr. CRAPO) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2148. Mr. KOHL (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. JOHNSON of South Dakota, Mr. BROWN of Ohio, Mr. BINGAMAN, and Mr. SANDERS) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2149. Mr. KOHL (for himself, Mr. GRASSLEY, and Mr. BLUMENTHAL) 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 2127. Mr. DURBIN (for himself and Mr. BLUMENTHAL) 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___. 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.''.

SA 2128. Mrs. GILLIBRAND (for herself and Mr. BLUMENTHAL) 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 of title IX, add the following:

SEC. 9___. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

(a) SHORT TITLE.—This section may be cited as the ''Cody Miller Initiative for Safer Prescriptions Act''.

(b) PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505E, as added by this Act, the following:

''SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (referred to in this section as 'PMI') for drugs subject to section 503(b)(1).

''(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the PMI with respect to a drug—

''(1) be scientifically accurate and based on the professional labeling approved by the Secretary and authoritative, peer-reviewed literature; and

''(2) includes nontechnical, understandable, plain language that is not promotional in tone or content, and contains at least—

''(A) the established name of drug, including the established name of such drug as a listed drug (as described in section 505(j)(2)(A)) and as a drug that is the subject of an approved abbreviated new drug application under section 505(j) or of an approved license for a biological product submitted under section 351(k) of the Public Health Service Act, if applicable;

''(B) drug uses and clinical benefits;

''(C) general directions for proper use;

''(D) contraindications, common side effects, and most serious risks of the drug, especially with respect to certain groups such as children, pregnant women, and the elderly;

''(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

''(F) when a patient should contact his or her health care professional;

''(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug; and

''(H) known clinically important interactions with other drugs and substances.

''(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards related to—

''(1) performing timely updates of drug information as new drugs and new information becomes available;

''(2) ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications in order to avoid patient confusion and harm; and

''(3) developing a process, including consumer testing, to assess the quality and effectiveness of PMI in ensuring that PMI promotes patient understanding and safe and effective medication use.

''(d) ELECTRONIC REPOSITORY.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all PMI documents and content to facilitate the availability of PMI.''.

(c) PUBLICATION ON INTERNET WEBSITE.—The Secretary of Health and Human Services shall publish on the Internet website of the Food and Drug Administration a link to the Daily Med website (http://dailymed.nlm.nih.gov/dailymed) (or any successor website).

SA 2129. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. 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).

SA 2130. Mr. BURR (for himself and Mr. COBURN) 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___. 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.''.

SA 2131. Mr. COBURN (for himself and Mr. BURR) 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 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 its 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.

SA 2132. Mr. COBURN (for himself and Mr. BURR) 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___. 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.

SA 2133. Mr. DEMINT (for himself and Mr. VITTER) 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 appropriate place, insert the following:

SEC. 11___. DOCUMENT DISCLOSURE RELATING TO THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, a representative of the Executive Office of the President shall provide to Congress all documents and correspondences exchanged between employees of the Executive Office of the President and the Pharmaceutical Research and Manufacturers of America since January 20, 2009.

(b) PUBLICATION OF DOCUMENTS AND CORRESPONDENCES.—The Secretary of Health and Human Services shall publish all documents and correspondences described in subsection (a) on the Internet website of the Department of Health and Human Services.

SA 2134. Mr. BLUMENTHAL 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 X, insert the following:

SEC. 10___. MARKET MANIPULATION WITH RESPECT TO DRUGS IN SHORTAGE.

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug'' has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) and is intended for human use.

(2) DRUG SHORTAGE.—The term ''drug shortage'' or ''shortage'', with respect to a drug defined in section 506C(a) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 356c(a)), means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (as defined in section 506(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 356(c)).

(b) PROHIBITION ON MARKET MANIPULATION.—It shall be unlawful for any person to directly or indirectly use any manipulative or deceptive device or contrivance, in connection with the purchase or sale of a drug in shortage, in contravention of rules or regulations the Federal Trade Commission may prescribe as necessary or appropriate in the public interest or for the protection of United States citizens.

(c) PROHIBITION ON FALSE INFORMATION.—It shall be unlawful for any person to report or distribute information related to the purchase or sale of a prescription drug in shortage if the person knew the information to be false or misleading, in order to support activities described in subsection (b).

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (b) shall be treated as an unfair and deceptive act or practice in violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) regarding unfair or deceptive acts or practices.

(2) POWERS OF COMMISSION.—

(A) IN GENERAL.—The Federal Trade Commission shall enforce this section 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.

(B) PRIVILEGES AND IMMUNITIES.—Any person who violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

(e) ENFORCEMENT BY STATES.—

(1) IN GENERAL.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of the State has been or is threatened or adversely affected by the engagement of any person in an act that violates subsection (b), the attorney general of the State may, as parens patriae, bring a civil action on behalf of the residents of the State in an appropriate district court of the United States—

(A) to enjoin further violation of such subsection by such person;

(B) to compel compliance with such subsection;

(C) to obtain damages, restitution, or other compensation on behalf of such residents;

(D) to obtain such other relief as the court considers appropriate; or

(E) to obtain civil penalties in the amount determined under paragraph (2).

(2) CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty applicable under the Federal Trade Commission Act (15 U.S.C. 41 et seq.), any person that violates subsection (b) or (c) shall be subject to a civil penalty of not more than $1,000,000.

(B) METHOD.—The civil penalty provided under subparagraph (A) shall be obtained in the same manner as civil penalties imposed under section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(C) MULTIPLE OFFENSES; OTHER CONSIDERATIONS.—In assessing the civil penalty under this paragraph—

(i) each day of a continuing violation shall be considered a separate violation; and

(ii) the seriousness of the violation, and the efforts of the person committing the violation to remedy the harm caused by the violation shall be considered.

(D) ADJUSTMENT FOR INFLATION.—Beginning on the date on which the Bureau of Labor Statistics first publishes the Consumer Price Index after the date that is 1 year after the date of the enactment of this Act, and annually thereafter, the maximum amount specified in subparagraph (A) shall be increased by the percentage increase in the Consumer Price Index published on that date from the Consumer Price Index published the previous year.

(3) RIGHTS OF FEDERAL TRADE COMMISSION.—

(A) NOTICE TO FEDERAL TRADE COMMISSION.—

(i) IN GENERAL.—Except as provided in clause (iii), the attorney general of a State shall notify the Federal Trade Commission in writing that the attorney general intends to bring a civil action under paragraph (1) before initiating the civil action.

(ii) CONTENTS.—The notification required by clause (i) with respect to a civil action shall include a copy of the complaint to be filed to initiate the civil action.

(iii) EXCEPTION.—If it is not feasible for the attorney general of a State to provide the notification required by clause (i) before initiating a civil action under paragraph (1), the attorney general shall notify the Federal Trade Commission immediately upon instituting the civil action.

(B) INTERVENTION BY FEDERAL TRADE COMMISSION.—The Federal Trade Commission may—

(i) intervene in any civil action brought by the attorney general of a State under paragraph (1); and

(ii) upon intervening—

(I) be heard on all matters arising in the civil action; and

(II) file petitions for appeal of a decision in the civil action.

(4) INVESTIGATORY POWERS.—Nothing in this subsection may be construed to prevent the attorney general of a State from exercising the powers conferred on the attorney general by the laws of the State to conduct investigations, to administer oaths or affirmations, or to compel the attendance of witnesses or the production of documentary or other evidence.

(5) PREEMPTIVE ACTION BY FEDERAL TRADE COMMISSION.—If the Federal Trade Commission institutes a civil action or an administrative action with respect to a violation of subsection (b), the attorney general of a State may not, during the pendency of such action, bring a civil action under paragraph (1) against any defendant named in the complaint of the Commission for the violation with respect to which the Commission instituted such action.

(6) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in—

(i) the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code; or

(ii) another court of competent jurisdiction.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) may be found.

(7) ACTIONS BY OTHER STATE OFFICIALS.—

(A) IN GENERAL.—In addition to civil actions brought by attorneys general under paragraph (1), any other officer of a State who is authorized by the State to do so may bring a civil action under paragraph (1), subject to the same requirements and limitations that apply under this subsection to civil actions brought by attorneys general.

(B) SAVINGS PROVISION.—Nothing in this subsection may be construed to prohibit an authorized official of a State from initiating or continuing any proceeding in a court of the State for a violation of any civil or criminal law of the State.

(f) REPORTING OF MARKET MANIPULATION WITH RESPECT TO DRUGS IN SHORTAGE, REFERRALS, AND EDUCATION AND OUTREACH.—

(1) LOGGING AND ACKNOWLEDGING COMPLAINTS OF MARKET MANIPULATION.—Not later than 1 year after the date of the enactment of this Act, the Federal Trade Commission shall establish a process by which the Commission shall log and acknowledge the receipt by the Commission of each complaint submitted to the Commission by a person in which the person—

(A) complains of a violation of subsection (b) about which the person certifies a reasonable belief or knowledge of such violation; or

(B) claims to be a victim of a violation of such section.

(2) REFERRALS.—To the degree practicable, the Commission shall refer each person from whom the Commission receives a complaint under paragraph (1) to an appropriate entity for—

(A) in the case of a victim of a violation of subsection (b), assistance in mitigating any damages caused by such violation; or

(B) enforcement of such subsection.

(3) PROGRAM OF EDUCATION AND OUTREACH.—The Commission shall carry out a program of education and outreach whereby the Commission informs consumers of the following:

(A) The prohibition set forth in subsection (b).

(B) Common ways in which such subsection is violated and how consumers can protect themselves from violations of such subsection.

(C) The process established under paragraph (1).

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SA 2135. Mr. BLUMENTHAL 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 X, add the following:

SEC. 10___. CRITICAL DRUG SUPPLY REINFORCEMENT PROGRAM.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter G—Drug Shortages

"SEC. 575. DEFINITIONS.

''For purposes of this subchapter—

''(1) the term 'critical reinforcement drug' means a drug that—

''(A) is the subject of a permanent discontinuance or an interruption in the manufacture of the drug that could lead to a meaningful disruption in the supply of that drug in the United States, as defined in section 506C(f)(3); and

''(B) is identified as vulnerable to a drug shortage based on the criteria established under section 575A;

''(2) the term 'drug'—

''(A) means a drug (as defined in section 201(g)) that is intended for human use and is the subject of an approved application under section 505(j); and

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act); and

''(3) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

"SEC. 575A. CRITICAL DRUG SUPPLY EVALUATION AND REINFORCEMENT.

''(a) DEVELOPMENT OF CRITERIA FOR EVALUATION OF CRITICAL REINFORCEMENT NEED.—

''(1) EVALUATION.—Not later than 180 days after the date of enactment of this section, the Secretary, in consultation with Office of Drug Shortages, shall conduct an evaluation to establish evidence-based criteria for identifying drugs that are vulnerable to a drug shortage.

''(2) CONTENT.—The evaluation under paragraph (1) shall include a comprehensive trend analysis to forecast drug shortages and target drugs that are vulnerable to a shortage. The Secretary is authorized to contract with a third party to conduct or participate in such evaluation. In conducting such evaluation, the Secretary or any authorized third party shall not use any confidential, trade secret, or proprietary information of any other entity without such entity's consent.

''(3) CONSULTATION WITH STAKEHOLDERS.—The Secretary, as part of the evaluation under paragraph (1), shall convene a discussion with stakeholders to assess methodology and findings applicable to such evaluation.

''(4) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit a report to Congress that describes the methods and processes used to conduct the evaluation under this subsection.

''(b) CRITICAL REINFORCEMENT.—To carry out this section, the Secretary may award the incentives under subsection (d) to qualified manufacturers to secure an agreement—

''(1) for the rapid production of a critical reinforcement drug;

''(2) that the qualified manufacturer will maintain production of a critical reinforcement drug; or

''(3) that would allow the Secretary to purchase supply of a critical reinforcement drug from the qualified manufacturer under certain market conditions and on terms and conditions mutually agreed upon.

''(c) QUALIFIED MANUFACTURERS.—To be a qualified manufacturer for purposes of this section—

''(1) an entity shall be a drug manufacturer; and

''(2) the Secretary shall ensure that the manufacturer—

''(A) is in compliance with good manufacturing practice regulations of the Food and Drug Administration to produce a critical reinforcement drug or a similar product; and

''(B)(i) currently produces a critical reinforcement drug or a similar product and can increase production immediately to address the shortage with no regulatory approvals required;

''(ii) does not currently produce a critical reinforcement drug but has the capability, capacity and regulatory authority to do so and could commence supply in time to address need; or

''(iii) has capability and capacity to produce a critical reinforcement drug but not the regulatory authority and could commence supply upon regulatory filing and approval.

''(d) INCENTIVES.—

''(1) IN GENERAL.—If the Secretary ensures a manufacturer is a qualified manufacturer, the Secretary shall negotiate a manufacturing contingency plan with the manufacturer to meet an identified critical reinforcement in subsection (c). The Secretary may—

''(A) expedite the review of any abbreviated new drug application submitted under section 505 by the qualified manufacturer for a drug that is vulnerable to shortage as identified pursuant to the criteria established under subsection (a); and

''(B) waive any application fees related to such an abbreviated new drug application.

''(2) LIMITATION.—If the qualified manufacturer fails to meet benchmarks specified by the Secretary in the agreement between the Secretary and the manufacturer, or otherwise violates such agreement, the Secretary may retroactively assess the application fees waived under paragraph (1)(B).

''(e) TRADEMARK PROTECTION.—Nothing in this section shall be construed to alter or modify in any way, any applicable patent, copyright, trademark, or other intellectual property rights of any holder of a new drug application, an abbreviated new drug application, or a biologics license application, including any applicable regulatory exclusivity periods or periods during which the Secretary may not accept for filing or approve any new drug application, an abbreviated new drug application, or a biologics license application, and procedures associated therewith, under this Act or the Public Health Service Act.''.

SA 2136. Mr. BLUMENTHAL (for himself, Mr. FRANKEN, Mr. SCHUMER, Mr. CARDIN, and Ms. KLOBUCHAR) 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 X, add the following:

SEC. 10___. CIVIL PENALTIES FOR FAILURE TO SUBMIT NOTIFICATION.

Section 303 (21 U.S.C. 333) is amended—

(1) in subsection (f)(5), by inserting ''or subsection (h)'' after ''or (9)'' each place such term appears; and

(2) by adding at the end the following:

''(h)(1) Any manufacturer that knowingly fails to submit a notification in violation of section 506C(a) shall be subject to a civil money penalty not to exceed $10,000 for each day on which the violation continues, and not to exceed $1,800,000 for all such violations adjudicated in a single proceeding.

''(2) Not later than 180 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall, subject to paragraph (1), promulgate final regulations establishing a schedule of civil monetary penalties for violations of section 506C(a).''.

SA 2137. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title VII, add the following:

SEC. 7___. PROHIBITION OF AUTHORIZED GENERICS.

(a) IN GENERAL.—Section 505 (21 U.S.C. 355), as amended by section 510(a), is further amended by adding at the end the following:

''(x) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, directly or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

''(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term 'authorized generic drug'—

''(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

''(B) does not include any drug to be marketed, sold, or distributed—

''(i) by an entity eligible for 180-day exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

''(ii) after expiration or forfeiture of any 180-day exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).''.

(b) CONFORMING AMENDMENT.—Section 505(t)(3) (21 U.S.C. 355(t)(3)) is amended by striking ''In this section'' and inserting ''In this subsection''.

SA 2138. Mr. VITTER 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, add the following:

DIVISION B—FLOOD INSURANCE

SEC. 100. REFERENCES.

Except as expressly provided otherwise, any reference to ''this Act'' contained in any division of this Act shall be treated as referring only to the provisions of that division.

TITLE I—FLOOD INSURANCE REFORM AND MODERNIZATION

SEC. 101. SHORT TITLE.

This title may be cited as the ''Flood Insurance Reform and Modernization Act of 2012''.

SEC. 102. FINDINGS.

Congress finds that—

(1) the flood insurance claims resulting from the hurricane season of 2005 exceeded all previous claims paid by the National Flood Insurance Program;

(2) in order to pay the legitimate claims of policyholders from the hurricane season of 2005, the Federal Emergency Management Agency has borrowed $19,000,000,000 from the Treasury;

(3) the interest alone on this debt has been as high as $800,000,000 annually, and that the Federal Emergency Management Agency has indicated that it will be unable to pay back this debt;

(4) the flood insurance program must be strengthened to ensure it can pay future claims;

(5) while flood insurance is mandatory in the 100-year floodplain, substantial flooding occurs outside of existing special flood hazard areas;

(6) events throughout the country involving areas behind flood control structures, known as ''residual risk'' areas, have produced catastrophic losses;

(7) although such flood control structures produce an added element of safety and therefore lessen the probability that a disaster will occur, they are nevertheless susceptible to catastrophic loss, even though such areas at one time were not included within the 100-year floodplain; and

(8) voluntary participation in the National Flood Insurance Program has been minimal and many families residing outside the 100-year floodplain remain unaware of the potential risk to their lives and property.

SEC. 103. DEFINITIONS.

(a) IN GENERAL.—In this title, the following definitions shall apply:

(1) 100-YEAR FLOODPLAIN.—The term ''100-year floodplain'' means that area which is subject to inundation from a flood having a 1-percent chance of being equaled or exceeded in any given year.

(2) 500-YEAR FLOODPLAIN.—The term ''500-year floodplain'' means that area which is subject to inundation from a flood having a 0.2-percent chance of being equaled or exceeded in any given year.

(3) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Federal Emergency Management Agency.

(4) NATIONAL FLOOD INSURANCE PROGRAM.—The term ''National Flood Insurance Program'' means the program established under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.).

(5) WRITE YOUR OWN.—The term ''Write Your Own'' means the cooperative undertaking between the insurance industry and the Federal Insurance Administration which allows participating property and casualty insurance companies to write and service standard flood insurance policies.

(b) COMMON TERMINOLOGY.—Except as otherwise provided in this title, any terms used in this title shall have the meaning given to such terms under section 1370 of the National Flood Insurance Act of 1968 (42 U.S.C. 4121).

SEC. 104. EXTENSION OF NATIONAL FLOOD INSURANCE PROGRAM.

(a) FINANCING.—Section 1309(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''September 30, 2016''.

(b) PROGRAM EXPIRATION.—Section 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4026) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''September 30, 2016''.

SEC. 105. AVAILABILITY OF INSURANCE FOR MULTIFAMILY PROPERTIES.

Section 1305 of the National Flood Insurance Act of 1968 (42 U.S.C. 4012) is amended—

(1) in subsection (b)(2)(A), by inserting ''not described in subsection (a) or (d)'' after ''properties''; and

(2) by adding at the end the following:

''(d) AVAILABILITY OF INSURANCE FOR MULTIFAMILY PROPERTIES.—

''(1) IN GENERAL.—The Administrator shall make flood insurance available to cover residential properties of more than 4 units. Notwithstanding any other provision of law, the maximum coverage amount that the Administrator may make available under this subsection to such residential properties shall be equal to the coverage amount made available to commercial properties.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the ability of individuals residing in residential properties of more than 4 units to obtain insurance for the contents and personal articles located in such residences.''.

SEC. 106. REFORM OF PREMIUM RATE STRUCTURE.

(a) TO EXCLUDE CERTAIN PROPERTIES FROM RECEIVING SUBSIDIZED PREMIUM RATES.—

(1) IN GENERAL.—Section 1307 of the National Flood Insurance Act of 1968 (42 U.S.C. 4014) is amended—

(A) in subsection (a)(2), by striking ''; and'' and inserting the following: '', except that the Administrator shall not estimate rates under this paragraph for—

''(A) any property which is not the primary residence of an individual;

''(B) any severe repetitive loss property;

''(C) any property that has incurred flood-related damage in which the cumulative amounts of payments under this title equaled or exceeded the fair market value of such property;

''(D) any business property; or

''(E) any property which on or after the date of the enactment of the Flood Insurance Reform and Modernization Act of 2012 has experienced or sustained—

''(i) substantial damage exceeding 50 percent of the fair market value of such property; or

''(ii) substantial improvement exceeding 30 percent of the fair market value of such property; and''; and

(B) by adding at the end the following:

''(g) NO EXTENSION OF SUBSIDY TO NEW POLICIES OR LAPSED POLICIES.—The Administrator shall not provide flood insurance to prospective insureds at rates less than those estimated under subsection (a)(1), as required by paragraph (2) of that subsection, for—

''(1) any property not insured by the flood insurance program as of the date of the enactment of the Flood Insurance Reform and Modernization Act of 2012;

''(2) any policy under the flood insurance program that has lapsed in coverage, as a result of the deliberate choice of the holder of such policy; or

''(3) any prospective insured who refuses to accept any offer for mitigation assistance by the Administrator (including an offer to relocate), including an offer of mitigation assistance—

''(A) following a major disaster, as defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122); or

''(B) in connection with—

''(i) a repetitive loss property; or

''(ii) a severe repetitive loss property.

''(h) DEFINITION.—In this section, the term 'severe repetitive loss property' has the following meaning:

''(1) SINGLE-FAMILY PROPERTIES.—In the case of a property consisting of 1 to 4 residences, such term means a property that—

''(A) is covered under a contract for flood insurance made available under this title; and

''(B) has incurred flood-related damage—

''(i) for which 4 or more separate claims payments have been made under flood insurance coverage under this chapter, with the amount of each such claim exceeding $5,000, and with the cumulative amount of such claims payments exceeding $20,000; or

''(ii) for which at least 2 separate claims payments have been made under such coverage, with the cumulative amount of such claims exceeding the value of the property.

''(2) MULTIFAMILY PROPERTIES.—In the case of a property consisting of more than 4 units, such term shall have such meaning as the Director shall by regulation provide.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall become effective 90 days after the date of the enactment of this Act.

(b) ESTIMATES OF PREMIUM RATES.—Section 1307(a)(1)(B) of the National Flood Insurance Act of 1968 (42 U.S.C. 4014(a)(1)(B)) is amended—

(1) in clause (ii), by striking ''and'' at the end;

(2) in clause (iii), by adding ''and'' at the end; and

(3) by inserting after clause (iii) the following:

''(iv) all costs, as prescribed by principles and standards of practice in ratemaking adopted by the American Academy of Actuaries and the Casualty Actuarial Society, including—

''(I) an estimate of the expected value of future costs,

''(II) all costs associated with the transfer of risk, and

''(III) the costs associated with an individual risk transfer with respect to risk classes, as defined by the Administrator,''.

(c) INCREASE IN ANNUAL LIMITATION ON PREMIUM INCREASES.—Section 1308(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4015(e)) is amended—

(1) by striking ''under this title for any properties within any single'' and inserting the following: ''under this title for any properties—

''(1) within any single'';

(2) by striking ''10 percent'' and inserting ''15 percent''; and

(3) by striking the period at the end and inserting the following: ''; and

''(2) described in subparagraphs (A) through (E) of section 1307(a)(2) shall be increased by 25 percent each year, until the average risk premium rate for such properties is equal to the average of the risk premium rates for properties described under paragraph (1).''.

(d) PREMIUM PAYMENT FLEXIBILITY FOR NEW AND EXISTING POLICYHOLDERS.—Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015) is amended by adding at the end the following:

''(g) FREQUENCY OF PREMIUM COLLECTION.—With respect to any chargeable premium rate prescribed under this section, the Administrator shall provide policyholders that are not required to escrow their premiums and fees for flood insurance as set forth under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a) with the option of paying their premiums either annually or in more frequent installments.''.

SEC. 107. MANDATORY COVERAGE AREAS.

(a) SPECIAL FLOOD HAZARD AREAS.—Not later than 90 days after the date of the enactment of this Act, the Administrator shall issue final regulations establishing a revised definition of areas of special flood hazards for purposes of the National Flood Insurance Program.

(b) RESIDUAL RISK AREAS.—The regulations required by subsection (a) shall require the expansion of areas of special flood hazards to include areas of residual risk that are located behind levees or near dams or other flood control structures, as determined by the Administrator.

(c) MANDATORY PARTICIPATION IN NATIONAL FLOOD INSURANCE PROGRAM.—

(1) IN GENERAL.—Any area described in subsection (b) shall be subject to the mandatory purchase requirements of sections 102 and 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a, 4106).

(2) LIMITATION.—The mandatory purchase requirement under paragraph (1) shall have no force or effect until the mapping of all residual risk areas in the United States that the Administrator determines essential in order to administer the National Flood Insurance Program, as required under section 118, are in the maintenance phase.

(3) ACCURATE PRICING.—In carrying out the mandatory purchase requirement under paragraph (1), the Administrator shall ensure that the price of flood insurance policies in areas of residual risk accurately reflects the level of flood protection provided by any levee, dam, or other flood control structure in such area, regardless of the certification status of the flood control structure.

(d) DECERTIFICATION.—Upon decertification of any levee, dam, or flood control structure under the jurisdiction of the Army Corps of Engineers, the Corps shall immediately provide notice to the Administrator of the National Flood Insurance Program.

SEC. 108. PREMIUM ADJUSTMENT.

Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015), as amended by section 106(c), is further amended by adding at the end the following:

''(h) PREMIUM ADJUSTMENT TO REFLECT CURRENT RISK OF FLOOD.—Notwithstanding subsection (f), upon the effective date of any revised or updated flood insurance rate map under this Act, the Flood Disaster Protection Act of 1973, or the Flood Insurance Reform and Modernization Act of 2012, any property located in an area that is participating in the national flood insurance program shall have the risk premium rate charged for flood insurance on such property adjusted to accurately reflect the current risk of flood to such property, subject to any other provision of this Act. Any increase in the risk premium rate charged for flood insurance on any property that is covered by a flood insurance policy on the effective date of such an update that is a result of such updating shall be phased in over a 4-year period, at the rate of 40 percent for the first year following such effective date and 20 percent for each of the second, third, and fourth years following such effective date. In the case of any area that was not previously designated as an area having special flood hazards and that, pursuant to any issuance, revision, updating, or other change in a flood insurance map, becomes designated as such an area, the chargeable risk premium rate for flood insurance under this title that is purchased on or after the date of enactment of this subsection with respect to any property that is located within such area shall be phased in over a 4-year period, at the rate of 40 percent for the first year following the effective date of such issuance, revision, updating, or change and 20 percent for each of the second, third, and fourth years following such effective date.''.

SEC. 109. STATE CHARTERED FINANCIAL INSTITUTIONS.

Section 1305(c) of the National Flood Insurance Act of 1968 (42 U.S.C. 4012(c)) is amended—

(1) in paragraph (1), by striking '', and'' and inserting a semicolon;

(2) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(3) given satisfactory assurance that by the date that is 6 months after the date of enactment of the Flood Insurance Reform and Modernization Act of 2012, lending institutions chartered by a State, and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration, shall be subject to regulations by that State that are consistent with the requirements of section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a).''.

SEC. 110. ENFORCEMENT.

Section 102(f)(5) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(f)(5)) is amended—

(1) in the first sentence, by striking ''$350'' and inserting ''$2,000''; and

(2) by striking the second sentence.

SEC. 111. ESCROW OF FLOOD INSURANCE PAYMENTS.

(a) IN GENERAL.—

(1) DEFINITIONS.—Section 3 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4003) is amended—

(A) in paragraph (10), by striking ''and'' at the end;

(B) in paragraph (11), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(12) 'State entity for lending regulation' means the State entity or agency with primary responsibility for the supervision or regulation of State lending institutions in a State; and

''(13) 'State lending institution' means any bank, savings and loan association, credit union, farm credit bank, production credit association, or similar lending institution subject to the supervision or regulation of a State entity for lending regulation.''.

(2) ESCROW REQUIREMENTS.—Paragraph (1) of section 102(d) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(d)) is amended to read as follows:

''(1) REGULATED LENDING INSTITUTIONS AND STATE LENDING INSTITUTIONS.—

''(A) FEDERAL ENTITIES RESPONSIBLE FOR LENDING REGULATIONS.—Each Federal entity for lending regulation (after consultation and coordination with the Federal Financial Institutions Examination Council) shall, by regulation, direct that all premiums and fees for flood insurance under the National Flood Insurance Act of 1968, for improved real estate or a mobile home, shall be paid to the regulated lending institution or servicer for any loan secured by the improved real estate or mobile home, with the same frequency as payments on the loan are made, for the duration of the loan. Except as provided in subparagraph (C), upon receipt of any premiums or fees, the regulated lending institution or servicer shall deposit such premiums and fees in an escrow account on behalf of the borrower. Upon receipt of a notice from the Administrator or the provider of the flood insurance that insurance premiums are due, the premiums deposited in the escrow account shall be paid to the provider of the flood insurance.

''(B) STATE ENTITIES RESPONSIBLE FOR LENDING REGULATIONS.—In order to continue to participate in the flood insurance program, each State shall direct that its State entity for lending regulation require that premiums and fees for flood insurance under the National Flood Insurance Act of 1968, for improved real estate or a mobile home shall be paid to the State lending institution or servicer for any loan secured by the improved real estate or mobile home, with the same frequency as payments on the loan are made, for the duration of the loan. Except as provided in subparagraph (C), upon receipt of any premiums or fees, the State lending institution or servicer shall deposit such premiums and fees in an escrow account on behalf of the borrower. Upon receipt of a notice from the Administrator or the provider of the flood insurance that insurance premiums are due, the premiums deposited in the escrow account shall be paid to the provider of the flood insurance.

''(C) LIMITATION.—Except as may be required under applicable State law, neither a Federal entity for lending regulation nor a State entity for lending regulation may direct or require a regulated lending institution or State lending institution to deposit premiums or fees for flood insurance under the National Flood Insurance Act of 1968 in an escrow account on behalf of a borrower under subparagraph (A) or (B), if—

''(i) the regulated lending institution or State lending institution has total assets of less than $1,000,000,000; and

''(ii) on or before the date of enactment of the Flood Insurance Reform and Modernization Act of 2012 the regulated lending institution or State lending institution—

''(I) was not required under Federal or State law to deposit taxes, insurance premiums, fees, or any other charges in an escrow account for a loan secured by residential improved real estate or a mobile home; and

''(II) did not have a policy of consistently and uniformly requiring the deposit of taxes, insurance premiums, fees, or any other charges in an escrow account for loans secured by residential improved real estate or a mobile home.''.

(b) APPLICABILITY.—The amendment made by subsection (a)(2) shall apply to any mortgage outstanding or entered into on or after the expiration of the 2-year period beginning on the date of the enactment of this Act.

SEC. 112. MINIMUM DEDUCTIBLES FOR CLAIMS UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.

Section 1312 of the National Flood Insurance Act of 1968 (42 U.S.C. 4019) is amended—

(1) by striking ''The Director is'' and inserting the following:

''(a) IN GENERAL.—The Administrator is''; and

(2) by adding at the end the following:

''(b) MINIMUM ANNUAL DEDUCTIBLE.—

''(1) PRE-FIRM PROPERTIES.—For any structure which is covered by flood insurance under this title, and on which construction or substantial improvement occurred on or before December 31, 1974, or before the effective date of an initial flood insurance rate map published by the Administrator under section 1360 for the area in which such structure is located, the minimum annual deductible for damage to such structure shall be—

''(A) $1,500, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount equal to or less than $100,000; and

''(B) $2,000, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount greater than $100,000.

''(2) POST-FIRM PROPERTIES.—For any structure which is covered by flood insurance under this title, and on which construction or substantial improvement occurred after December 31, 1974, or after the effective date of an initial flood insurance rate map published by the Administrator under section 1360 for the area in which such structure is located, the minimum annual deductible for damage to such structure shall be—

''(A) $1,000, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount equal to or less than $100,000; and

''(B) $1,250, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount greater than $100,000.''.

SEC. 113. CONSIDERATIONS IN DETERMINING CHARGEABLE PREMIUM RATES.

Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015), as amended by this Act, is amended—

(1) in subsection (a), by striking '', after consultation with'' and all that follows through ''by regulation'' and inserting ''prescribe, after providing notice'';

(2) in subsection (b)—

(A) in paragraph (1), by striking the period at the end and inserting a semicolon;

(B) in paragraph (2), by striking the comma at the end and inserting a semicolon;

(C) in paragraph (3), by striking '', and'' and inserting a semicolon;

(D) in paragraph (4), by striking the period and inserting ''; and''; and

(E) by adding at the end the following:

''(5) adequate, on the basis of accepted actuarial principles, to cover the average historical loss year obligations incurred by the National Flood Insurance Fund.''; and

(3) by adding at the end the following:

''(i) RULE OF CONSTRUCTION.—For purposes of this section, the calculation of an 'average historical loss year'—

''(1) includes catastrophic loss years; and

''(2) shall be computed in accordance with generally accepted actuarial principles.''.

SEC. 114. RESERVE FUND.

Chapter I of the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1310 (42 U.S.C. 4017) the following:

''SEC. 1310A. RESERVE FUND.

''(a) ESTABLISHMENT OF RESERVE FUND.—In carrying out the flood insurance program authorized by this chapter, the Administrator shall establish in the Treasury of the United States a National Flood Insurance Reserve Fund (in this section referred to as the 'Reserve Fund') which shall—

''(1) be an account separate from any other accounts or funds available to the Administrator; and

''(2) be available for meeting the expected future obligations of the flood insurance program.

''(b) RESERVE RATIO.—Subject to the phase-in requirements under subsection (d), the Reserve Fund shall maintain a balance equal to—

''(1) 1 percent of the sum of the total potential loss exposure of all outstanding flood insurance policies in force in the prior fiscal year; or

''(2) such higher percentage as the Administrator determines to be appropriate, taking into consideration any circumstance that may raise a significant risk of substantial future losses to the Reserve Fund.

''(c) MAINTENANCE OF RESERVE RATIO.—

''(1) IN GENERAL.—The Administrator shall have the authority to establish, increase, or decrease the amount of aggregate annual insurance premiums to be collected for any fiscal year necessary—

''(A) to maintain the reserve ratio required under subsection (b); and

''(B) to achieve such reserve ratio, if the actual balance of such reserve is below the amount required under subsection (b).

''(2) CONSIDERATIONS.—In exercising the authority granted under paragraph (1), the Administrator shall consider—

''(A) the expected operating expenses of the Reserve Fund;

''(B) the insurance loss expenditures under the flood insurance program;

''(C) any investment income generated under the flood insurance program; and

''(D) any other factor that the Administrator determines appropriate.

''(3) LIMITATIONS.—In exercising the authority granted under paragraph (1), the Administrator shall be subject to all other provisions of this Act, including any provisions relating to chargeable premium rates or annual increases of such rates.

''(d) PHASE-IN REQUIREMENTS.—The phase-in requirements under this subsection are as follows:

''(1) IN GENERAL.—Beginning in fiscal year 2012 and not ending until the fiscal year in which the ratio required under subsection (b) is achieved, in each such fiscal year the Administrator shall place in the Reserve Fund an amount equal to not less than 7.5 percent of the reserve ratio required under subsection (b).

''(2) AMOUNT SATISFIED.—As soon as the ratio required under subsection (b) is achieved, and except as provided in paragraph (3), the Administrator shall not be required to set aside any amounts for the Reserve Fund.

''(3) EXCEPTION.—If at any time after the ratio required under subsection (b) is achieved, the Reserve Fund falls below the required ratio under subsection (b), the Administrator shall place in the Reserve Fund for that fiscal year an amount equal to not less than 7.5 percent of the reserve ratio required under subsection (b).

''(e) LIMITATION ON RESERVE RATIO.—In any given fiscal year, if the Administrator determines that the reserve ratio required under subsection (b) cannot be achieved, the Administrator shall submit a report to Congress that—

''(1) describes and details the specific concerns of the Administrator regarding the consequences of the reserve ratio not being achieved;

''(2) demonstrates how such consequences would harm the long-term financial soundness of the flood insurance program; and

''(3) indicates the maximum attainable reserve ratio for that particular fiscal year.''.

SEC. 115. REPAYMENT PLAN FOR BORROWING AUTHORITY.

Section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016) is amended by adding at the end the following:

''(c) Upon the exercise of the authority established under subsection (a), the Administrator shall transmit a schedule for repayment of such amounts to—

''(1) the Secretary of the Treasury;

''(2) the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(3) the Committee on Financial Services of the House of Representatives.

''(d) In connection with any funds borrowed by the Administrator under the authority established in subsection (a), the Administrator, beginning 6 months after the date on which such funds are borrowed, and continuing every 6 months thereafter until such borrowed funds are fully repaid, shall submit a report on the progress of such repayment to—

''(1) the Secretary of the Treasury;

''(2) the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(3) the Committee on Financial Services of the House of Representatives.''.

SEC. 116. PAYMENT OF CONDOMINIUM CLAIMS.

Section 1312 of the National Flood Insurance Act of 1968 (42 U.S.C. 4019), as amended by section 112, is amended by adding at the end the following:

''(c) PAYMENT OF CLAIMS TO CONDOMINIUM OWNERS.—The Administrator may not deny payment for any damage to or loss of property which is covered by flood insurance to condominium owners who purchased such flood insurance separate and apart from the flood insurance purchased by the condominium association in which such owner is a member, based solely, or in any part, on the flood insurance coverage of the condominium association or others on the overall property owned by the condominium association.''.

SEC. 117. TECHNICAL MAPPING ADVISORY COUNCIL.

(a) ESTABLISHMENT.—There is established a council to be known as the Technical Mapping Advisory Council (in this section referred to as the ''Council'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—The Council shall consist of the Administrator, or the designee thereof, and 17 additional members to be appointed by the Administrator or the designee of the Administrator, who shall be—

(A) the Under Secretary of Commerce for Oceans and Atmosphere (or the designee thereof);

(B) a member of a recognized professional surveying association or organization;
(C) a member of a recognized professional mapping association or organization;
(D) a member of a recognized professional engineering association or organization;
(E) a member of a recognized professional association or organization representing flood hazard determination firms;
(F) a representative of the United States Geological Survey;
(G) a representative of a recognized professional association or organization representing State geographic information;
(H) a representative of State national flood insurance coordination offices;
(I) a representative of the Corps of Engineers;
(J) the Secretary of the Interior (or the designee thereof);
(K) the Secretary of Agriculture (or the designee thereof);
(L) a member of a recognized regional flood and storm water management organization;
(M) a representative of a State agency that has entered into a cooperating technical partnership with the Administrator and has demonstrated the capability to produce flood insurance rate maps;
(N) a representative of a local government agency that has entered into a cooperating technical partnership with the Administrator and has demonstrated the capability to produce flood insurance rate maps;
(O) a member of a recognized floodplain management association or organization;
(P) a member of a recognized risk management association or organization; and
(Q) a State mitigation officer.

(2) QUALIFICATIONS.—Members of the Council shall be appointed based on their demonstrated knowledge and competence regarding surveying, cartography, remote sensing, geographic information systems, or the technical aspects of preparing and using flood insurance rate maps.

(c) DUTIES.—The Council shall—
(1) recommend to the Administrator how to improve in a cost-effective manner the—
(A) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and
(B) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States;
(2) recommend to the Administrator mapping standards and guidelines for—
(A) flood insurance rate maps; and
(B) data accuracy, data quality, data currency, and data eligibility;
(3) recommend to the Administrator how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification;
(4) recommend procedures for delegating mapping activities to State and local mapping partners;
(5) recommend to the Administrator and other Federal agencies participating in the Council—
(A) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination; and
(B) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies; and
(6) submit an annual report to the Administrator that contains—
(A) a description of the activities of the Council;
(B) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update flood insurance rate maps, as required under section 118; and
(C) a summary of recommendations made by the Council to the Administrator.

(d) FUTURE CONDITIONS RISK ASSESSMENT AND MODELING REPORT.—
(1) IN GENERAL.—The Council shall consult with scientists and technical experts, other Federal agencies, States, and local communities to—
(A) develop recommendations on how to—
(i) ensure that flood insurance rate maps incorporate the best available climate science to assess flood risks; and
(ii) ensure that the Federal Emergency Management Agency uses the best available methodology to consider the impact of—
(I) the rise in the sea level; and
(II) future development on flood risk; and
(B) not later than 1 year after the date of the enactment of this Act, prepare written recommendations in a future conditions risk assessment and modeling report and to submit such recommendations to the Administrator.

(2) RESPONSIBILITY OF THE ADMINISTRATOR.—The Administrator, as part of the ongoing program to review and update National Flood Insurance Program rate maps under section 118, shall incorporate any future risk assessment submitted under paragraph (1)(B) in any such revision or update.

(e) CHAIRPERSON.—The members of the Council shall elect 1 member to serve as the chairperson of the Council (in this section referred to as the ''Chairperson'').

(f) COORDINATION.—To ensure that the Council's recommendations are consistent, to the maximum extent practicable, with national digital spatial data collection and management standards, the Chairperson shall consult with the Chairperson of the Federal Geographic Data Committee (established pursuant to Office of Management and Budget Circular A–16).

(g) COMPENSATION.—Members of the Council shall receive no additional compensation by reason of their service on the Council.

(h) MEETINGS AND ACTIONS.—
(1) IN GENERAL.—The Council shall meet not less frequently than twice each year at the request of the Chairperson or a majority of its members, and may take action by a vote of the majority of the members.
(2) INITIAL MEETING.—The Administrator, or a person designated by the Administrator, shall request and coordinate the initial meeting of the Council.

(i) OFFICERS.—The Chairperson may appoint officers to assist in carrying out the duties of the Council under subsection (c).

(j) STAFF.—
(1) STAFF OF FEMA.—Upon the request of the Chairperson, the Administrator may detail, on a nonreimbursable basis, personnel of the Federal Emergency Management Agency to assist the Council in carrying out its duties.
(2) STAFF OF OTHER FEDERAL AGENCIES.—Upon request of the Chairperson, any other Federal agency that is a member of the Council may detail, on a nonreimbursable basis, personnel to assist the Council in carrying out its duties.

(k) POWERS.—In carrying out this section, the Council may hold hearings, receive evidence and assistance, provide information, and conduct research, as it considers appropriate.

(l) REPORT TO CONGRESS.—The Administrator, on an annual basis, shall report to the Committee on Banking, Housing, and Urban Affairs of the Senate, the Committee on Financial Services of the House of Representatives, and the Office of Management and Budget on the—
(1) recommendations made by the Council;
(2) actions taken by the Federal Emergency Management Agency to address such recommendations to improve flood insurance rate maps and flood risk data; and
(3) any recommendations made by the Council that have been deferred or not acted upon, together with an explanatory statement.

SEC. 118. NATIONAL FLOOD MAPPING PROGRAM.

(a) REVIEWING, UPDATING, AND MAINTAINING MAPS.—The Administrator, in coordination with the Technical Mapping Advisory Council established under section 117, shall establish an ongoing program under which the Administrator shall review, update, and maintain National Flood Insurance Program rate maps in accordance with this section.

(b) MAPPING.—
(1) IN GENERAL.—In carrying out the program established under subsection (a), the Administrator shall—
(A) identify, review, update, maintain, and publish National Flood Insurance Program rate maps with respect to—
(i) all populated areas and areas of possible population growth located within the 100-year floodplain;
(ii) all populated areas and areas of possible population growth located within the 500-year floodplain;
(iii) areas of residual risk, including areas that are protected by levees, dams, and other flood control structures;
(iv) areas that could be inundated as a result of the failure of a levee, dam, or other flood control structure; and
(v) the level of protection provided by flood control structures;
(B) establish or update flood-risk zone data in all such areas, and make estimates with respect to the rates of probable flood caused loss for the various flood risk zones for each such area; and
(C) use, in identifying, reviewing, updating, maintaining, or publishing any National Flood Insurance Program rate map required under this section or under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.), the most accurate topography and elevation data available.

(2) MAPPING ELEMENTS.—Each map updated under this section shall—
(A) assess the accuracy of current ground elevation data used for hydrologic and hydraulic modeling of flooding sources and mapping of the flood hazard and wherever necessary acquire new ground elevation data utilizing the most up-to-date geospatial technologies in accordance with guidelines and specifications of the Federal Emergency Management Agency; and
(B) develop National Flood Insurance Program flood data on a watershed basis—
(i) to provide the most technically effective and efficient studies and hydrologic and hydraulic modeling; and
(ii) to eliminate, to the maximum extent possible, discrepancies in base flood elevations between adjacent political subdivisions.

(3) OTHER INCLUSIONS.—In updating maps under this section, the Administrator shall include—
(A) any relevant information on coastal inundation from—
(i) an applicable inundation map of the Corps of Engineers; and
(ii) data of the National Oceanic and Atmospheric Administration relating to storm surge modeling;
(B) any relevant information of the United States Geological Survey on stream flows, watershed characteristics, and topography that is useful in the identification of flood hazard areas, as determined by the Administrator;
(C) any relevant information on land subsidence, coastal erosion areas, and other floor-related hazards;
(D) any relevant information or data of the National Oceanic and Atmospheric Administration and the United States Geological Survey relating to the best available climate

science and the potential for future inundation from sea level rise, increased precipitation, and increased intensity of hurricanes due to global warming; and

(E) any other relevant information as may be recommended by the Technical Mapping Advisory Committee.

(c) STANDARDS.—In updating and maintaining maps under this section, the Administrator shall—

(1) establish standards to—

(A) ensure that maps are adequate for—

(i) flood risk determinations; and

(ii) use by State and local governments in managing development to reduce the risk of flooding; and

(B) facilitate identification and use of consistent methods of data collection and analysis by the Administrator, in conjunction with State and local governments, in developing maps for communities with similar flood risks, as determined by the Administrator; and

(2) publish maps in a format that is—

(A) digital geospatial data compliant;

(B) compliant with the open publishing and data exchange standards established by the Open Geospatial Consortium; and

(C) aligned with official data defined by the National Geodetic Survey.

(d) COMMUNICATION AND OUTREACH.—

(1) IN GENERAL.—The Administrator shall—

(A) work to enhance communication and outreach to States, local communities, and property owners about the effects—

(i) of any potential changes to National Flood Insurance Program rate maps that may result from the mapping program required under this section; and

(ii) that any such changes may have on flood insurance purchase requirements; and

(B) engage with local communities to enhance communication and outreach to the residents of such communities on the matters described under subparagraph (A).

(2) REQUIRED ACTIVITIES.—The communication and outreach activities required under paragraph (1) shall include—

(A) notifying property owners when their properties become included in, or when they are excluded from, an area covered by the mandatory flood insurance purchase requirement under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a);

(B) educating property owners regarding the flood risk and reduction of this risk in their community, including the continued flood risks to areas that are no longer subject to the flood insurance mandatory purchase requirement;

(C) educating property owners regarding the benefits and costs of maintaining or acquiring flood insurance, including, where applicable, lower-cost preferred risk policies under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) for such properties and the contents of such properties;

(D) educating property owners about flood map revisions and the process available to such owners to appeal proposed changes in flood elevations through their community; and

(E) encouraging property owners to maintain or acquire flood insurance coverage.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Administrator to carry out this section $400,000,000 for each of fiscal years 2012 through 2016.

SEC. 119. SCOPE OF APPEALS.

Section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) is amended—

(1) in subsection (a)—

(A) in the heading, by inserting ''AND DESIGNATIONS OF SPECIAL FLOOD HAZARD AREAS'' after ''ELEVATION DETERMINATIONS'';

(B) by inserting ''and designating special flood hazard areas'' after ''flood elevations''; and

(C) by striking ''such determinations'' and inserting ''such determinations and designations''; and

(2) in subsection (b)—

(A) in the heading, by inserting ''AND DESIGNATIONS OF SPECIAL FLOOD HAZARD AREAS'' after ''ELEVATION DETERMINATIONS'';

(B) in the first sentence, by inserting ''and designation of special flood hazard areas'' after ''flood elevation determinations''; and

(C) by amending the third sentence to read as follows: ''The sole grounds for appeal shall be the possession of knowledge or information indicating that (1) the elevations being proposed by the Administrator with respect to an identified area having special flood hazards are scientifically or technically incorrect, or (2) the designation of an identified special flood hazard area is scientifically or technically incorrect.''

SEC. 120. SCIENTIFIC RESOLUTION PANEL.

(a) ESTABLISHMENT.—The National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1363 (42 U.S.C. 4104) the following:

''SEC. 1363A. SCIENTIFIC RESOLUTION PANEL.

''(a) AVAILABILITY.—

''(1) IN GENERAL.—Pursuant to the authority provided under section 1363(e), the Administrator shall make available an independent review panel, to be known as the Scientific Resolution Panel, to any community—

''(A) that has—

''(i) filed a timely map appeal in accordance with section 1363;

''(ii) completed 60 days of consultation with the Federal Emergency Management Agency on the appeal; and

''(iii) not allowed more than 120 days, or such longer period as may be provided by the Administrator by waiver, to pass since the end of the appeal period; or

''(B) that has received an unsatisfactory ruling under the map revision process established pursuant to section 1360(f).

''(2) APPEALS BY OWNERS AND LESSEES.—If a community and an owner or lessee of real property within the community appeal a proposed determination of a flood elevation under section 1363(b), upon the request of the community—

''(A) the owner or lessee shall submit scientific and technical data relating to the appeals to the Scientific Resolution Panel; and

''(B) the Scientific Resolution Panel shall make a determination with respect to the appeals in accordance with subsection (c).

''(3) DEFINITION.—For purposes of paragraph (1)(B), an 'unsatisfactory ruling' means that a community—

''(A) received a revised Flood Insurance Rate Map from the Federal Emergency Management Agency, via a Letter of Final Determination, after September 30, 2008 and prior to the date of enactment of this section;

''(B) has subsequently applied for a Letter of Map Revision or Physical Map Revision with the Federal Emergency Management Agency; and

''(C) has received an unfavorable ruling on their request for a map revision.

''(b) MEMBERSHIP.—The Scientific Resolution Panel made available under subsection (a) shall consist of 5 members with expertise that relate to the creation and study of flood hazard maps and flood insurance. The Scientific Resolution Panel may include representatives from Federal agencies not involved in the mapping study in question and from other impartial experts. Employees of the Federal Emergency Management Agency may not serve on the Scientific Resolution Panel.

''(c) DETERMINATION.—

''(1) IN GENERAL.—Following deliberations, and not later than 90 days after its formation, the Scientific Resolution Panel shall issue a determination of resolution of the dispute. Such determination shall set forth recommendations for the base flood elevation determination or the determination of an area having special flood hazards that shall be reflected in the Flood Insurance Rate Maps.

''(2) BASIS.—The determination of the Scientific Resolution Panel shall be based on—

''(A) data previously provided to the Administrator by the community, and, in the case of a dispute submitted under subsection (a)(2), an owner or lessee of real property in the community; and

''(B) data provided by the Administrator.

''(3) NO ALTERNATIVE DETERMINATIONS PERMISSIBLE.—The Scientific Resolution Panel—

''(A) shall provide a determination of resolution of a dispute that—

''(i) is either in favor of the Administrator or in favor of the community on each distinct element of the dispute; or

''(ii) in the case of a dispute submitted under subsection (a)(2), is in favor of the Administrator, in favor of the community, or in favor of the owner or lessee of real property in the community on each distinct element of the dispute; and

''(B) may not offer as a resolution any other alternative determination.

''(4) EFFECT OF DETERMINATION.—

''(A) BINDING.—The recommendations of the Scientific Resolution Panel shall be binding on all appellants and not subject to further judicial review unless the Administrator determines that implementing the determination of the panel would—

''(i) pose a significant threat due to failure to identify a substantial risk of special flood hazards; or

''(ii) violate applicable law.

''(B) WRITTEN JUSTIFICATION NOT TO ENFORCE.—If the Administrator elects not to implement the determination of the Scientific Resolution Panel pursuant to subparagraph (A), then not later than 60 days after the issuance of the determination, the Administrator shall issue a written justification explaining such election.

''(C) APPEAL OF DETERMINATION NOT TO ENFORCE.—If the Administrator elects not to implement the determination of the Scientific Resolution Panel pursuant to subparagraph (A), the community may appeal the determination of the Administrator as provided for under section 1363(g).

''(d) MAPS USED FOR INSURANCE AND MANDATORY PURCHASE REQUIREMENTS.—With respect to any community that has a dispute that is being considered by the Scientific Resolution Panel formed pursuant to this subsection, the Federal Emergency Management Agency shall ensure that for each such community that—

''(1) the Flood Insurance Rate Map described in the most recently issued Letter of Final Determination shall be in force and effect with respect to such community; and

''(2) flood insurance shall continue to be made available to the property owners and residents of the participating community.''.

(b) CONFORMING AMENDMENTS.—

(1) ADMINISTRATIVE REVIEW.—Section 1363(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(e)) is amended by striking ''an independent scientific body or appropriate Federal agency for advice'' and inserting ''the Scientific Resolution Panel provided for in section 1363A''.

(2) JUDICIAL REVIEW.—The first sentence of section 1363(g) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(g)) is amended by striking ''Any appellant'' and inserting

''Except as provided in section 1363A, any appellant''.

SEC. 121. REMOVAL OF LIMITATION ON STATE CONTRIBUTIONS FOR UPDATING FLOOD MAPS.

Section 1360(f)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4101(f)(2)) is amended by striking '', but which may not exceed 50 percent of the cost of carrying out the requested revision or update''.

SEC. 122. COORDINATION.

(a) INTERAGENCY BUDGET CROSSCUT AND COORDINATION REPORT.—

(1) IN GENERAL.—The Secretary of Homeland Security, the Administrator, the Director of the Office of Management and Budget, and the heads of each Federal department or agency carrying out activities under sections 118 and 119 shall work together to ensure that flood risk determination data and geospatial data are shared among Federal agencies in order to coordinate the efforts of the Nation to reduce its vulnerability to flooding hazards.

(2) REPORT.—Not later than 30 days after the submission of the budget of the United States Government by the President to Congress, the Director of the Office of Management and Budget, in coordination with the Federal Emergency Management Agency, the United States Geological Survey, the National Oceanic and Atmospheric Administration, the Army Corps of Engineers, and other Federal agencies, as appropriate, shall submit to the appropriate authorizing and appropriating committees of the Senate and the House of Representatives an interagency budget crosscut and coordination report, certified by the Secretary or head of each such agency, that—

(A) contains an interagency budget crosscut report that displays relevant sections of the budget proposed for each of the Federal agencies working on flood risk determination data and digital elevation models, including any planned interagency or intra-agency transfers; and

(B) describes how the efforts aligned with such sections complement one another.

(b) DUTIES OF THE ADMINISTRATOR.—In carrying out sections 118 and 119, the Administrator shall—

(1) participate, pursuant to section 216 of the E–Government Act of 2002 (44 U.S.C. 3501 note), in the establishment of such standards and common protocols as are necessary to assure the interoperability of geospatial data for all users of such information;

(2) coordinate with, seek assistance and cooperation of, and provide a liaison to the Federal Geographic Data Committee pursuant to the Office of Management and Budget Circular A–16 and Executive Order 12906 (43 U.S.C. 1457 note; relating to the National Spatial Data Infrastructure) for the implementation of and compliance with such standards;

(3) integrate with, leverage, and coordinate funding of, to the maximum extent practicable, the current flood mapping activities of each unit of State and local government;

(4) integrate with, leverage, and coordinate, to the maximum extent practicable, the current geospatial activities of other Federal agencies and units of State and local government; and

(5) develop a funding strategy to leverage and coordinate budgets and expenditures, and to maintain or establish joint funding and other agreement mechanisms with other Federal agencies and units of State and local government to share in the collection and utilization of geospatial data among all governmental users.

SEC. 123. INTERAGENCY COORDINATION STUDY.

(a) IN GENERAL.—The Administrator shall enter into a contract with the National Academy of Public Administration to conduct a study on how the Federal Emergency Management Agency—

(1) should improve interagency and intergovernmental coordination on flood mapping, including a funding strategy to leverage and coordinate budgets and expenditures; and

(2) can establish joint funding mechanisms with other Federal agencies and units of State and local government to share the collection and utilization of data among all governmental users.

(b) TIMING.—Not later than 180 days after the date of the enactment of this title, the National Academy of Public Administration shall report the findings of the study required under subsection (a) to—

(1) the Committee on Banking, Housing, and Urban Affairs of the Senate;

(2) the Committee on Financial Services of the House of Representatives;

(3) the Committee on Appropriations of the Senate; and

(4) the Committee on Appropriations of the House of Representatives.

SEC. 124. NONMANDATORY PARTICIPATION.

(a) NONMANDATORY PARTICIPATION IN NATIONAL FLOOD INSURANCE PROGRAM FOR 500-YEAR FLOODPLAIN.—Any area located within the 500-year floodplain shall not be subject to the mandatory purchase requirements of sections 102 or 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a and 4106).

(b) NOTICE.—

(1) BY ADMINISTRATOR.—In carrying out the National Flood Insurance Program, the Administrator shall provide notice to any community located in an area within the 500-year floodplain.

(2) TIMING OF NOTICE.—The notice required under paragraph (1) shall be made not later than 6 months after the date of completion of the initial mapping of the 500-year floodplain, as required under section 118.

(3) LENDER REQUIRED NOTICE.—

(A) REGULATED LENDING INSTITUTIONS.—Each Federal or State entity for lending regulation (after consultation and coordination with the Federal Financial Institutions Examination Council) shall, by regulation, require regulated lending institutions, as a condition of making, increasing, extending, or renewing any loan secured by property located in an area within the 500-year floodplain, to notify the purchaser or lessee (or obtain satisfactory assurances that the seller or lessor has notified the purchaser or lessee) and the servicer of the loan that such property is located in an area within the 500-year floodplain, in a manner that is consistent with, and substantially identical to, the notice required under section 1364(a)(1) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104a(a)(1)).

(B) FEDERAL OR STATE AGENCY LENDERS.—Each Federal or State agency lender shall, by regulation, require notification in the same manner as provided under subparagraph (A) with respect to any loan that is made by a Federal or State agency lender and secured by property located in an area within the 500-year floodplain.

(C) PENALTY FOR NONCOMPLIANCE.—Any regulated lending institution or Federal or State agency lender that fails to comply with the notice requirements established by this paragraph shall be subject to the penalties prescribed under section 102(f)(5) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(f)(5)).

SEC. 125. NOTICE OF FLOOD INSURANCE AVAILABILITY UNDER RESPA.

Section 5(b) of the Real Estate Settlement Procedures Act of 1974 (12 U.S.C. 2604(b)), as amended by section 1450 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Public Law 111–203; 124 Stat. 2174), is amended by adding at the end the following:

''(14) An explanation of flood insurance and the availability of flood insurance under the National Flood Insurance Program, whether or not the real estate is located in an area having special flood hazards.''.

SEC. 126. PARTICIPATION IN STATE DISASTER CLAIMS MEDIATION PROGRAMS.

Chapter I of the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1313 (42 U.S.C. 4020) the following:

''SEC. 1314. PARTICIPATION IN STATE DISASTER CLAIMS MEDIATION PROGRAMS.

''(a) REQUIREMENT TO PARTICIPATE.—In the case of the occurrence of a major disaster, as defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122), that may have resulted in flood damage covered under the flood insurance program established under this chapter and other personal lines residential property insurance coverage offered by a State regulated insurer, upon a request made by the insurance commissioner of a State (or such other official responsible for regulating the business of insurance in the State) for the participation of representatives of the Administrator in a program sponsored by such State for nonbinding mediation of insurance claims resulting from a major disaster, the Administrator shall cause representatives of the flood insurance program to participate in such a State program where claims under the flood insurance program are involved to expedite settlement of flood damage claims resulting from such disaster.

''(b) EXTENT OF PARTICIPATION.—In satisfying the requirements of subsection (a), the Administrator shall require that each representative of the Administrator—

''(1) be certified for purposes of the flood insurance program to settle claims against such program resulting from such disaster in amounts up to the limits of policies under such program;

''(2) attend State-sponsored mediation meetings regarding flood insurance claims resulting from such disaster at such times and places as may be arranged by the State;

''(3) participate in good faith negotiations toward the settlement of such claims with policyholders of coverage made available under the flood insurance program; and

''(4) finalize the settlement of such claims on behalf of the flood insurance program with such policyholders.

''(c) COORDINATION.—Representatives of the Administrator shall at all times coordinate their activities with insurance officials of the State and representatives of insurers for the purposes of consolidating and expediting settlement of claims under the national flood insurance program resulting from such disaster.

''(d) QUALIFICATIONS OF MEDIATORS.—Each State mediator participating in State-sponsored mediation under this section shall be—

''(1)(A) a member in good standing of the State bar in the State in which the mediation is to occur with at least 2 years of practical experience; and

''(B) an active member of such bar for at least 1 year prior to the year in which such mediator's participation is sought; or

''(2) a retired trial judge from any United States jurisdiction who was a member in good standing of the bar in the State in which the judge presided for at least 5 years prior to the year in which such mediator's participation is sought.

''(e) MEDIATION PROCEEDINGS AND DOCUMENTS PRIVILEGED.—As a condition of participation, all statements made and documents produced pursuant to State-sponsored

mediation involving representatives of the Administrator shall be deemed privileged and confidential settlement negotiations made in anticipation of litigation.

''(f) LIABILITY, RIGHTS, OR OBLIGATIONS NOT AFFECTED.—Participation in State-sponsored mediation, as described in this section does not—

''(1) affect or expand the liability of any party in contract or in tort; or

''(2) affect the rights or obligations of the parties, as established—

''(A) in any regulation issued by the Administrator, including any regulation relating to a standard flood insurance policy;

''(B) under this Act; and

''(C) under any other provision of Federal law.

''(g) EXCLUSIVE FEDERAL JURISDICTION.—Participation in State-sponsored mediation shall not alter, change, or modify the original exclusive jurisdiction of United States courts, as set forth in this Act.

''(h) COST LIMITATION.—Nothing in this section shall be construed to require the Administrator or a representative of the Administrator to pay additional mediation fees relating to flood insurance claims associated with a State-sponsored mediation program in which such representative of the Administrator participates.

''(i) EXCEPTION.—In the case of the occurrence of a major disaster that results in flood damage claims under the national flood insurance program and that does not result in any loss covered by a personal lines residential property insurance policy—

''(1) this section shall not apply; and

''(2) the provisions of the standard flood insurance policy under the national flood insurance program and the appeals process established under section 205 of the Bunning-Bereuter-Blumenauer Flood Insurance Reform Act of 2004 (42 U.S.C. 4011 note) and the regulations issued pursuant to such section shall apply exclusively.

''(j) REPRESENTATIVES OF THE ADMINISTRATOR.—For purposes of this section, the term 'representatives of the Administrator' means representatives of the national flood insurance program who participate in the appeals process established under section 205 of the Bunning-Bereuter-Blumenauer Flood Insurance Reform Act of 2004 (42 U.S.C. 4011 note).''.

SEC. 127. ADDITIONAL AUTHORITY OF FEMA TO COLLECT INFORMATION ON CLAIMS PAYMENTS.

(a) IN GENERAL.—The Administrator shall collect, from property and casualty insurance companies that are authorized by the Administrator to participate in the Write Your Own program any information and data needed to determine the accuracy of the resolution of flood claims filed on any property insured with a standard flood insurance policy obtained under the program that was subject to a flood.

(b) TYPE OF INFORMATION TO BE COLLECTED.—The information and data to be collected under subsection (a) may include—

(1) any adjuster estimates made as a result of flood damage, and if the insurance company also insures the property for wind damage—

(A) any adjuster estimates for both wind and flood damage;

(B) the amount paid to the property owner for wind and flood claims;

(C) the total amount paid to the policyholder for damages as a result of the event that caused the flooding and other losses;

(2) any amounts paid to the policyholder by the insurance company for damages to the insured property other than flood damages; and

(3) the total amount paid to the policyholder by the insurance company for all damages incurred to the insured property as a result of the flood.

SEC. 128. OVERSIGHT AND EXPENSE REIMBURSEMENTS OF INSURANCE COMPANIES.

(a) SUBMISSION OF BIENNIAL REPORTS.—

(1) TO THE ADMINISTRATOR.—Not later than 20 days after the date of the enactment of this Act, each property and casualty insurance company that is authorized by the Administrator to participate in the Write Your Own program shall submit to the Administrator any biennial report required by the Federal Emergency Management Agency to be prepared in the prior 5 years by such company.

(2) TO GAO.—Not later than 10 days after the submission of the biennial reports under paragraph (1), the Administrator shall submit all such reports to the Comptroller General of the United States.

(3) NOTICE TO CONGRESS OF FAILURE TO COMPLY.—The Administrator shall notify and report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives on any property and casualty insurance company participating in the Write Your Own program that failed to submit its biennial reports as required under paragraph (1).

(4) FAILURE TO COMPLY.—A property and casualty insurance company that is authorized by the Administrator to participate in the Write Your Own program which fails to comply with the reporting requirement under this subsection or the requirement under section 62.23(j)(1) of title 44, Code of Federal Regulations (relating to biennial audit of the flood insurance financial statements) shall be subject to a civil penalty in an amount equal to $1,000 per day for each day that the company remains in noncompliance with either such requirement.

(b) METHODOLOGY TO DETERMINE REIMBURSED EXPENSES.—Not later than 180 days after the date of the enactment of this Act, the Administrator shall develop a methodology for determining the appropriate amounts that participating property and casualty insurance companies should be reimbursed for selling, writing, and servicing flood insurance policies and adjusting flood insurance claims on behalf of the National Flood Insurance Program. The methodology shall be developed using actual expense data for the flood insurance line and can be derived from—

(1) flood insurance expense data produced by participating property and casualty insurance companies;

(2) flood insurance expense data collected by the National Association of Insurance Commissioners; or

(3) a combination of the methodologies described in paragraphs (1) and (2).

(c) SUBMISSION OF EXPENSE REPORTS.—To develop the methodology established under subsection (b), the Administrator may require each property and casualty insurance company participating in the Write Your Own program to submit a report to the Administrator, in a format determined by the Administrator and within 60 days of the request, that details the expense levels of each such company for selling, writing, and servicing standard flood insurance policies and adjusting and servicing claims.

(d) FEMA RULEMAKING ON REIMBURSEMENT OF EXPENSES UNDER THE WYO PROGRAM.—Not later than 12 months after the date of the enactment of this Act, the Administrator shall conduct a rulemaking proceeding to formulate revised expense reimbursements to property and casualty insurance companies participating in the Write Your Own program for their expenses (including their operating and administrative expenses for adjustment of claims) in selling, writing, and servicing standard flood insurance policies, including how such companies shall be reimbursed in both catastrophic and noncatastrophic years. Such reimbursements shall be structured to ensure reimbursements track the actual expenses, including standard business costs and operating expenses, of such companies as close as practicably possible.

(e) REPORT OF THE ADMINISTRATOR.—Not later than 60 days after the effective date of any final rule established pursuant to subsection (d), the Administrator shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report containing—

(1) the specific rationale and purposes of such rule;

(2) the reasons for the adoption of the policies contained in such rule; and

(3) the degree to which such rule accurately represents the true operating costs and expenses of property and casualty insurance companies participating in the Write Your Own program.

(f) GAO STUDY AND REPORT ON EXPENSES OF WYO PROGRAM.—

(1) STUDY.—Not later than 180 days after the effective date of the final rule established pursuant to subsection (d), the Comptroller General of the United States shall—

(A) conduct a study on the efficacy, adequacy, and sufficiency of the final rules established pursuant to subsection (d); and

(B) report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives on the findings of the study conducted under subparagraph (A).

(2) GAO AUTHORITY.—In conducting the study and report required under paragraph (1), the Comptroller General—

(A) may use any previous findings, studies, or reports that the Comptroller General previously completed on the Write Your Own program;

(B) shall determine if—

(i) the final rules established pursuant to subsection (d) allow the Federal Emergency Management Agency to access adequate information regarding the actual expenses of property and casualty insurance companies participating in the Write Your Own program; and

(ii) the actual reimbursements paid out under the final rule established in subsection (d) accurately reflect the expenses reported by property and casualty insurance companies participating in the Write Your Own program, including the standard business costs and operating expenses of such companies; and

(C) shall analyze the effect of such rules on the level of participation of property and casualty insurers in the Write Your Own program.

SEC. 129. MITIGATION.

(a) MITIGATION ASSISTANCE GRANTS.—Section 1366 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104c) is amended—

(1) by striking subsections (b), (d), (f), (g), (h), (k), and (m);

(2) by redesignating subsections (c), (e), (i), and (j) as subsections (b), (c), (e), and (f), respectively;

(3) in subsection (a), by striking the last sentence and inserting the following: ''Such financial assistance shall be made available—

''(1) to States and communities in the form of grants under this section for carrying out mitigation activities;

''(2) to States and communities in the form of grants under this section for carrying out mitigation activities that reduce flood damage to severe repetitive loss structures; and

''(3) to property owners in the form of direct grants under this section for carrying out mitigation activities that reduce flood damage to individual structures for which 2 or more claim payments for losses have been made under flood insurance coverage under this title if the Administrator, after consultation with the State and community, determines that neither the State nor community in which such a structure is located has the capacity to manage such grants.'';

(4) in subsection (b), as so redesignated, in the first sentence—

(A) by striking ''and provides protection against'' and inserting ''provides for reduction of''; and

(B) by inserting before the period at the end the following: '', and may be included in a multi-hazard mitigation plan'';

(5) in subsection (c), as so redesignated—

(A) in paragraph (1), by striking ''(1) USE OF AMOUNTS.—'' and all that follows through the end of the first sentence and inserting the following:

''(1) REQUIREMENT OF CONSISTENCY WITH APPROVED MITIGATION PLAN.—Amounts provided under this section may be used only for mitigation activities that are consistent with mitigation plans that are approved by the Administrator and identified under paragraph (4).'';

(B) by striking paragraphs (2), (3), and (4) and inserting the following new paragraphs:

''(2) REQUIREMENTS OF TECHNICAL FEASIBILITY, COST EFFECTIVENESS, AND INTEREST OF NFIF.—The Administrator may approve only mitigation activities that the Administrator determines are technically feasible and cost-effective and in the interest of, and represent savings to, the National Flood Insurance Fund. In making such determinations, the Administrator shall take into consideration recognized ancillary benefits.

''(3) PRIORITY FOR MITIGATION ASSISTANCE.—In providing grants under this section for mitigation activities, the Administrator shall give priority for funding to activities that the Administrator determines will result in the greatest savings to the National Flood Insurance Fund, including activities for—

''(A) severe repetitive loss structures;

''(B) repetitive loss structures; and

''(C) other subsets of structures as the Administrator may establish.'';

(C) by redesignating paragraph (5) as paragraph (4);

(D) in paragraph (4), as so redesignated—

(i) in the matter preceding subparagraph (A), by striking ''The Director'' and all that follows through ''Such activities may'' and inserting ''Eligible activities under a mitigation plan may'';

(ii) by striking subparagraphs (E) and (H);

(iii) by redesignating subparagraphs (D), (F), and (G) as subparagraphs (E), (G), and (H), respectively;

(iv) by inserting after subparagraph (C) the following new subparagraph:

''(D) elevation, relocation, or floodproofing of utilities (including equipment that serve structures);'';

(v) by inserting after subparagraph (E), as so redesignated, the following new subparagraph:

''(F) the development or update of mitigation plans by a State or community which meet the planning criteria established by the Administrator, except that the amount from grants under this section that may be used under this subparagraph may not exceed $50,000 for any mitigation plan of a State or $25,000 for any mitigation plan of a community;'';

(vi) in subparagraph (H); as so redesignated, by striking ''and'' at the end; and

(vii) by adding at the end the following new subparagraphs:

''(I) other mitigation activities not described in subparagraphs (A) through (G) or the regulations issued under subparagraph (H), that are described in the mitigation plan of a State or community; and

''(J) without regard to the requirements under subsections (d)(1) and (d)(2), and if the State applied for and was awarded at least $1,000,000 in grants available under this section in the prior fiscal year, technical assistance to communities to identify eligible activities, to develop grant applications, and to implement grants awarded under this section, not to exceed $50,000 to any one State in any fiscal year.'';

(E) by adding at the end the following new paragraph:

''(5) ELIGIBILITY OF DEMOLITION AND REBUILDING OF PROPERTIES.—The Administrator shall consider as an eligible activity the demolition and rebuilding of properties to at least base flood elevation or greater, if required by the Administrator or if required by any State regulation or local ordinance, and in accordance with criteria established by the Administrator.''; and

(6) by inserting after subsection (c), as so redesignated, the following new subsection:

''(d) MATCHING REQUIREMENT.—The Administrator may provide grants for eligible mitigation activities as follows:

''(1) SEVERE REPETITIVE LOSS STRUCTURES.—In the case of mitigation activities to severe repetitive loss structures, in an amount up to 100 percent of all eligible costs.

''(2) REPETITIVE LOSS STRUCTURES.—In the case of mitigation activities to repetitive loss structures, in an amount up to 90 percent of all eligible costs.

''(3) OTHER MITIGATION ACTIVITIES.—In the case of all other mitigation activities, in an amount up to 75 percent of all eligible costs.'';

(7) in subsection (e)(2), as so redesignated—

(A) by striking ''certified under subsection (g)'' and inserting ''required under subsection (d)''; and

(B) by striking ''3 times the amount'' and inserting ''the amount'';

(8) in subsection (f)(1), as so redesignated, by striking ''Riegle Community Development and Regulatory Improvement Act of 1994'' and inserting ''Flood Insurance Reform and Modernization Act of 2012''; and

(9) by adding at the end the following new subsections:

''(g) FAILURE TO MAKE GRANT AWARD WITHIN 5 YEARS.—For any application for a grant under this section for which the Administrator fails to make a grant award within 5 years of the date of the application, the grant application shall be considered to be denied and any funding amounts allocated for such grant applications shall remain in the National Flood Mitigation Fund under section 1367 of this title and shall be made available for grants under this section.

''(h) DEFINITIONS.—For purposes of this section, the following definitions shall apply:

''(1) COMMUNITY.—The term 'community' means—

''(A) a political subdivision that—

''(i) has zoning and building code jurisdiction over a particular area having special flood hazards; and

''(ii) is participating in the national flood insurance program; or

''(B) a political subdivision of a State, or other authority, that is designated by political subdivisions, all of which meet the requirements of subparagraph (A), to administer grants for mitigation activities for such political subdivisions.

''(2) REPETITIVE LOSS STRUCTURE.—The term 'repetitive loss structure' has the meaning given such term in section 1370.

''(3) SEVERE REPETITIVE LOSS STRUCTURE.—The term 'severe repetitive loss structure' means a structure that—

''(A) is covered under a contract for flood insurance made available under this title; and

''(B) has incurred flood-related damage—

''(i) for which 4 or more separate claims payments have been made under flood insurance coverage under this title, with the amount of each such claim exceeding $5,000, and with the cumulative amount of such claims payments exceeding $20,000; or

''(ii) for which at least 2 separate claims payments have been made under such coverage, with the cumulative amount of such claims exceeding the value of the insured structure.''.

(b) ELIMINATION OF GRANTS PROGRAM FOR REPETITIVE INSURANCE CLAIMS PROPERTIES.—Chapter I of the National Flood Insurance Act of 1968 is amended by striking section 1323 (42 U.S.C. 4030).

(c) ELIMINATION OF PILOT PROGRAM FOR MITIGATION OF SEVERE REPETITIVE LOSS PROPERTIES.—Chapter III of the National Flood Insurance Act of 1968 is amended by striking section 1361A (42 U.S.C. 4102a).

(d) NATIONAL FLOOD INSURANCE FUND.—Section 1310(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4017(a)) is amended—

(1) in paragraph (6), by inserting ''and'' after the semicolon;

(2) in paragraph (7), by striking the semicolon and inserting a period; and

(3) by striking paragraphs (8) and (9).

(e) NATIONAL FLOOD MITIGATION FUND.—Section 1367 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104d) is amended—

(1) in subsection (b)—

(A) by striking paragraph (1) and inserting the following new paragraph:

''(1) in each fiscal year, amounts from the National Flood Insurance Fund not to exceed $90,000,000 and to remain available until expended, of which—

''(A) not more than $40,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(1);

''(B) not more than $40,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(2); and

''(C) not more than $10,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(3);''; and

(B) in paragraph (3), by striking ''section 1366(i)'' and inserting ''section 1366(e)'';

(2) in subsection (c), by striking ''sections 1366 and 1323'' and inserting ''section 1366'';

(3) by redesignating subsections (d) and (e) as subsections (f) and (g), respectively; and

(4) by inserting after subsection (c) the following new subsections:

''(d) PROHIBITION ON OFFSETTING COLLECTIONS.—Notwithstanding any other provision of this title, amounts made available pursuant to this section shall not be subject to offsetting collections through premium rates for flood insurance coverage under this title.

''(e) CONTINUED AVAILABILITY AND REALLOCATION.—Any amounts made available pursuant to subparagraph (A), (B), or (C) of subsection (b)(1) that are not used in any fiscal year shall continue to be available for the purposes specified in such subparagraph of subsection (b)(1) pursuant to which such amounts were made available, unless the Administrator determines that reallocation of such unused amounts to meet demonstrated need for other mitigation activities under section 1366 is in the best interest of the National Flood Insurance Fund.''.

(f) INCREASED COST OF COMPLIANCE COVERAGE.—Section 1304(b)(4) of the National

Flood Insurance Act of 1968 (42 U.S.C. 4011(b)(4)) is amended—

(1) by striking subparagraph (B); and

(2) by redesignating subparagraphs (C), (D), and (E) as subparagraphs (B), (C), and (D), respectively.

SEC. 130. FLOOD PROTECTION STRUCTURE ACCREDITATION TASK FORCE.

(a) DEFINITIONS.—In this section—

(1) the term ''flood protection structure accreditation requirements'' means the requirements established under section 65.10 of title 44, Code of Federal Regulations, for levee systems to be recognized on maps created for purposes of the National Flood Insurance Program;

(2) the term ''National Committee on Levee Safety'' means the Committee on Levee Safety established under section 9003 of the National Levee Safety Act of 2007 (33 U.S.C. 3302); and

(3) the term ''task force'' means the Flood Protection Structure Accreditation Task Force established under subsection (b).

(b) ESTABLISHMENT.—

(1) IN GENERAL.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, in cooperation with the National Committee on Levee Safety, shall jointly establish a Flood Protection Structure Accreditation Task Force.

(2) DUTIES.—

(A) DEVELOPING PROCESS.—The task force shall develop a process to better align the information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program with the flood protection structure accreditation requirements so that—

(i) information and data collected for either purpose can be used interchangeably; and

(ii) information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program is sufficient to satisfy the flood protection structure accreditation requirements.

(B) GATHERING RECOMMENDATIONS.—The task force shall gather, and consider in the process developed under subparagraph (A), recommendations from interested persons in each region relating to the information, data, and accreditation requirements described in subparagraph (A).

(3) CONSIDERATIONS.—In developing the process under paragraph (2), the task force shall consider changes to—

(A) the information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program; and

(B) the flood protection structure accreditation requirements.

(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require a reduction in the level of public safety and flood control provided by accredited levees, as determined by the Administrator for purposes of this section.

(c) IMPLEMENTATION.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, shall implement the process developed by the task force under subsection (b).

(d) REPORTS.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, in cooperation with the National Committee on Levee Safety, shall jointly submit to the Committee on Banking, Housing, and Urban Affairs and the Committee on Environment and Public Works of the Senate and the Committee on Financial Services, the Committee on Transportation and Infrastructure, and the Committee on Natural Resources of the House of Representatives reports concerning the activities of the task force and the implementation of the process developed by the task force under subsection (b), including—

(1) an interim report, not later than 180 days after the date of enactment of this Act; and

(2) a final report, not later than 1 year after the date of enactment of this Act.

(e) TERMINATION.—The task force shall terminate on the date of submission of the report under subsection (d)(2).

SEC. 131. FLOOD IN PROGRESS DETERMINATIONS.

(a) REPORT.—

(1) REVIEW.—The Administrator shall review—

(A) the processes and procedures for determining that a flood event has commenced or is in progress for purposes of flood insurance coverage made available under the National Flood Insurance Program;

(B) the processes and procedures for providing public notification that such a flood event has commenced or is in progress;

(C) the processes and procedures regarding the timing of public notification of flood insurance requirements and availability; and

(D) the effects and implications that weather conditions, including rainfall, snowfall, projected snowmelt, existing water levels, and other conditions, have on the determination that a flood event has commenced or is in progress.

(2) REPORT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall submit a report to Congress that describes—

(A) the results and conclusions of the review under paragraph (1); and

(B) any actions taken, or proposed actions to be taken, by the Administrator to provide for more precise and technical processes and procedures for determining that a flood event has commenced or is in progress.

(b) EFFECTIVE DATE OF POLICIES COVERING PROPERTIES AFFECTED BY FLOODING OF THE MISSOURI RIVER IN 2011.—

(1) ELIGIBLE COVERAGE.—For purposes of this subsection, the term ''eligible coverage'' means coverage under a new contract for flood insurance coverage under the National Flood Insurance Program, or a modification to coverage under an existing flood insurance contract, for property damaged by the flooding of the Missouri River that commenced on June 1, 2011, that was purchased or made during the period beginning May 1, 2011, and ending June 6, 2011.

(2) EFFECTIVE DATES.—Notwithstanding section 1306(c) of the National Flood Insurance Act of 1968 (42 U.S.C. 4013(c)), or any other provision of law, any eligible coverage shall—

(A) be deemed to take effect on the date that is 30 days after the date on which all obligations for the eligible coverage (including completion of the application and payment of any initial premiums owed) are satisfactorily completed; and

(B) cover damage to property occurring after the effective date described in subparagraph (A) that resulted from the flooding of the Missouri River that commenced on June 1, 2011, if the property did not suffer damage or loss as a result of such flooding before the effective date described in subparagraph (A).

SEC. 132. CLARIFICATION OF RESIDENTIAL AND COMMERCIAL COVERAGE LIMITS.

Section 1306(b) of the National Flood Insurance Act of 1968 (42 U.S.C. 4013(b)) is amended—

(1) in paragraph (2)—

(A) by striking ''in the case of any residential property'' and inserting ''in the case of any residential building designed for the occupancy of from one to four families''; and

(B) by striking ''shall be made available to every insured upon renewal and every applicant for insurance so as to enable such insured or applicant to receive coverage up to a total amount (including such limits specified in paragraph (1)(A)(i)) of $250,000'' and inserting ''shall be made available, with respect to any single such building, up to an aggregate liability (including such limits specified in paragraph (1)(A)(i)) of $250,000''; and

(2) in paragraph (4)—

(A) by striking ''in the case of any nonresidential property, including churches,'' and inserting ''in the case of any nonresidential building, including a church,''; and

(B) by striking ''shall be made available to every insured upon renewal and every applicant for insurance, in respect to any single structure, up to a total amount (including such limit specified in subparagraph (B) or (C) of paragraph (1), as applicable) of $500,000 for each structure and $500,000 for any contents related to each structure'' and inserting ''shall be made available with respect to any single such building, up to an aggregate liability (including such limits specified in subparagraph (B) or (C) of paragraph (1), as applicable) of $500,000, and coverage shall be made available up to a total of $500,000 aggregate liability for contents owned by the building owner and $500,000 aggregate liability for each unit within the building for contents owned by the tenant''.

SEC. 133. LOCAL DATA REQUIREMENT.

(a) IN GENERAL.—Notwithstanding any other provision of this title, an area that is within or includes a community that is identified by the Administrator as Community Identification Number 360467 and impacted by the Jamaica Bay flooding source or identified by the Administrator as Community Identification Number 360495 may not be or become designated as an area having special flood hazards for purposes of the National Flood Insurance Program, unless the designation is made on the basis of—

(1) flood hazard analyses of hydrologic, hydraulic, or coastal flood hazards that have been properly calibrated and validated, and are specific and directly relevant to the geographic area being studied; and

(2) ground elevation information of sufficient accuracy and precision to meet the guidelines of the Administration for accuracy at the 95 percent confidence level.

(b) REMAPPING.—

(1) REMAPPING REQUIRED.—If the Administrator determines that an area described in subsection (a) has been designated as an area of special flood hazard on the basis of information that does not comply with the requirements under subsection (a), the Administrator shall revise and update any National Flood Insurance Program rate map for the area—

(A) using information that complies with the requirements under subsection (a); and

(B) in accordance with the procedures established under section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) for flood elevation determinations.

(2) INTERIM PERIOD.—A National Flood Insurance Program rate map in effect on the date of enactment of this Act for an area for which the Administrator has made a determination under paragraph (1) shall continue in effect with respect to the area during the period—

(A) beginning on the date of enactment of this Act; and

(B) ending on the date on which the Administrator determines that the requirements under section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) for flood elevation determinations have been met with respect to a revision and update under paragraph (1) of a National Flood Insurance rate map for the area.

(3) DEADLINE.—The Administrator shall issue a preliminary National Flood Insurance Program rate map resulting from a revision and update required under paragraph (1) not later than 1 year after the date of enactment of this Act.

(4) RISK PREMIUM RATE CLARIFICATION.—

(A) IN GENERAL.—If a revision and update required under paragraph (1) results in a reduction in the risk premium rate for a property in an area for which the Administrator has made a determination under paragraph (1), the Administrator shall—

(i) calculate the difference between the reduced risk premium rate and the risk premium rate paid by a policyholder with respect to the property during the period—

(I) beginning on the date on which the National Flood Insurance Program rate map in effect for the area on the date of enactment of this Act took effect; and

(II) ending on the date on which the revised or updated National Flood Insurance Program rate map takes effect; and

(ii) reimburse the policyholder an amount equal to such difference.

(B) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from premiums deposited in the National Flood Insurance Fund pursuant to subsection (d) of such section 1310, of amounts not otherwise obligated, the amount necessary to carry out this paragraph.

(c) TERMINATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), this section shall cease to have effect on the effective date of a National Flood Insurance Program rate map revised and updated under subsection (b)(1).

(2) REIMBURSEMENTS.—Subsection (b)(4) shall cease to have effect on the date on which the Administrator has made all reimbursements required under subsection (b)(4).

SEC. 134. ELIGIBILITY FOR FLOOD INSURANCE FOR PERSONS RESIDING IN COMMUNITIES THAT HAVE MADE ADEQUATE PROGRESS ON THE CONSTRUCTION, RECONSTRUCTION, OR IMPROVEMENT OF A FLOOD PROTECTION SYSTEM.

(a) ELIGIBILITY FOR FLOOD INSURANCE COVERAGE.—

(1) IN GENERAL.—Notwithstanding any other provision of law, a person residing in a community that the Administrator determines has made adequate progress on the reconstruction or improvement of a flood protection system that will afford flood protection for a 100-year floodplain (without regard to the level of Federal funding of or participation in the construction, reconstruction, or improvement), shall be eligible for flood insurance coverage under the National Flood Insurance Program—

(A) if the person resides in a community that is a participant in the National Flood Insurance Program; and

(B) at a risk premium rate that does not exceed the risk premium rate that would be chargeable if the flood protection system had been completed.

(2) ADEQUATE PROGRESS.—

(A) RECONSTRUCTION OR IMPROVEMENT.—For purposes of paragraph (1), the Administrator shall determine that a community has made adequate progress on the reconstruction or improvement of a flood protection system if—

(i) 100 percent of the project cost has been authorized;

(ii) not less than 60 percent of the project cost has been secured or appropriated;

(iii) not less than 50 percent of the flood protection system has been assessed as being without deficiencies; and

(iv) the reconstruction or improvement has a project schedule that does not exceed 5 years, beginning on the date on which the reconstruction or construction of the improvement commences.

(B) CONSIDERATIONS.—In determining whether a flood protection system have been assessed as being without deficiencies, the Administrator shall consider the requirements under section 65.10 of chapter 44, Code of Federal Regulations, or any successor thereto.

(b) TERMINATION OF ELIGIBILITY.—

(1) ADEQUATE CONTINUING PROGRESS.—The Administrator shall issue rules to establish a method of determining whether a community has made adequate continuing progress on the reconstruction or improvement of a flood protection system that includes—

(A) a requirement that the Administrator shall—

(i) consult with the owner of the flood protection system—

(I) 6 months after the date of a determination under subsection (a);

(II) 18 months after the date of a determination under subsection (a); and

(III) 36 months after the date of a determination under subsection (a); and

(ii) after each consultation under clause (i), determine whether the reconstruction or improvement is reasonably likely to be completed in accordance with the project schedule described in subsection (a)(2)(A)(iv); and

(B) a requirement that, if the Administrator makes a determination under subparagraph (A)(ii) that reconstruction or improvement is not reasonably likely to be completed in accordance with the project schedule, the Administrator shall—

(i) not later than 30 days after the date of the determination, notify the owner of the flood protection system of the determination and provide the rationale and evidence for the determination; and

(ii) provide the owner of the flood protection system the opportunity to appeal the determination.

(2) TERMINATION.—The Administrator shall terminate the eligibility for flood insurance coverage under the National Flood Insurance Program of persons residing in a community with respect to which the Administrator made a determination under subsection (a) if—

(A) the Administrator determines that the community has not made adequate continuing progress; or

(B) on the date that is 5 years after the date on which the reconstruction or construction of the improvement commences, the project has not been completed.

(3) WAIVER.—A person whose eligibility would otherwise be terminated under paragraph (2)(B) shall continue to be eligible to purchase flood insurance coverage described in subsection (a) if the Administrator determines—

(A) the community has made adequate continuing progress on the reconstruction or improvement of a flood protection system; and

(B) there is a reasonable expectation that the reconstruction or improvement of the flood protection system will be completed not later than 1 year after the date of the determination under this paragraph.

(4) RISK PREMIUM RATE.—If the Administrator terminates the eligibility of persons residing in a community to purchase flood insurance coverage described in subsection (a), the Administrator shall establish an appropriate risk premium rate for flood insurance coverage under the National Flood Insurance Program for persons residing in the community that purchased flood insurance coverage before the date on which the termination of eligibility takes effect, taking into consideration the then-current state of the flood protection system.

SEC. 135. STUDIES AND REPORTS.

(a) REPORT ON EXPANDING THE NATIONAL FLOOD INSURANCE PROGRAM.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives, on—

(1) the number of flood insurance policy holders currently insuring—

(A) a residential structure up to the maximum available coverage amount, as established in section 61.6 of title 44, Code of Federal Regulations, of—

(i) $250,000 for the structure; and

(ii) $100,000 for the contents of such structure; or

(B) a commercial structure up to the maximum available coverage amount, as established in section 61.6 of title 44, Code of Federal Regulations, of $500,000;

(2) the increased losses the National Flood Insurance Program would have sustained during the 2004 and 2005 hurricane season if the National Flood Insurance Program had insured all policyholders up to the maximum conforming loan limit for fiscal year 2006 of $417,000, as established under section 302(b)(2) of the Federal National Mortgage Association Charter Act (12 U.S.C. 1717(b)(2));

(3) the availability in the private marketplace of flood insurance coverage in amounts that exceed the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations; and

(4) what effect, if any—

(A) raising the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations, would have on the ability of private insurers to continue providing flood insurance coverage; and

(B) reducing the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations, would have on the ability of private insurers to provide sufficient flood insurance coverage to effectively replace the current level of flood insurance coverage being provided under the National Flood Insurance Program.

(b) REPORT OF THE ADMINISTRATOR ON ACTIVITIES UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.—

(1) IN GENERAL.—The Administrator shall, on an annual basis, submit a full report on the operations, activities, budget, receipts, and expenditures of the National Flood Insurance Program for the preceding 12-month period to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives.

(2) TIMING.—Each report required under paragraph (1) shall be submitted to the committees described in paragraph (1) not later than 3 months following the end of each fiscal year.

(3) CONTENTS.—Each report required under paragraph (1) shall include—

(A) the current financial condition and income statement of the National Flood Insurance Fund established under section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), including—

(i) premiums paid into such Fund;

(ii) policy claims against such Fund; and

(iii) expenses in administering such Fund;

(B) the number and face value of all policies issued under the National Flood Insurance Program that are in force;

(C) a description and summary of the losses attributable to repetitive loss structures;

(D) a description and summary of all losses incurred by the National Flood Insurance Program due to—

(i) hurricane related damage; and

(ii) nonhurricane related damage;

(E) the amounts made available by the Administrator for mitigation assistance under section 1366(c)(4) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104c(c)(4) for the purchase of properties substantially damaged by flood for that fiscal year, and the actual number of flood damaged properties purchased and the total cost expended to purchase such properties;

(F) the estimate of the Administrator as to the average historical loss year, and the basis for that estimate;

(G) the estimate of the Administrator as to the maximum amount of claims that the National Flood Insurance Program would have to expend in the event of a catastrophic year;

(H) the average—

(i) amount of insurance carried per flood insurance policy;

(ii) premium per flood insurance policy; and

(iii) loss per flood insurance policy; and

(I) the number of claims involving damages in excess of the maximum amount of flood insurance available under the National Flood Insurance Program and the sum of the amount of all damages in excess of such amount.

(c) GAO STUDY ON PRE-FIRM STRUCTURES.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives, on the—

(1) composition of the remaining pre-FIRM structures that are explicitly receiving discounted premium rates under section 1307 of the National Flood Insurance Act of 1968 (42 U.S.C. 4014), including the historical basis for the receipt of such subsidy and the extent to which pre-FIRM structures are currently owned by the same owners of the property at the time of the original FIRM;

(2) number and fair market value of such structures;

(3) respective income level of the owners of such structures;

(4) number of times each such structure has been sold since 1968, including specific dates, sales price, and any other information the Secretary determines appropriate;

(5) total losses incurred by such structures since the establishment of the National Flood Insurance Program compared to the total losses incurred by all structures that are charged a nondiscounted premium rate;

(6) total cost of foregone premiums since the establishment of the National Flood Insurance Program, as a result of the subsidies provided to such structures;

(7) annual cost as a result of the subsidies provided to such structures;

(8) the premium income collected and the losses incurred by the National Flood Insurance Program as a result of such explicitly subsidized structures compared to the premium income collected and the losses incurred by such Program as a result of structures that are charged a nondiscounted premium rate, on a State-by-State basis; and

(9) the options for eliminating the subsidy to such structures.

(d) GAO REVIEW OF FEMA CONTRACTORS.—The Comptroller General of the United States, in conjunction with the Office of the Inspector General of the Department of Homeland Security, shall—

(1) conduct a review of the 3 largest contractors the Administrator uses in administering the National Flood Insurance Program; and

(2) not later than 18 months after the date of the enactment of this Act, submit a report on the findings of such review to the Administrator, the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Financial Services of the House of Representatives.

SEC. 136. REINSURANCE.

(a) REINSURANCE ASSESSMENT.—

(1) PRIVATE MARKET PRICING ASSESSMENT.—Not later than 12 months after the date of the enactment of this Act, the Administrator shall submit to Congress a report that—

(A) assesses the capacity of the private reinsurance, capital, and financial markets to assist communities, on a voluntary basis, in managing the full range of financial risks associated with flooding by requesting proposals to assume a portion of the insurance risk of the National Flood Insurance Program;

(B) describes any responses to the request for proposals under subparagraph (A);

(C) assesses whether the rates and terms contained in any proposals received by the Administrator are—

(i) reasonable and appropriate; and

(ii) in an amount sufficient to maintain the ability of the National Flood Insurance Program to pay claims;

(D) describes the extent to which carrying out the proposals received by the Administrator would minimize the likelihood that the Administrator would use the borrowing authority under section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016);

(E) describes fluctuations in historical reinsurance rates; and

(F) includes an economic cost-benefit analysis of the impact on the National Flood Insurance Program if the Administrator were to exercise the authority under section 1335(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4055(a)(2)), as added by this section, to secure reinsurance of coverage provided by the National Flood Insurance Program from the private market.

(2) PROTOCOL FOR RELEASE OF DATA.—The Administrator shall develop a protocol, including adequate privacy protections, to provide for the release of data sufficient to conduct the assessment required under paragraph (1).

(b) REINSURANCE.—The National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended—

(1) in section 1331(a)(2) (42 U.S.C. 4051(a)(2)), by inserting ‘‘, including as reinsurance of coverage provided by the flood insurance program’’ before ‘‘, on such terms’’;

(2) in section 1332(c)(2) (42 U.S.C. 4052(c)(2)), by inserting ‘‘or reinsurance’’ after ‘‘flood insurance coverage’’;

(3) in section 1335(a) (42 U.S.C. 4055(a))—

(A) by striking ‘‘The Director’’ and inserting the following:

‘‘(1) IN GENERAL.—The Administrator’’; and

(B) by adding at the end the following:

‘‘(2) PRIVATE REINSURANCE.—The Administrator is authorized to secure reinsurance of coverage provided by the flood insurance program from the private market at rates and on terms determined by the Administrator to be reasonable and appropriate, in an amount sufficient to maintain the ability of the program to pay claims.’’;

(4) in section 1346(a) (12 U.S.C. 4082(a))—

(A) in the matter preceding paragraph (1), by inserting after ‘‘for the purpose of’’ the following: ‘‘securing reinsurance of insurance coverage provided by the program or for the purpose of’’;

(B) in paragraph (1)—

(i) by striking ‘‘estimating’’ and inserting ‘‘Estimating’’; and

(ii) by striking the semicolon at the end and inserting a period;

(C) in paragraph (2)—

(i) by striking ‘‘receiving’’ and inserting ‘‘Receiving’’; and

(ii) by striking the semicolon at the end and inserting a period;

(D) in paragraph (3)—

(i) by striking ‘‘making’’ and inserting ‘‘Making’’; and

(ii) (ii) by striking ‘‘ ‘; and’ ’’ and inserting a period;

(E) by redesignating paragraph (4) as paragraph (5);

(F) in paragraph (5), as so redesignated, by striking ‘‘otherwise’’ and inserting ‘‘Otherwise’’; and

(G) by inserting after paragraph (3) the following new paragraph:

‘‘(4) Placing reinsurance coverage on insurance provided by such program;’’; and

(5) in section 1370(a)(3) (42 U.S.C. 4121(a)(3)), by striking ‘‘include any’’ and all that follows and inserting the following: ‘‘include any organization or person that is authorized to engage in the business of insurance under the laws of any State, subject to the reporting requirements of the Securities Exchange Act of 1934 pursuant to section 13(a) or 15(d) of such Act (15 U.S.C. 78m(a) and 78o(d)), or authorized by the Administrator to assume reinsurance on risks insured by the flood insurance program;’’.

(c) ASSESSMENT OF CLAIMS-PAYING ABILITY.—

(1) ASSESSMENT.—

(A) ASSESSMENT REQUIRED.—

(i) IN GENERAL.—Not later than September 30 of each year, the Administrator shall conduct an assessment of the ability of the National Flood Insurance Program to pay claims.

(ii) PRIVATE MARKET REINSURANCE.—The assessment under this paragraph for any year in which the Administrator exercises the authority under section 1335(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4055(a)(2)), as added by this section, to secure reinsurance of coverage provided by the National Flood Insurance Program from the private market shall include information relating the use of private sector reinsurance and reinsurance equivalents by the Administrator, whether or not the Administrator used the borrowing authority under section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016).

(iii) FIRST ASSESSMENT.—The Administrator shall conduct the first assessment required under this paragraph not later than September 30, 2012.

(B) CONSIDERATIONS.—In conducting an assessment under subparagraph (A), the Administrator shall take into consideration regional concentrations of coverage written by the National Flood Insurance Program, peak flood zones, and relevant mitigation measures.

(2) ANNUAL REPORT OF THE ADMINISTRATOR OF ACTIVITIES UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.—The Administrator shall—

(A) include the results of each assessment in the report required under section 135(b); and

(B) not later than 30 days after the date on which the Administrator completes an assessment required under paragraph (1), make the results of the assessment available to the public.

SEC. 137. GAO STUDY ON BUSINESS INTERRUPTION AND ADDITIONAL LIVING EXPENSES COVERAGES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study concerning—

(1) the availability of additional living expenses and business interruption coverage in the private marketplace for flood insurance;

(2) the feasibility of allowing the National Flood Insurance Program to offer such coverage at the option of the consumer;

(3) the estimated cost to consumers if the National Flood Insurance Program priced such optional coverage at true actuarial rates;

(4) the impact such optional coverage would have on consumer participation in the National Flood Insurance Program; and

(5) the fiscal impact such optional coverage would have upon the National Flood Insurance Fund if such optional coverage were included in the National Flood Insurance Program, as described in paragraph (2), at the price described in paragraph (3).

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report containing the results of the study under subsection (a).

SEC. 138. POLICY DISCLOSURES.

(a) IN GENERAL.—Notwithstanding any other provision of law, in addition to any other disclosures that may be required, each policy under the National Flood Insurance Program shall state all conditions, exclusions, and other limitations pertaining to coverage under the subject policy, regardless of the underlying insurance product, in plain English, in boldface type, and in a font size that is twice the size of the text of the body of the policy.

(b) VIOLATIONS.—Any person that violates the requirements of this section shall be subject to a fine of not more than $50,000 at the discretion of the Administrator.

SEC. 139. REPORT ON INCLUSION OF BUILDING CODES IN FLOODPLAIN MANAGEMENT CRITERIA.

Not later than 6 months after the date of the enactment of this Act, the Administrator of the Federal Emergency Management Agency shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives regarding the impact, effectiveness, and feasibility of amending section 1361 of the National Flood Insurance Act of 1968 (42 U.S.C. 4102) to include widely used and nationally recognized building codes as part of the floodplain management criteria developed under such section, and shall determine—

(1) the regulatory, financial, and economic impacts of such a building code requirement on homeowners, States and local communities, local land use policies, and the Federal Emergency Management Agency;

(2) the resources required of State and local communities to administer and enforce such a building code requirement;

(3) the effectiveness of such a building code requirement in reducing flood-related damage to buildings and contents;

(4) the impact of such a building code requirement on the actuarial soundness of the National Flood Insurance Program;

(5) the effectiveness of nationally recognized codes in allowing innovative materials and systems for flood-resistant construction;

(6) the feasibility and effectiveness of providing an incentive in lower premium rates for flood insurance coverage under such Act for structures meeting whichever of such widely used and nationally recognized building codes or any applicable local building codes provides greater protection from flood damage;

(7) the impact of such a building code requirement on rural communities with different building code challenges than urban communities; and

(8) the impact of a such a building code requirement on Indian reservations.

SEC. 140. STUDY OF PARTICIPATION AND AFFORDABILITY FOR CERTAIN POLICYHOLDERS.

(a) FEMA STUDY.—The Administrator shall conduct a study of—

(1) methods to encourage and maintain participation in the National Flood Insurance Program;

(2) methods to educate consumers about the National Flood Insurance Program and the flood risk associated with their property;

(3) methods for establishing an affordability framework for the National Flood Insurance Program, including methods to aid individuals to afford risk-based premiums under the National Flood Insurance Program through targeted assistance rather than generally subsidized rates, including means-tested vouchers; and

(4) the implications for the National Flood Insurance Program and the Federal budget of using each such method.

(b) NATIONAL ACADEMY OF SCIENCES ECONOMIC ANALYSIS.—To inform the Administrator in the conduct of the study under subsection (a), the National Academy of Sciences, in consultation with the Comptroller General of the United States, shall conduct and submit to the Administrator an economic analysis of the costs and benefits to the Federal Government of a flood insurance program with full risk-based premiums, combined with means-tested Federal assistance to aid individuals who cannot afford coverage, through an insurance voucher program. The analysis shall compare the costs of a program of risk-based rates and means-tested assistance to the current system of subsidized flood insurance rates and federally funded disaster relief for people without coverage.

(c) REPORT.—Not later than 270 days after the date of enactment of this Act, the Administrator shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report that contains the results of the study and analysis under this section.

(d) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from the National Flood Insurance Fund, of amounts not otherwise obligated, not more than $750,000 to carry out this section.

SEC. 141. STUDY AND REPORT CONCERNING THE PARTICIPATION OF INDIAN TRIBES AND MEMBERS OF INDIAN TRIBES IN THE NATIONAL FLOOD INSURANCE PROGRAM.

(a) DEFINITION.—In this section, the term ''Indian tribe'' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

(b) FINDINGS.—Congress finds that participation by Indian tribes in the National Flood Insurance Program is low. Only 45 of 565 Indian tribes participate in the National Flood Insurance Program.

(c) STUDY.—The Comptroller General of the United States, in coordination and consultation with Indian tribes and members of Indian tribes throughout the United States, shall carry out a study that examines—

(1) the factors contributing to the current rates of participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program; and

(2) methods of encouraging participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program.

(d) REPORT.—Not later than 6 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report that—

(1) contains the results of the study carried out under subsection (c);

(2) describes the steps that the Administrator should take to increase awareness and encourage participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program; and

(3) identifies any legislative changes that would encourage participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program.

SEC. 142. TECHNICAL CORRECTIONS.

(a) FLOOD DISASTER PROTECTION ACT OF 1973.—The Flood Disaster Protection Act of 1973 (42 U.S.C. 4002 et seq.) is amended—

(1) by striking ''Director'' each place that term appears, except in section 102(f)(3) (42 U.S.C. 4012a(f)(3)), and inserting ''Administrator''; and

(2) in section 201(b) (42 U.S.C. 4105(b)), by striking ''Director's'' and inserting ''Administrator's''.

(b) NATIONAL FLOOD INSURANCE ACT OF 1968.—The National Flood Insurance Act of 1968 (42 U.S.C. 4001 et seq.) is amended—

(1) by striking ''Director'' each place that term appears and inserting ''Administrator''; and

(2) in sections 1363 (42 U.S.C. 4104), by striking ''Director's'' each place that term appears and inserting ''Administrator's''.

(c) FEDERAL FLOOD INSURANCE ACT OF 1956.—Section 15(e) of the Federal Flood Insurance Act of 1956 (42 U.S.C. 2414(e)) is amended by striking ''Director'' each place that term appears and inserting ''Administrator''.

SEC. 143. PRIVATE FLOOD INSURANCE POLICIES.

(a) DEFINITIONS.—In this section the following definitions shall apply:

(1) GUIDELINES.—The term ''Guidelines'' means the Mandatory Purchase of Flood Insurance Guidelines issued by the Administrator.

(2) STATE ENTITY FOR LENDING REGULATION.—The term ''State entity for lending regulation'' means, with respect to a State, the entity or agency with primary responsibility for the supervision of lending institutions chartered by the State and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration.

(b) AMENDMENTS REQUIRED.—

(1) IN GENERAL.—Not later than 120 days after the date of enactment of this Act, the Administrator shall amend the Guidelines to clarify that a lender or a lending institution chartered by a State and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration may accept a private primary flood insurance policy in lieu of a National Flood Insurance Program flood policy to satisfy the mandatory purchase requirements under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a), if the private primary flood insurance policy—

(A) is available for sale under the laws of the State in which the private primary flood insurance policy is to be written;

(B) meets the minimum requirements for flood insurance coverage under subsections (a) and (b) of such section 102; and

(C) complies with applicable Federal regulations.

(2) STATE LAW CONSIDERATIONS.—Neither the Guidelines nor the amendments to the Guidelines made under paragraph (1) shall be construed to preempt State insurance law, regulation, or guidance.

(c) NOTIFICATION.—

(1) TO FEDERAL AND STATE ENTITIES FOR LENDING REGULATION.—Not later than 30 days after the date on which the Administrator

amends the Guidelines under subsection (b), the Administrator shall notify the Federal entities for lending regulation and the State entities for lending regulation of the amendment, in order to encourage the acceptance of private primary flood insurance in lieu of a National Flood Insurance Program flood policy to satisfy the mandatory purchase requirements under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a).

(2) TO LENDERS.—The Administrator and each Federal entity for lending regulation shall include the notification required under paragraph (1) in any edition of a publication that the Administrator or Federal entity for lending regulation provides to lenders that is published after the date of enactment of this Act.

(d) TRAINING.—Not later than 60 days after the date on which the Administrator makes the notification under subsection (c), the Federal entities for lending regulation shall train each employee having responsibility for compliance audits to implement the amendments to the Guidelines under subsection (b).

SEC. 144. TREATMENT OF SWIMMING POOL ENCLOSURES OUTSIDE OF HURRICANE SEASON.

Notwithstanding any other provision of law, the adequate land use and control measures developed pursuant to section 1361 of the National Flood Insurance Act of 1968 (42 U.S.C. 4102) and applicable to non-residential structures located within coastal areas as identified by the Administrator may permit, at the discretion of the appropriate State and local authority, the use of non-supporting breakaway walls in V Zones and openings in walls in coastal A Zones in the space below the lowest floor used solely for swimming pools after November 30 and before June 1 of any year. Permitting this use does not alter the terms and conditions of eligibility and insurability of coverage for a building as set out in the Standard Flood Insurance Policy of the Federal Emergency Management Agency.

TITLE II—COMMISSION ON NATURAL CATASTROPHE RISK MANAGEMENT AND INSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Commission on Natural Catastrophe Risk Management and Insurance Act of 2012''.

SEC. 202. FINDINGS.

Congress finds that—

(1) Hurricanes Katrina, Rita, and Wilma, which struck the United States in 2005, caused, by some estimates, in excess of $200,000,000,000 in total economic losses;

(2) many meteorologists predict that the United States is in a period of increased hurricane activity;

(3) the Federal Government and State governments have provided billions of dollars to pay for losses from natural catastrophes, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(4) many Americans are finding it increasingly difficult to obtain and afford property and casualty insurance coverage;

(5) some insurers are not renewing insurance policies, are excluding certain risks, such as wind damage, and are increasing rates and deductibles in some markets;

(6) the inability of property and business owners in vulnerable areas to obtain and afford property and casualty insurance coverage endangers the national economy and public health and safety;

(7) almost every State in the United States is at risk of a natural catastrophe, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(8) building codes and land use regulations play an indispensable role in managing catastrophe risks, by preventing building in high risk areas and ensuring that appropriate mitigation efforts are completed where building has taken place;

(9) several proposals have been introduced in Congress to address the affordability and availability of natural catastrophe insurance across the United States, but there is no consensus on what, if any, role the Federal Government should play; and

(10) an efficient and effective approach to assessing natural catastrophe risk management and insurance is to establish a nonpartisan commission to study the management of natural catastrophe risk, and to require such commission to timely report to Congress on its findings.

SEC. 203. ESTABLISHMENT.

There is established a nonpartisan Commission on Natural Catastrophe Risk Management and Insurance (in this title referred to as the ''Commission'').

SEC. 204. MEMBERSHIP.

(a) APPOINTMENT.—The Commission shall be composed of 16 members, of whom—

(1) 2 members shall be appointed by the majority leader of the Senate;

(2) 2 members shall be appointed by the minority leader of the Senate;

(3) 2 members shall be appointed by the Speaker of the House of Representatives;

(4) 2 members shall be appointed by the minority leader of the House of Representatives;

(5) 2 members shall be appointed by the Chairman of the Committee on Banking, Housing, and Urban Affairs of the Senate;

(6) 2 members shall be appointed by the Ranking Member of the Committee on Banking, Housing, and Urban Affairs of the Senate;

(7) 2 members shall be appointed by the Chairman of the Committee on Financial Services of the House of Representatives; and

(8) 2 members shall be appointed by the Ranking Member of the Committee on Financial Services of the House of Representatives.

(b) QUALIFICATION OF MEMBERS.—

(1) IN GENERAL.—Members of the Commission shall be appointed under subsection (a) from among persons who—

(A) have expertise in insurance, reinsurance, insurance regulation, policyholder concerns, emergency management, risk management, public finance, financial markets, actuarial analysis, flood mapping and planning, structural engineering, building standards, land use planning, natural catastrophes, meteorology, seismology, environmental issues, or other pertinent qualifications or experience; and

(B) are not officers or employees of the United States Government or of any State or local government.

(2) DIVERSITY.—In making appointments to the Commission—

(A) every effort shall be made to ensure that the members are representative of a broad cross section of perspectives within the United States; and

(B) each member of Congress described in subsection (a) shall appoint not more than 1 person from any single primary area of expertise described in paragraph (1)(A) of this subsection.

(c) PERIOD OF APPOINTMENT.—

(1) IN GENERAL.—Each member of the Commission shall be appointed for the duration of the Commission.

(2) VACANCIES.—A vacancy on the Commission shall not affect its powers, but shall be filled in the same manner as the original appointment.

(d) QUORUM.—

(1) MAJORITY.—A majority of the members of the Commission shall constitute a quorum, but a lesser number, as determined by the Commission, may hold hearings.

(2) APPROVAL ACTIONS.—All recommendations and reports of the Commission required by this title shall be approved only by a majority vote of all of the members of the Commission.

(e) CHAIRPERSON.—The Commission shall, by majority vote of all of the members, select 1 member to serve as the Chairperson of the Commission (in this title referred to as the ''Chairperson'').

(f) MEETINGS.—The Commission shall meet at the call of its Chairperson or a majority of the members.

SEC. 205. DUTIES OF THE COMMISSION.

The Commission shall examine the risks posed to the United States by natural catastrophes, and means for mitigating those risks and for paying for losses caused by natural catastrophes, including assessing—

(1) the condition of the property and casualty insurance and reinsurance markets prior to and in the aftermath of Hurricanes Katrina, Rita, and Wilma in 2005, and the 4 major hurricanes that struck the United States in 2004;

(2) the current condition of, as well as the outlook for, the availability and affordability of insurance in all regions of the country;

(3) the current ability of States, communities, and individuals to mitigate their natural catastrophe risks, including the affordability and feasibility of such activities;

(4) the ongoing exposure of the United States to natural catastrophes, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(5) the catastrophic insurance and reinsurance markets and the relevant practices in providing insurance protection to different sectors of the American population;

(6) implementation of a catastrophic insurance system that can resolve key obstacles currently impeding broader implementation of catastrophic risk management and financing with insurance;

(7) the financial feasibility and sustainability of a national, regional, or other pooling mechanism designed to provide adequate insurance coverage and increased underwriting capacity to insurers and reinsurers, including private-public partnerships to increase insurance capacity in constrained markets;

(8) methods to promote public or private insurance policies to reduce losses caused by natural catastrophes in the uninsured sectors of the American population;

(9) approaches for implementing a public or private insurance scheme for low-income communities, in order to promote risk reduction and insurance coverage in such communities;

(10) the impact of Federal and State laws, regulations, and policies (including rate regulation, market access requirements, reinsurance regulations, accounting and tax policies, State residual markets, and State catastrophe funds) on—

(A) the affordability and availability of catastrophe insurance;

(B) the capacity of the private insurance market to cover losses inflicted by natural catastrophes;

(C) the commercial and residential development of high-risk areas; and

(D) the costs of natural catastrophes to Federal and State taxpayers;

(11) the present and long-term financial condition of State residual markets and catastrophe funds in high-risk regions, including the likelihood of insolvency following a natural catastrophe, the concentration of risks within such funds, the reliance on post-event assessments and State funding, and the adequacy of rates;

(12) the role that innovation in financial services could play in improving the affordability and availability of natural catastrophe insurance, specifically addressing measures that would foster the development of financial products designed to cover natural catastrophe risk, such as risk-linked securities;

(13) the need for strengthened land use regulations and building codes in States at high risk for natural catastrophes, and methods to strengthen the risk assessment and enforcement of structural mitigation and vulnerability reduction measures, such as zoning and building code compliance;

(14) the benefits and costs of proposed Federal natural catastrophe insurance programs (including the Federal Government's provision of reinsurance to State catastrophe funds, private insurers, or other entities), specifically addressing the costs to taxpayers, tax equity considerations, and the record of other government insurance programs (particularly with regard to charging actuarially sound prices);

(15) the ability of the United States private insurance market—

(A) to cover insured losses caused by natural catastrophes, including an estimate of the maximum amount of insured losses that could be sustained during a single year and the probability of natural catastrophes occurring in a single year that would inflict more insured losses than the United States insurance and reinsurance markets could sustain; and

(B) to recover after covering substantial insured losses caused by natural catastrophes;

(16) the impact that demographic trends could have on the amount of insured losses inflicted by future natural catastrophes;

(17) the appropriate role, if any, for the Federal Government in stabilizing the property and casualty insurance and reinsurance markets; and

(18) the role of the Federal, State, and local governments in providing incentives for feasible risk mitigation efforts.

SEC. 206. REPORT.

(a) IN GENERAL.—Not later than 9 months after the date of the enactment of this Act, the Commission shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a final report containing—

(1) a detailed statement of the findings and assessments conducted by the Commission pursuant to section 205; and

(2) any recommendations for legislative, regulatory, administrative, or other actions at the Federal, State, or local levels that the Commission considers appropriate, in accordance with the requirements of section 205.

(b) EXTENSION OF TIME.—The Commission may request Congress to extend the period of time for the submission of the report required under subsection (a) for an additional 3 months.

SEC. 207. POWERS OF THE COMMISSION.

(a) MEETINGS; HEARINGS.—The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers necessary to carry out the purposes of this title. Members may attend meetings of the Commission and vote in person, via telephone conference, or via video conference.

(b) AUTHORITY OF MEMBERS OR AGENTS OF THE COMMISSION.—Any member or agent of the Commission may, if authorized by a vote of the Commission, take any action which the Commission is authorized to take by this title.

(c) OBTAINING OFFICIAL DATA.—

(1) AUTHORITY.—Notwithstanding any provision of section 552a of title 5, United States Code, the Commission may secure directly from any department or agency of the United States any information necessary to enable the Commission to carry out this title.

(2) PROCEDURE.—Upon the request of the Chairperson, the head of such department or agency shall furnish to the Commission the information requested.

(d) POSTAL SERVICES.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(e) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, any administrative support services necessary for the Commission to carry out its responsibilities under this title.

(f) ACCEPTANCE OF GIFTS.—The Commission may accept, hold, administer, and utilize gifts, donations, and bequests of property, both real and personal, for the purposes of aiding or facilitating the work of the Commission. The Commission shall issue internal guidelines governing the receipt of donations of services or property.

(g) VOLUNTEER SERVICES.—Notwithstanding the provisions of section 1342 of title 31, United States Code, the Commission may accept and utilize the services of volunteers serving without compensation. The Commission may reimburse such volunteers for local travel and office supplies, and for other travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code.

(h) FEDERAL PROPERTY AND ADMINISTRATIVE SERVICES ACT OF 1949.—Subject to the Federal Property and Administrative Services Act of 1949, the Commission may enter into contracts with Federal and State agencies, private firms, institutions, and individuals for the conduct of activities necessary to the discharge of its duties and responsibilities.

(i) LIMITATION ON CONTRACTS.—A contract or other legal agreement entered into by the Commission may not extend beyond the date of the termination of the Commission.

SEC. 208. COMMISSION PERSONNEL MATTERS.

(a) TRAVEL EXPENSES.—The members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Commission.

(b) SUBCOMMITTEES.—The Commission may establish subcommittees and appoint members of the Commission to such subcommittees as the Commission considers appropriate.

(c) STAFF.—Subject to such policies as the Commission may prescribe, the Chairperson may appoint and fix the pay of such additional personnel as the Chairperson considers appropriate to carry out the duties of the Commission. The Commission shall confirm the appointment of the executive director by majority vote of all of the members of the Commission.

(d) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—Staff of the Commission may be—

(1) appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service; and

(2) paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates, except that an individual so appointed may not receive pay in excess of the annual rate of basic pay prescribed for GS–15 of the General Schedule under section 5332 of that title.

(e) EXPERTS AND CONSULTANTS.—In carrying out its objectives, the Commission may procure temporary and intermittent services of consultants and experts under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for GS–15 of the General Schedule under section 5332 of that title.

(f) DETAIL OF GOVERNMENT EMPLOYEES.—Upon request of the Chairperson, any Federal Government employee may be detailed to the Commission to assist in carrying out the duties of the Commission—

(1) on a reimbursable basis; and

(2) such detail shall be without interruption or loss of civil service status or privilege.

SEC. 209. TERMINATION.

The Commission shall terminate 90 days after the date on which the Commission submits its report under section 206.

SEC. 210. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Commission, such sums as may be necessary to carry out this title, to remain available until expended.

TITLE III—ALTERNATIVE LOSS ALLOCATION

SEC. 301. SHORT TITLE.

This title may be cited as the ''Consumer Option for an Alternative System to Allocate Losses Act of 2012'' or the ''COASTAL Act of 2012''.

SEC. 302. ASSESSING AND MODELING NAMED STORMS OVER COASTAL STATES.

Subtitle C of title XII of the Omnibus Public Land Management Act of 2009 (33 U.S.C. 3601 et seq.) (also known as the ''Integrated Coastal and Ocean Observation System Act of 2009'') is amended by adding at the end the following:

''SEC. 12312. ASSESSING AND MODELING NAMED STORMS OVER COASTAL STATES.

''(a) DEFINITIONS.—In this section:

''(1) COASTAL FORMULA.—The term 'COASTAL Formula' has the meaning given the term in section 1337(a) of the National Flood Insurance Act of 1968.

''(2) COASTAL STATE.—The term 'coastal State' has the meaning given the term 'coastal state' in section 304 of the Coastal Zone Management Act of 1972 (16 U.S.C. 1453).

''(3) COASTAL WATERS.—The term 'coastal waters' has the meaning given the term in such section.

''(4) COVERED DATA.—The term 'covered data' means, with respect to a named storm identified by the Administrator under subsection (b)(2)(A), empirical data that are—

''(A) collected before, during, or after such storm; and

''(B) necessary to determine magnitude and timing of wind speeds, rainfall, the barometric pressure, river flows, the extent, height, and timing of storm surge, topographic and bathymetric data, and other measures required to accurately model and assess damage from such storm.

''(5) INDETERMINATE LOSS.—The term 'indeterminate loss' has the meaning given the

term in section 1337(a) of the National Flood Insurance Act of 1968.

''(6) NAMED STORM.—The term 'named storm' means any organized weather system with a defined surface circulation and maximum winds of at least 39 miles per hour which the National Hurricane Center of the United States National Weather Service names as a tropical storm or a hurricane.

''(7) NAMED STORM EVENT MODEL.—The term 'Named Storm Event Model' means the official meteorological and oceanographic computerized model, developed by the Administrator under subsection (b)(1)(A), which utilizes covered data to replicate the magnitude, timing, and spatial variations of winds, rainfall, and storm surges associated with named storms that threaten any portion of a coastal State.

''(8) PARTICIPANT.—The term 'participant' means a Federal, State, or private entity that chooses to cooperate with the Administrator in carrying out the provisions of this section by collecting, contributing, and maintaining covered data.

''(9) POST-STORM ASSESSMENT.—The term 'post-storm assessment' means a scientific assessment produced and certified by the Administrator to determine the magnitude, timing, and spatial variations of winds, rainfall, and storm surges associated with a specific named storm to be used in the COASTAL Formula.

''(10) STATE.—The term 'State' means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

''(b) NAMED STORM EVENT MODEL AND POST-STORM ASSESSMENT.—

''(1) ESTABLISHMENT OF NAMED STORM EVENT MODEL.—

''(A) IN GENERAL.—Not later than 540 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall develop by regulation the Named Storm Event Model.

''(B) ACCURACY.—The Named Storm Event Model shall be designed to generate post-storm assessments, as provided in paragraph (2), that have a degree of accuracy of not less than 90 percent for every indeterminate loss for which a post-storm assessment is utilized.

''(2) POST-STORM ASSESSMENT.—

''(A) IDENTIFICATION OF NAMED STORMS THREATENING COASTAL STATES.—After the establishment of the COASTAL Formula, the Administrator shall, in consultation with the Secretary of Homeland Security, identify named storms that may reasonably constitute a threat to any portion of a coastal State.

''(B) POST-STORM ASSESSMENT REQUIRED.—Upon identification of a named storm under subparagraph (A), the Administrator shall develop a post-storm assessment for such named storm using the Named Storm Event Model and covered data collected for such named storm pursuant to the protocol established under subsection (c)(1).

''(C) SUBMITTAL OF POST-STORM ASSESSMENT.—Not later than 90 days after an identification of a named storm is made under subparagraph (A), the Administrator shall submit to the Secretary of Homeland Security the post-storm assessment developed for such storm under subparagraph (B).

''(3) ACCURACY.—The Administrator shall ensure, to the greatest extent practicable, that each post-storm assessment developed under paragraph (2) has a degree of accuracy of not less than 90 percent.

''(4) CERTIFICATION.—For each post-storm assessment carried out under paragraph (2), the Administrator shall—

''(A) certify the degree of accuracy for such assessment, including specific reference to any segments or geographic areas for which the assessment is less than 90 percent accurate; and

''(B) report such certification to the Secretary of Homeland Security for the purposes of use with indeterminate loss claims under section 1337 of the National Flood Insurance Act of 1968.

''(5) FINALITY OF DETERMINATIONS.—A certification of the degree of accuracy of a post-storm assessment under this subsection by the Administrator shall be final and shall not be subject to judicial review.

''(6) AVAILABILITY.—The Administrator shall make available to the public the Named Storm Event Model and any post-storm assessment developed under this subsection.

''(c) ESTABLISHMENT OF A PROTOCOL FOR POST-STORM ASSESSMENT.—

''(1) IN GENERAL.—Not later than 540 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall establish a protocol, based on the plan submitted under subsection (d)(3), to collect and assemble all covered data required by the Administrator to produce post-storm assessments required by subsection (b), including assembling data collected by participants and stored in the database established under subsection (f) and from such other sources as the Administrator considers appropriate.

''(2) ACQUISITION OF SENSORS AND STRUCTURES.—If the Administrator is unable to use a public or private asset to obtain covered data as part of the protocol established under paragraph (1), the Administrator may acquire such sensors and structures for the placement of sensors as may be necessary to obtain such data.

''(3) USE OF FEDERAL ASSETS.—If the protocol requires placement of a sensor to develop assessments pursuant to subsection (b), the Administrator shall, to the extent practicable, use Federal assets for the placement of such sensors.

''(4) USE OF ACQUIRED STRUCTURES.—

''(A) IN GENERAL.—If the Administrator acquires a structure for the placement of a sensor for purposes of such protocol, the Administrator shall to the extent practical permit other public and private entities to place sensors on such structure to collect—

''(i) meteorological data;

''(ii) national security-related data;

''(iii) navigation-related data;

''(iv) hydrographic data; or

''(v) such other data as the Administrator considers appropriate.

''(B) RECEIPT OF CONSIDERATION.—The Administrator may receive consideration for the placement of a sensor on a structure under subparagraph (A).

''(C) IN-KIND CONSIDERATION.—Consideration received under subparagraph (B) may be received in-kind.

''(D) USE OF CONSIDERATION.—To the extent practicable, consideration received under subparagraph (B) shall be used for the maintenance of sensors used to collect covered data.

''(5) COORDINATED DEPLOYMENTS AND DATA COLLECTION PRACTICES.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, coordinate the deployment of sensors as part of the protocol established under paragraph (1) and related data collection carried out by Federal, State, academic, and private entities who choose to cooperate with the Administrator in carrying out this subsection.

''(6) PRIORITY ACQUISITION AND DEPLOYMENT.—The Administrator shall give priority in the acquisition for and deployment of sensors under the protocol required by paragraph (1) to areas of coastal States that have the highest risk of being harmed by named storms.

''(d) ASSESSMENT OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—

''(1) IDENTIFICATION OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—Not later than 180 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology—

''(A) carry out a survey to identify all Federal and State efforts and systems that are capable of collecting covered data; and

''(B) consult with private and academic sector entities to identify domestic private and academic systems that are capable of collecting covered data.

''(2) IDENTIFICATION OF GAPS.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology and individuals and entities consulted under subsection (e)(3), assess the systems identified under paragraph (1) and identify which systems meet the needs of the National Oceanic and Atmospheric Administration for the collection of covered data, including with respect to the accuracy requirement for post-storm assessment under subsection (b)(3).

''(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, submit to Congress a plan for the collection of covered data necessary to develop the Named Storm Event Model and post-storm assessment required by subsection (b) that addresses any gaps identified in paragraph (2).

''(e) COORDINATION OF COVERED DATA COLLECTION AND MAINTENANCE BY PARTICIPANTS.—

''(1) IN GENERAL.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, coordinate the collection and maintenance of covered data by participants under this section—

''(A) to streamline the process of collecting covered data in accordance with the protocol established under subsection (c)(1); and

''(B) to maintain transparency of such process and the database established under subsection (f).

''(2) SHARING INFORMATION.—The Administrator shall establish a process for sharing among participants information relevant to collecting and using covered data for—

''(A) academic research;

''(B) private sector use;

''(C) public outreach; and

''(D) such other purposes as the Administrator considers appropriate.

''(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Administrator shall consult with the following:

''(A) The Commanding General of the United States Army Corps of Engineers.

''(B) The Administrator of the Federal Emergency Management Agency.

''(C) The Commandant of the Coast Guard.

''(D) The Director of the United States Geological Survey.

''(E) The Office of the Federal Coordinator for Meteorology.

''(F) The Director of the National Science Foundation.

''(G) The Administrator of the National Aeronautics and Space Administration.

''(H) Such public, private, and academic sector entities as the Administrator considers appropriate for purposes of carrying out the provisions of this section.

''(f) ESTABLISHMENT OF COASTAL WIND AND WATER EVENT DATABASE.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall establish a database for the collection and compilation of covered data—

''(A) to support the protocol established under subsection (c)(1); and

''(B) for the purposes listed in subsection (e)(2).

''(2) DESIGNATION.—The database established under paragraph (1) shall be known as the 'Coastal Wind and Water Event Database'.

''(g) COMPTROLLER GENERAL STUDY.—Not later than 1 year after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Comptroller General of the United States shall—

''(1) complete an audit of Federal efforts to collect covered data for purposes of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, which audit shall—

''(A) examine duplicated Federal efforts to collect covered data; and

''(B) determine the cost effectiveness of such efforts; and

''(2) submit to the Committee on Banking, Housing, and Urban Affairs and the Commerce, Science, and Transportation of the Senate and the Committee on Financial Services and the Committee on Science, Space, and Technology of the House of Representatives a report on the findings of the Comptroller General with respect to the audit completed under paragraph (1).''.

SEC. 303. ALTERNATIVE LOSS ALLOCATION SYSTEM FOR INDETERMINATE CLAIMS.

Part A of chapter II of the National Flood Insurance Act of 1968 (42 U.S.C. 4051 et seq.) is amended by adding at the end the following:

''SEC. 1337. ALTERNATIVE LOSS ALLOCATION SYSTEM FOR INDETERMINATE CLAIMS.

''(a) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Federal Emergency Management Agency.

''(2) COASTAL FORMULA.—The term 'COASTAL Formula' means the formula established under subsection (b).

''(3) COASTAL STATE.—The term 'coastal State' has the meaning given the term 'coastal state' in section 304 of the Coastal Zone Management Act of 1972 (16 U.S.C. 1453).

''(4) INDETERMINATE LOSS.—

''(A) IN GENERAL.—The term 'indeterminate loss' means, as determined by an insurance claims adjuster certified under the national flood insurance program and in consultation with an engineer as appropriate, a loss resulting from physical damage to, or loss of, property located in any coastal State arising from the combined perils of flood and wind associated with a named storm.

''(B) REQUIREMENTS.—An insurance claims adjuster certified under the national flood insurance program shall only determine that a loss is an indeterminate loss if the claims adjuster determines that—

''(i) no material remnant of physical buildings or man-made structures remain except building foundations for the specific property for which the claim is made; and

''(ii) there is insufficient or no tangible evidence created, yielded, or otherwise left behind of the specific property for which the claim is made as a result of the named storm.

''(5) NAMED STORM.—The term 'named storm' means any organized weather system with a defined surface circulation and maximum winds of not less than 39 miles per hour which the National Hurricane Center of the United States National Weather Service names as a tropical storm or a hurricane.

''(6) POST-STORM ASSESSMENT.—The term 'post-storm assessment' means the post-storm assessment developed under section 12312(b) of the Omnibus Public Land Management Act of 2009.

''(7) STATE.—The term 'State' means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

''(8) SECRETARY.—The term 'Secretary' means the Secretary of Homeland Security.

''(9) STANDARD INSURANCE POLICY.—The term 'standard insurance policy' means any insurance policy issued under the national flood insurance program that covers loss or damage to property resulting from water peril.

''(10) PROPERTY.—The term 'property' means real or personal property that is insured under a standard insurance policy for loss or damage to structure or contents.

''(11) UNDER SECRETARY.—The term 'Under Secretary' means the Under Secretary of Commerce for Oceans and Atmosphere, in the Under Secretary's capacity as Administrator of the National Oceanic and Atmospheric Administration.

''(b) ESTABLISHMENT OF FLOOD LOSS ALLOCATION FORMULA FOR INDETERMINATE CLAIMS.—

''(1) IN GENERAL.—Not later than 180 days after the date on which the protocol is established under section 12312(c)(1) of the Omnibus Public Land Management Act of 2009, the Secretary, acting through the Administrator and in consultation with the Under Secretary, shall establish by rule a standard formula to determine and allocate wind losses and flood losses for claims involving indeterminate losses.

''(2) CONTENTS.—The standard formula established under paragraph (1) shall—

''(A) incorporate data available from the Coastal Wind and Water Event Database established under section 12312(f) of the Omnibus Public Land Management Act of 2009;

''(B) use relevant data provided on the National Flood Insurance Program Elevation Certificate for each indeterminate loss for which the formula is used;

''(C) consider any sufficient and credible evidence, approved by the Administrator, of the pre-event condition of a specific property, including the findings of any policyholder or insurance claims adjuster in connection with the indeterminate loss to that specific property;

''(D) include other measures, as the Administrator considers appropriate, required to determine and allocate by mathematical formula the property damage caused by flood or storm surge associated with a named storm; and

''(E) subject to paragraph (3), for each indeterminate loss, use the post-storm assessment to allocate water damage (flood or storm surge) associated with a named storm.

''(3) DEGREE OF ACCURACY REQUIRED.—The standard formula established under paragraph (1) shall specify that the Administrator may only use the post-storm assessment for purposes of the formula if the Under Secretary certifies that the post-storm assessment has a degree of accuracy of not less than 90 percent in connection with the specific indeterminate loss for which the assessment and formula are used.

''(c) AUTHORIZED USE OF POST-STORM ASSESSMENT AND COASTAL FORMULA.—

''(1) IN GENERAL.—Subject to paragraph (3), the Administrator may use the post-storm assessment and the COASTAL Formula to—

''(A) review flood loss payments for indeterminate losses, including as part of the quality assurance reinspection program of the Federal Emergency Management Agency for claims under the national flood insurance program and any other process approved by the Administrator to review and validate payments under the national flood insurance program for indeterminate losses following a named storm; and

''(B) assist the national flood insurance program to—

''(i) properly cover qualified flood loss for claims for indeterminate losses; and

''(ii) avoid paying for any loss or damage to property caused by any peril (including wind), other than flood or storm surge, that is not covered under a standard policy under the national flood insurance program.

''(2) FEDERAL DISASTER DECLARATION.—Subject to paragraph (3), in order to expedite claims and reduce costs to the national flood insurance program, following any major disaster declared by the President under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) relating to a named storm in a coastal State, the Administrator may use the COASTAL Formula to determine and pay for any flood loss covered under a standard insurance policy under the national flood insurance program, if the loss is an indeterminate loss.

''(3) NATIONAL ACADEMY OF SCIENCES EVALUATION.—

''(A) EVALUATION REQUIRED.—

''(i) EVALUATION.—Upon the issuance of the rule establishing the COASTAL Formula, and each time the Administrator modifies the COASTAL Formula, the National Academy of Sciences shall—

''(I) evaluate the expected financial impact on the national flood insurance program of the use of the COASTAL Formula as so established or modified; and

''(II) evaluate the validity of the scientific assumptions upon which the formula is based and determine whether the COASTAL formula can achieve a degree of accuracy of not less than 90 percent in allocating flood losses for indeterminate losses.

''(ii) REPORT.—The National Academy of Sciences shall submit a report containing the results of each evaluation under clause (i) to the Administrator, the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Financial Services of the House of Representatives.

''(B) EFFECTIVE DATE AND APPLICABILITY.—

''(i) EFFECTIVE DATE.—Paragraphs (1) and (2) of this subsection shall not take effect unless the report under subparagraph (A) relating to the establishment of the COASTAL Formula concludes that the use of the COASTAL Formula for purposes of paragraph (1) and (2) would not have an adverse financial impact on the national flood insurance program and that the COASTAL Formula is based on valid scientific assumptions that would allow a degree of accuracy of not less than 90 percent to be achieved in allocating flood losses for indeterminate losses.

''(ii) EFFECT OF MODIFICATIONS.—Unless the report under subparagraph (A) relating to a modification of the COASTAL Formula concludes that the use of the COASTAL Formula, as so modified, for purposes of paragraphs (1) and (2) would not have an adverse financial impact on the national flood insurance program and that the COASTAL Formula is based on valid scientific assumptions that would allow a degree of accuracy of not less than 90 percent to be achieved in allocating flood losses for indeterminate losses the Administrator may not use the COASTAL Formula, as so modified, for purposes of paragraphs (1) and (2).

''(C) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from the National

Flood Insurance Fund, of amounts not otherwise obligated, not more than $750,000 to carry out this paragraph.

''(d) DISCLOSURE OF COASTAL FORMULA.—Not later than 30 days after the date on which a post-storm assessment is submitted to the Secretary under section 12312(b)(2)(C) of the Omnibus Public Land Management Act of 2009, for each indeterminate loss for which the COASTAL Formula is used pursuant to subsection (c)(2), the Administrator shall disclose to the policyholder that makes a claim relating to the indeterminate loss—

''(1) that the Administrator used the COASTAL Formula with respect to the indeterminate loss; and

''(2) a summary of the results of the use of the COASTAL Formula.

''(e) CONSULTATION.—In carrying out subsections (b) and (c), the Secretary shall consult with—

''(1) the Under Secretary for Oceans and Atmosphere;

''(2) the Director of the National Institute of Standards and Technology;

''(3) the Chief of Engineers of the United States Army Corps of Engineers;

''(4) the Director of the United States Geological Survey;

''(5) the Office of the Federal Coordinator for Meteorology;

''(6) State insurance regulators of coastal States; and

''(7) such public, private, and academic sector entities as the Secretary considers appropriate for purposes of carrying out such subsections.

''(f) RECORDKEEPING.—Each consideration and measure the Administrator determines necessary to carry out subsection (b) may be required, with advanced approval of the Administrator, to be provided for on the National Flood Insurance Program Elevation Certificate, or maintained otherwise on record if approved by the Administrator, for any property that qualifies for the COASTAL Formula under subsection (c).

''(g) CIVIL PENALTY.—

''(1) IN GENERAL.—If an insurance claims adjuster knowingly and willfully makes a false or inaccurate determination relating to an indeterminate loss, the Administrator may, after notice and opportunity for hearing, impose on the insurance claims adjuster a civil penalty of not more than $1,000.

''(2) DEPOSIT.—Notwithstanding section 3302 of title 31, United States Code, or any other law relating to the crediting of money, the Administrator shall deposit in the National Flood Insurance Fund any amounts received under this subsection, which shall remain available until expended and be available to the Administrator for purposes authorized for the National Flood Insurance Fund without further appropriation.

''(h) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the Administrator to make any payment under the national flood insurance program, or an insurance company to make any payment, for an indeterminate loss based upon post-storm assessment or the COASTAL Formula.

''(i) APPLICABILITY.—Subsection (c) shall apply with respect to an indeterminate loss associated with a named storm that occurs after the date on which the Administrator issues the rule establishing the COASTAL Formula under subsection (b).

''(j) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to negate, set aside, or void any policy limit, including any loss limitation, set forth in a standard insurance policy.''.

SA 2139. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

Subtitle D—Theft of Medical Products

SEC. 1141. SHORT TITLE.

This subtitle may be cited as the ''Safe Doses Act''.

SEC. 1142. THEFT OF MEDICAL PRODUCTS.

(a) PROHIBITED CONDUCT AND PENALTIES.—Chapter 31 of title 18, United States Code, is amended by adding at the end the following:

''§ 670. Theft of medical products

''(a) PROHIBITED CONDUCT.—Whoever, in, or using any means or facility of, interstate or foreign commerce—

''(1) embezzles, steals, or by fraud or deception obtains, or knowingly and unlawfully takes, carries away, or conceals, a pre-retail medical product;

''(2) knowingly and falsely makes, alters, forges, or counterfeits the labeling or documentation (including documentation relating to origination or shipping) of a pre-retail medical product;

''(3) knowingly possesses, transports, or traffics in a pre-retail medical product that was involved in a violation of paragraph (1) or (2);

''(4) with intent to defraud, buys, or otherwise obtains, a pre-retail medical product that has expired or been stolen;

''(5) with intent to defraud, sells, or distributes, a pre-retail medical product that is expired or stolen; or

''(6) attempts or conspires to violate any of paragraphs (1) through (5);

shall be punished as provided in subsection (c) and subject to the other sanctions provided in this section.

''(b) AGGRAVATED OFFENSES.—An offense under this section is an aggravated offense if—

''(1) the defendant is employed by, or is an agent of, an organization in the supply chain for the pre-retail medical product; or

''(2) the violation—

''(A) involves the use of violence, force, or a threat of violence or force;

''(B) involves the use of a deadly weapon;

''(C) results in serious bodily injury or death, including serious bodily injury or death resulting from the use of the medical product involved; or

''(D) is subsequent to a prior conviction for an offense under this section.

''(c) CRIMINAL PENALTIES.—Whoever violates subsection (a)—

''(1) if the offense is an aggravated offense under subsection (b)((2)(C), shall be fined under this title or imprisoned not more than 30 years, or both;

''(2) if the value of the medical products involved in the offense is $5,000 or greater, shall be fined under this title, imprisoned for not more than 15 years, or both, but if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 20 years; and

''(3) in any other case, shall be fined under this title, imprisoned for not more than 3 years, or both, but if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 5 years.

''(d) CIVIL PENALTIES.—Whoever violates subsection (a) is subject to a civil penalty in an amount not more than the greater of—

''(1) three times the economic loss attributable to the violation; or

''(2) $1,000,000.

''(e) DEFINITIONS.—In this section—

''(1) the term 'pre-retail medical product' means a medical product that has not yet been made available for retail purchase by a consumer;

''(2) the term 'medical product' means a drug, biological product, device, medical food, or infant formula;

''(3) the terms 'device', 'drug', 'infant formula', and 'labeling' have, respectively, the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act;

''(4) the term 'biological product' has the meaning given the term in section 351 of the Public Health Service Act;

''(5) the term 'medical food' has the meaning given the term in section 5(b) of the Orphan Drug Act; and

''(6) the term 'supply chain' includes manufacturer, wholesaler, repacker, own-labeled distributor, private-label distributor, jobber, broker, drug trader, transportation company, hospital, pharmacy, or security company.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 31 of title 18, United States Code, is amended by adding after the item relating to section 669 the following:

''670. Theft of medical products.''.

SEC. 1143. CIVIL FORFEITURE.

Section 981(a)(1)(C) of title 18, United States Code, is amended by inserting ''670,'' after ''657,''.

SEC. 1144. PENALTIES FOR THEFT-RELATED OFFENSES.

(a) INTERSTATE OR FOREIGN SHIPMENTS BY CARRIER.—Section 659 of title 18, United States Code, is amended by adding at the end of the fifth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670), it shall be punished under section 670 unless the penalties provided for under this section are greater.''.

(b) RACKETEERING.—

(1) TRAVEL ACT VIOLATIONS.—Section 1952 of title 18, United States Code, is amended by adding that the end the following:

''(d) If the offense under this section involves an act described in paragraph (1) or (3) of subsection (a) and also involves a pre-retail medical product (as defined in section 670), the punishment for the offense shall be the same as the punishment for an offense under section 670, unless the punishment under subsection (a) is greater.''.

(2) MONEY LAUNDERING.—Section 1957(b)(1) of title 18, United States Code, is amended by adding at the end the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this subsection is greater.''

(c) BREAKING OR ENTERING CARRIER FACILITIES.—Section 2117 of title 18, United States Code, is amended by adding at the end of the first undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

(d) STOLEN PROPERTY.—

(1) TRANSPORTATION OF STOLEN GOODS AND RELATED OFFENSES.—Section 2314 of title 18, United States Code, is amended by adding at the end of the sixth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

(2) SALE OR RECEIPT OF STOLEN GOODS AND RELATED OFFENSES.—Section 2315 of title 18, United States Code, is amended by adding at the end of the fourth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

SEC. 1145. INCLUSION OF NEW OFFENSE AS RICO PREDICATE.

Section 1961(1)(B) of title 18, United States Code, is amended by inserting '', section 670 (relating to theft of medical products)'' before '', sections 891''.

SEC. 1146. AMENDMENT TO EXTEND WIRETAPPING AUTHORITY TO NEW OFFENSE.

Section 2516(1) of title 18, United States Code, is amended—

(1) by redesignating paragraph (s) as paragraph (t);

(2) by striking ''or'' at the end of paragraph (r); and

(3) by inserting after paragraph (r) the following:

''(s) any violation of section 670 (relating to theft of medical products); or''.

SEC. 1147. REQUIRED RESTITUTION.

Section 3663A(c)(1)(A) of title 18, United States Code, is amended—

(1) in clause (ii), by striking ''or'' at the end;

(2) in clause (iii), by striking ''and'' at the end and inserting ''or''; and

(3) by adding at the end the following:

''(iv) an offense under section 670 (relating to theft of medical products); and''.

SEC. 1148. DIRECTIVE TO THE UNITED STATES SENTENCING COMMISSION.

(a) IN GENERAL.—Pursuant to its authority under section 994 of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and, if appropriate, amend the Federal sentencing guidelines and policy statements applicable to persons convicted of offenses under section 670 of title 18, United States Code, as added by this Act, section 2118 of title 18, United States Code, or any another section of title 18, United States Code, amended by this Act, to reflect the intent of Congress that penalties for such offenses be sufficient to deter and punish such offenses, and appropriately account for the actual harm to the public from these offenses.

(b) REQUIREMENTS.—In carrying out this section, the United States Sentencing Commission shall—

(1) consider the extent to which the Federal sentencing guidelines and policy statements appropriately reflect—

(A) the serious nature of such offenses;

(B) the incidence of such offenses; and

(C) the need for an effective deterrent and appropriate punishment to prevent such offenses;

(2) consider establishing a minimum offense level under the Federal sentencing guidelines and policy statements for offenses covered by this Act;

(3) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

(4) ensure reasonable consistency with other relevant directives, Federal sentencing guidelines and policy statements;

(5) make any necessary conforming changes to the Federal sentencing guidelines and policy statements; and

(6) ensure that the Federal sentencing guidelines and policy statements adequately meet the purposes of sentencing set forth in section 3553(a)(2) of title 18, United States Code.

SA 2140. Mr. SCHUMER (for himself, Mr. MERKLEY, and Mr. BLUMENTHAL) 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, insert the following:

TITLE ____—PROTECTING PATIENTS AND HOSPITALS FROM PRICE GOUGING ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Protecting Patients and Hospitals From Price Gouging Act''.

SEC. __02. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds that—

(1) many pharmaceutical drugs are necessary to maintain the health and welfare of the American people;

(2) currently the Nation is facing a chronic shortage of vital drugs necessary in surgery, to treat cancer, and to fight other life-threatening illnesses; and

(3) in order to prevent any party within the chain of distribution of any vital drugs from taking unfair advantage of consumers during market shortages, the public interest requires that such conduct be prohibited and made subject to criminal penalties.

(b) PURPOSE.—The purpose of this title is to prohibit excessive pricing during market shortages.

SEC. __03. DEFINITIONS.

As used in this title—

(1) the term ''market shortage'' means a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level;

(2) the term ''drug'' means a drug intended for use by human beings, which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to use under the professional supervision of a practitioner licensed by law to administer such drug;

(3) the term ''biologic'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings; and

(4) the term ''vital drug'' means any drug or biologic used to prevent or treat a serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or biologic or alternative drug or biologic available.

SEC. __04. UNREASONABLY EXCESSIVE DRUG PRICING.

(a) IN GENERAL.—

(1) AUTHORITY.—The President may issue an Executive Order declaring a market shortage for a period of 6 months with regard to one or more vital drugs due to a market shortage under this title.

(2) UNLAWFUL ACT.—If the President issues an Executive Order under paragraph (1), it shall be unlawful for any person to sell vital drugs at a price that is unreasonably excessive and indicates that the seller is taking unfair advantage of the circumstances related to a market shortage to unreasonably increase prices during such period.

(b) AUTHORITY.—The Attorney General is authorized to enforce penalties under this title.

SEC. __05. ENFORCEMENT.

(a) ENFORCEMENT.—

(1) IN GENERAL.—Whoever sells, or offers to sell, any vital drug during a declared market shortage with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances shall be guilty of an offense under this section and subject to injunction and penalties as provided in paragraphs (2) and (3).

(2) ACTION IN DISTRICT COURT FOR INJUNCTION.—Whenever it shall appear to the Attorney General that any person is engaged in or about to engage in acts or practices constituting a violation of any provision of this section and until such complaint is dismissed by the Attorney General or set aside by a court on review, the Attorney General may in his or her discretion bring an action in the proper district court of the United States, the United States District Court for the District of Columbia, or the United States courts of any territory or other place subject to the jurisdiction of the United States to enjoin such acts or practices, and upon a proper showing a permanent or temporary injunction or restraining order shall be granted without bond in the interest of the public.

(3) CRIMINAL PENALTIES.—Any person acting with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances shall be guilty of an offense under this section and title 18, United States Code, and subject to imprisonment for a term not to exceed 3 years, fined an amount not to exceed $5,000,000, or both.

(b) ENFORCEMENT.—The criminal penalty provided by subsection (a) may be imposed only pursuant to a criminal action brought by the Attorney General or other officer of the Department of Justice.

(c) MULTIPLE OFFENSES.—In assessing the penalty provided by subsection (a) each day of a continuing violation shall be considered a separate violation.

(d) APPLICATION.—

(1) IN GENERAL.—This section shall apply—

(A) in the geographical area where the vital drug market shortage has been declared; and

(B) to all wholesalers and distributors in the chain of distribution.

(2) INAPPLICABLE.—This section shall not apply to a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)) or a physician (as defined in section 1861(q) of the Social Security Act (42 U.S.C. 1395x(q)).

SEC. __06. DETERMINATION OF UNREASONABLY EXCESSIVE.

(a) IN GENERAL.—The Attorney General, in determining whether an alleged violator's price was unreasonably excessive, shall consider whether—

(1) the price reasonably reflected additional costs, not within the control of that person or company, that were paid, incurred, or reasonably anticipated by that person or company;

(2) the price reasonably reflected additional risks taken by that person or company to produce, distribute, obtain, or sell such product under the circumstances;

(3) there is a gross disparity between the challenged price and the price at which the same or similar goods were readily available in the same region and during the same Presidentially-declared market shortage;

(4) the marginal benefit received by the wholesaler or distributor is significantly changed in comparison with marginal earnings in the year before a market shortage was declared;

(5) the price charged was comparable to the price at which the goods were generally available in the trade area if the wholesaler or distributor did not sell or offer to sell the prescription drug in question prior to the time a market shortage was declared; and

(6) the price was substantially attributable to local, regional, national, or international market conditions.

(b) CONSULTATION.—Not later than 1 year after the date of enactment of this title and annually thereafter, the Attorney General or designee, shall consult with representatives of the National Association of Wholesalers, Group Purchasing Organizations, Pharmaceutical Distributors, Hospitals, Manufacturers, patients, and other interested community organizations to reassess the criteria set forth in subsection (a) in determining unreasonably excessive and prepare and submit to Congress a report on the results of the reassessment.

SEC. __07. DURATION.

(a) IN GENERAL.—Any market shortage declared by the President in accordance with this title shall be in effect for a period of not to exceed 6 months from the date on which the President issues the Executive Order.

(b) TERMINATION.—Any market shortage declared by the President in accordance with this title shall terminate if—

(1) there is enacted a law terminating the market shortage which shall be passed by Congress after a national market shortage is declared; or

(2) the President issues a proclamation terminating the market shortage;

whichever comes first.

(c) DECLARATION RENEWAL.—The President may renew the state of market shortage declared under subsection (a), if the President declares that the severe shortage continues to affect the health and well being of citizens beyond the initial 6-month period.

SA 2141. Mr. CARDIN (for himself and Ms. LANDRIEU) 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___. 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.

SA 2142. Mr. LEAHY 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:

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

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENT AGENCIES RELATING TO DRUG INSPECTIONS.—

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

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

''(B) the foreign government agency, in writing, requests that the information be kept confidential; and

''(C) the Secretary determines that the requirements under subparagraphs (A) and (B) have been satisfied.

''(2) TIME LIMITATIONS.—A foreign government agency may specify in a request described in paragraph (1)(B) that the voluntarily-provided information be withheld from disclosure for a specified time period. Such information may not be withheld under this subsection after the date specified. If no such date is specified, the withholding period shall not exceed 3 years.

''(3) DISCLOSURES NOT AFFECTED.—Nothing in this subsection authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

SA 2143. Mr. PAUL 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 appropriate place, insert the following:

SEC. 11___. LIMITATION ON SUPPRESSION BY FEDERAL GOVERNMENT OF CLAIMS IN FOOD AND DIETARY SUPPLEMENTS.

(a) IN GENERAL.—The Federal Government may not take any action to prevent use of a claim describing any nutrient in a food or dietary supplement (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) as mitigating, treating, or preventing any disease, disease symptom, or health-related condition, unless a Federal court in a final order following a trial on the merits finds clear and convincing evidence based on qualified expert opinion and published peer-reviewed scientific research that—

(1) the claim is false and misleading in a material respect; and

(2) there is no less speech restrictive alternative to claim suppression, such as use of disclaimers or qualifications, that can render the claim non-misleading.

(b) DEFINITION.—In this section, the term ''material'' means that the Food and Drug Administration has identified a competent consumer survey demonstrating that consumers decided to purchase the food or dietary supplement based on the portion of the claim alleged to be false or misleading.

SEC. 11___. DEFINITION OF DRUG.

(a) IN GENERAL.—Subparagraph (1) of section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by striking the second and third sentences and inserting the following: ''A food or dietary supplement for which a claim is made in accordance with section 403(r)(1)(B) is not a drug solely because of such claim.''.

(b) RULES.—All rules of the Food and Drug Administration in existence on the date of the enactment of this Act prohibiting nutrient-disease relationship claims are revoked.

SEC. 11___. MISBRANDED FOOD.

Section 403(r) (21 U.S.C. 343(r)) is amended—

(1) by striking clause (B) of subparagraph (1) and inserting the following:

''(B) describes any nutrient as mitigating, treating, or preventing any disease, disease symptom, or health-related condition if, and only if, the claim has been adjudicated false and misleading in a material respect by final order of a Federal court of competent jurisdiction in accordance with section 1202 of the Health Freedom Act.'';

(2) by striking subparagraph (3);

(3) in the first sentence of subparagraph (4)(A)(i)—

(A) by striking ''or (3)(B)''; and

(B) by striking ''or (1)(B)'';

(4) by striking clause (C) of subparagraph (4);

(5) by striking clause (D) of subparagraph (5); and

(6) in subparagraph (6), in the matter following clause (C), by striking the first sentence.

SEC. 11___. DIETARY SUPPLEMENT LABELING EXEMPTIONS.

Section 403B (21 U.S.C. 343–2) is amended to read as follows:

''FOOD AND DIETARY SUPPLEMENT LABELING

''SEC. 403B. The Federal Government shall take no action to prevent distribution of any publication in connection with the sale of a food or dietary supplement to consumers unless it establishes that a claim contained in the publication—

''(1) names the specific food or dietary supplement sold by the person causing the publication to be distributed;

''(2) represents that the specific food or dietary supplement mitigates, treats, or prevents a disease; and

''(3) proves the claim to be false and misleading in a material respect by final order of a Federal court of competent jurisdiction.''.

SEC. 11___. PROHIBITIONS ON FDA OFFICIALS CARRYING FIREARMS AND MAKING ARRESTS WITHOUT WARRANTS.

Section 702(e) (21 U.S.C. 372(e)) is amended—

(1) by striking paragraph (1);

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

(3) in paragraph (2), as so redesignated, by adding ''and'' after the semicolon at the end;

(4) by striking paragraph (4); and

(5) by redesignating paragraph (5) as paragraph (3).

SEC. 11___. PROHIBITED ACTS.

Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''knowing and willful'' before ''introduction or delivery'';

(2) in subsection (b), by inserting ''knowing and willful'' before ''adulteration'';

(3) in subsection (c), by inserting ''knowing and willful'' before ''receipt'';

(4) in subsection (d), by inserting ''knowing and willful'' before ''introduction or delivery'';

(5) in subsection (e), by striking ''The refusal'' and inserting ''The knowing and willful refusal'';

(6) in subsection (f), by inserting ''knowing and willful'' before ''refusal'';

(7) in subsection (g), by inserting ''knowing and willful'' before ''manufacture'';

(8) in subsection (h), by striking ''The giving'' and inserting ''The knowing and willful giving'';

(9) in subsection (i)—

(A) in paragraph (1)—

(i) by striking ''Forging'' and inserting ''Knowingly and willfully forging''; and

(ii) by inserting ''knowingly and willfully'' after ''proper authority'';

(B) in paragraph (2), by striking ''Making'' and inserting ''Knowingly and willfully making''; and

(C) in paragraph (3), by striking ''The doing'' and inserting ''The knowing and willful doing'';

(10) in subsection (j), by striking ''The using'' and inserting ''The knowing and willful using'';

(11) in subsection (k)—

(A) by inserting ''knowing and willful'' before ''alteration''; and

(B) by inserting ''knowing and willful'' before ''doing'';

(12) in subsection (m), by striking ''The sale'' and inserting ''The knowing and willful sale'';

(13) in subsection (n), by striking ''The using'' and inserting ''The knowing and willful using'';

(14) in subsection (o), by inserting ''knowing and willful'' before ''failure'';

(15) in subsection (p), by striking ''The failure'' and inserting ''The knowing and willful failure'';

(16) in subsection (q)—

(A) in paragraph (1), by striking ''The failure'' and inserting ''The knowing and willful failure''; and

(B) in paragraph (2), by inserting ''knowing and willful'' before ''submission'';

(17) in subsection (r), by inserting ''knowing and willful'' before ''movement'';

(18) in subsection (s), by striking ''The failure'' and inserting ''The knowing and willful failure'';

(19) in subsection (t), by striking ''The importation'' and inserting ''The knowing and willful importation'';

(20) in subsection (u), by inserting ''knowing and willful'' before ''failure'';

(21) in subsection (v), by striking ''The introduction'' and inserting ''The knowing and willful introduction'';

(22) in subsection (w), by inserting ''The making'' and inserting ''The knowing and willful making'';

(23) in subsection (x), by inserting ''knowing and willful'' before falsification;

(24) in subsection (y)—

(A) in paragraph (1), by inserting ''knowing and willful'' before ''submission'';

(B) in paragraph (2), by inserting ''knowing and willful'' before ''disclosure''; and

(C) in paragraph (3), by inserting ''knowing and willful'' before ''receipt'';

(25) in subsection (aa), by inserting ''knowing and willful'' before ''importation'';

(26) in subsection (bb), by inserting ''knowing and willful'' before ''transfer'';

(27) in subsection (cc), by inserting ''knowing and willful'' before ''importing'';

(28) in subsection (dd), by inserting ''knowing and willful'' before ''failure'';

(29) in subsection (ee), by inserting ''knowing and willful'' before ''importing'';

(30) in subsection (ff), by inserting ''knowing and willful'' before ''importing'';

(31) in subsection (gg), by inserting ''and willful'' after ''knowing'' each place such term appears;

(32) in subsection (hh), by inserting ''knowing and willful'' before ''failure'';

(33) in subsection (ii), by inserting ''knowing and willful'' before ''falsification of a report'';

(34) in subsection (jj)—

(A) in paragraph (1)—

(i) by inserting ''knowing and willful'' before ''failure''; and

(ii) by inserting ''and willfully'' after ''knowingly'';

(B) in paragraph (2), by inserting ''knowing and willful'' before ''failure''; and

(C) in paragraph (3), by inserting ''knowing and willful'' before ''submission'';

(35) in subsection (kk), by inserting ''knowing and willful'' before ''dissemination'';

(36) in subsection (ll), by striking ''The introduction'' and inserting ''The knowing and willful introduction'';

(37) in subsection (mm), by inserting ''knowing and willful'' before ''failure'';

(38) in subsection (nn), by inserting ''knowing and willful'' before ''falsification'';

(39) in subsection (oo), by inserting ''knowing and willful'' before ''introduction or delivery'';

(40) in subsection (pp), by inserting ''knowing and willful'' before ''introduction or delivery'';

(41) in subsection (qq)—

(A) in paragraph (1), by striking ''Forging'' and inserting ''Knowingly and willfully forging'';

(B) in paragraph (2), by striking ''Making'' and inserting ''Knowingly and willfully making''; and

(C) in paragraph (3), by inserting ''knowingly and willfully'' before ''doing'';

(42) in subsection (rr), by inserting ''knowing and willful'' before ''charitable'';

(43) in subsection (ss), by inserting ''knowing and willful'' before ''failure'';

(44) in subsection (tt), by striking ''Making'' and inserting ''Knowingly and willfully making'';

(45) in subsection (vv), by inserting ''knowing and willful'' before ''failure'';

(46) in subsection (ww), by inserting ''knowing and willful'' before ''failure'';

(47) in subsection (xx), by inserting ''knowing and willful'' before ''refusal'';

(48) in subsection (aaa), as added by section 712, by inserting ''knowing and willful'' before ''failure''; and

(49) in subsection (bbb), as added by section 722, by inserting ''knowing and willful'' before ''violation''.

SA 2144. Mr. HATCH (for himself, Mr. BURR, Mr. ALEXANDER, and Mr. ROBERTS) 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:

On page 150, between lines 2 and 3, insert the following:

''(C)(i) Reclassification by administrative order under subparagraph (A) shall apply only in the case of reclassification of a class III or class II device as a class II or class I device. The Secretary may reclassify a class I or class II device as a class II or class III device by regulation and revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

''(ii) In the case of a device reclassified as described in clause (i), paragraph (2), section 514(a)(1), and section 517(a)(1) shall apply to a regulation promulgated under clause (i) in the same manner such provisions apply to an order issued under subparagraph (A).''.

SA 2145. 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:

Subtitle D—Interstate Drug Monitoring Efficiency and Data Sharing

SECTION 1141. SHORT TITLE.

This subtitle may be cited as the ''Interstate Drug Monitoring Efficiency and Data Sharing Act of 2012'' or the ''ID MEDS Act''.

SEC. 1142. NATIONAL INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish national interoperability standards to facilitate the exchange of prescription information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies

Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

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

(b) REQUIREMENTS.—The Attorney General, in consultation with the Secretary of Health and Human Services, shall ensure that the national interoperability standards established under subsection (a)—

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

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

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

SEC. 1143. STATE RECIPIENT REQUIREMENTS.

(a) HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM.—

(1) IN GENERAL.—Not later than 1 year after the date on which the Attorney General establishes national interoperability standards under section 1142(a), a recipient of a grant under 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) shall ensure that the databases of the State comply with such national interoperability standards.

(2) USE OF ENHANCEMENT GRANT FUNDS.—A recipient of an enhancement grant under 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) may use enhancement grant funds to standardize the technology architecture used by the recipient to comply with the national interoperability standards established under section 1142(a).

(b) CONTROLLED SUBSTANCE MONITORING PROGRAM.—Section 399O(e) of the Public Health Service Act (42 U.S.C. 280g–3(e)) is amended by adding at the end the following:

''(5) Not later than 1 year after the date on which the Attorney General establishes national interoperability standards under section 1142(a) of the ID MEDS Act, the State shall ensure that the database complies with such national interoperability standards.''.

SEC. 1144. REPORT.

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

(b) CONTENTS.—The report required under subsection (a) shall include—

(1) a discussion of the feasibility of making State prescription monitoring programs interoperable with other relevant technologies and databases, including—

(A) electronic prescribing systems;

(B) databases operated by the Drug Enforcement Agency;

(C) electronic health records; and

(D) pre-payment fraud-detecting analytics technologies;

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

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

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

SA 2146. 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, insert the following:

Subtitle D—Synthetic Drugs

SECTION 1141. SHORT TITLE.

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

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

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

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

''(2) In paragraph (1):

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

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

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

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

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

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

''(B) Such term includes—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SA 2147. Mr. HATCH (for himself, Mr. BROWN of Massachusetts, Mr. BURR, Mr. COBURN, Mr. CORNYN, Mr. LUGAR, Mr. ROBERTS, Mr. HOEVEN, Mrs. HUTCHISON, Mr. LEE, Mr. WICKER, Mr. COATS, Mr. BARRASSO, Mr. TOOMEY, Mr. MORAN, Ms. COLLINS, Mr. INHOFE, Mr. BLUNT, Mr. PORTMAN, Mr. ALEXANDER, Ms. AYOTTE, and Mr. CRAPO) 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___. REPEAL OF MEDICAL DEVICE EXCISE TAX.

Subsections (a), (b), and (c) of section 1405 of the Health Care and Education Reconciliation Act of 2010, and the amendments made thereby, are hereby repealed; and the Internal Revenue Code of 1986 shall be applied as if such section and amendments had never been enacted.

SA 2148. Mr. KOHL (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. JOHNSON of South Dakota, Mr. BROWN of Ohio, Mr. BINGAMAN, and Mr. SANDERS) 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 the bill, insert the following:

TITLE ___.—PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Preserve Access to Affordable Generics Act''.

SEC. __02. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this title as the ''1984 Act''), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

(2) Prescription drugs make up 10 percent of the national health care spending but for the past decade have been one of the fastest growing segments of health care expenditures.

(3) Until recently, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers—although 67 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 20 percent of all expenditures.

(4) Generic drugs cost substantially less than brand name drugs, with discounts off the brand price sometimes exceeding 90 percent.

(5) Federal dollars currently account for an estimated 30 percent of the $235,000,000,000 spent on prescription drugs in 2008, and this share is expected to rise to 40 percent by 2018.

(6)(A) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make ''reverse payments'' which are payments by the brand company to the generic company.

(B) These settlement agreements have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(C) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition, and will become increasingly common unless prohibited.

(D) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

(b) PURPOSES.—The purposes of this title are—

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

SEC. __03. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by—

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

''SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

''(2) PRESUMPTION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

''(i) an ANDA filer receives anything of value; and

''(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

''(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

''(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

''(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

''(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

''(4) the revenue the ANDA filer would have received by winning the patent litigation;

''(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

''(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and

''(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

''(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive, although such evidence may be relevant to the fact finder's determination under this section.

''(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market the ANDA product in the United States prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

''(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

''(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

''(e) REGULATIONS AND ENFORCEMENT.—

''(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

''(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

''(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 CFR 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(g) PENALTIES.—

''(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but

in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

''(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

''(A) the nature, circumstances, extent, and gravity of the violation;

''(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(h) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) DRUG PRODUCT.—The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

''(7) NDA.—The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(8) NDA HOLDER.—The term 'NDA holder' means—

''(A) the party that received FDA approval to market a drug product pursuant to an NDA;

''(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

''(10) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

''(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act.''.

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 28(a)(1) of that Act entered into after November 15, 2009. Section 28(g) of the Federal Trade Commission Act, as added by this section, shall not apply to agreements entered into before the date of enactment of this Act.

SEC. __04. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking ''the Commission the'' and inserting the following: ''the Commission—

''(1) the'';

(2) striking the period and inserting ''; and''; and

(3) inserting at the end the following:

''(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).''.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.''.

SEC. __05. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 28 of the Federal Trade Commission Act or'' after ''that the agreement has violated''.

SEC. __06. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking ''or'' after the semicolon;

(2) in subparagraph (E), by inserting ''or'' after the semicolon; and

(3) inserting after subparagraph (E) the following:

''(F) under section 28;''.

SEC. __07. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section 03, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. __08. SEVERABILITY.

If any provision of this title, an amendment made 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 title or amendments to any person or circumstance shall not be affected thereby.

SA 2149. Mr. KOHL (for himself, Mr. GRASSLEY, and Mr. BLUMENTHAL) 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___. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–6. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

''(a) PROTOCOL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall develop a standardized protocol for designated health care providers to obtain informed consent from an older individual with dementia prior to administering an antipsychotic to the individual for a use not approved by the Food and Drug Administration. Such protocol shall include an alternative protocol for obtaining such informed consent in the case of emergencies.

''(b) DEFINITION OF INFORMED CONSENT.—In this section, the term 'informed consent' means, with respect to an older individual with dementia, that—

''(1) the health care provider has informed the individual (or, if applicable, the individual's designated health care agent or legal representative) of—

''(A) possible side effects and risks associated with the antipsychotic;

''(B) treatment modalities that were attempted prior to the use of the antipsychotic; and

''(C) any other information the Secretary determines appropriate;

''(2) the individual (or, if applicable, the individual's designated health care agent or legal representative) has provided authorization for the administration of the antipsychotic; and

''(3) the administration of the antipsychotic is in accordance with any plan of care that the individual has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.''.

SEC. 11___. PRESCRIBER EDUCATION PROGRAMS.

(a) IN GENERAL.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 11__, is amended by adding at the end the following:

''SEC. 399V–7. PRESCRIBER EDUCATION PROGRAMS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in consultation with the Commissioner of Food and Drugs, shall establish and implement prescriber education programs.

''(b) IMPLEMENTATION.—The Secretary shall establish and begin implementation of prescriber education programs under this section by not later than 6 months after the date on which funds are first made available under section 3734 of title 31, United States Code.

''(c) PRESCRIBER EDUCATION PROGRAM DEFINED.—In this section, the term 'prescriber education program' means a program to promote high quality evidence-based treatment and non-pharmacological interventions through the provision of objective, educational, and informational materials to physicians and other prescribing practitioners, including such a program developed by the Agency for Healthcare Research and Quality.''.

(b) FUNDING.—

(1) IN GENERAL.—Chapter 37 of title 31, United States Code, is amended by adding at the end the following:

''SEC. 3734. FUNDING FOR PRESCRIBER EDUCATION PROGRAMS.

''(a) FUNDING.—In each fiscal year, the Attorney General may make some portion of the covered funds paid to the United States in that fiscal year available for prescriber education programs in accordance with section 399V–7 of the Public Health Service Act.

''(b) DEFINITIONS.—In this section:

''(1) COVERED FUNDS.—The term 'covered funds' means all funds payable to the United States Government from any judgement or settlement of a civil action brought by the Attorney General under section 3730 of this title, relating to off-label marketing of any prescription drug.

''(2) OFF-LABEL MARKETING.—The term 'off-label marketing' means the marketing of a prescription drug for an indication or use in a manner for which the drug has not been approved by the Food and Drug Administration.''.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. CARDIN. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on May 22, 2012, at 10 a.m., to conduct a committee hearing entitled ''Implementing Derivatives Reform: Reducing Systemic Risk and Improving Market Oversight.''

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

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. CARDIN. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate on May 22, 2012, at 10 a.m., in room 366 of the Dirksen Senate Office Building.

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

SELECT COMMITTEE ON INTELLIGENCE

Mr. CARDIN. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on May 22, 2012, at 2:30 p.m.

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

SUBCOMMITTEE ON AIRLAND

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Airland of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 3:30 p.m.

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

SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Emerging Threats and Capabilities of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 2 p.m.

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

SUBCOMMITTEE ON PERSONNEL

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Personnel of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 5 p.m.

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

SUBCOMMITTEE ON READINESS AND MANAGEMENT SUPPORT

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Readiness and Management Support of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 11 a.m.

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

SUBCOMMITTEE ON SEAPOWER

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Seapower of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 9:30 a.m.

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

PRIVILEGES OF THE FLOOR

Mr. REID. Mr. President, I ask unanimous consent that Tiffany Griffin, a fellow in the office of Senator BINGAMAN, be granted the privilege of the floor during consideration of S. 3187, the Food and Drug Administration Safety and Innovation Act.

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

Mr. HARKIN. Mr. President, I ask unanimous consent that Lauren Boyer and Jimmy Fremgen of my staff be granted the privilege of the floor for the duration of today's session.

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

Mr. BROWN of Massachusetts. Mr. President, I ask unanimous consent that my military fellow, Major Jay Rose, be granted floor privileges for the duration of my remarks.

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

Mr. HATCH. Mr. President, I ask unanimous consent that Paul Williams, a detailee to the Senate Finance Committee from the Food and Drug Administration; Jesse Baker, a detailee to the Senate Finance Committee from the U.S. Secret Service; Angela Sheldon, a detailee to the Senate Judiciary Committee; and Maureen McLaughlin, a detailee to the Senate Finance Committee from the Federal Communications Commission, all be granted privileges of the floor for the remainder of the second session of the 112th Congress.

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

MEASURES READ THE FIRST TIME EN BLOC—S. 3220 AND S. 3221

Mr. BROWN of Ohio. Mr. President, I understand there are two bills at the desk, and I ask for their first reading en bloc.

The PRESIDING OFFICER. Without objection, the clerk will report the bills by title.

The bill 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. BROWN of Ohio. Mr. President, I now ask for a second reading en bloc, and I object to my own request en bloc.

The PRESIDING OFFICER. Objection is heard. The bills will be read for the second time on the next legislative day.

ORDERS FOR WEDNESDAY, MAY 23, 2012

Mr. BROWN of Ohio. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 9:30 a.m. on Wednesday, May 23; that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, and the time for the two leaders be reserved for their use later in the day; that the majority leader be recognized; that the first hour following the remarks of the majority leader and Republican leader be equally divided and controlled between the two sides, with the Republicans controlling the first half and the majority controlling the final half; further, that the majority control the time from 1 p.m. until 2 p.m.

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

PROGRAM

Mr. BROWN of Ohio. Mr. President, it is the majority leader's intention to resume consideration of S. 3187, the FDA user fees bill, when the Senate convenes tomorrow. We are working on an agreement for amendments to the bill. We hope we can reach an agreement and avoid filing cloture on the bill.

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. BROWN of Ohio. Mr. President, if there is no business to come before the Senate, I ask unanimous consent that it adjourn under the previous order.

There being no objection, the Senate, at 6:27 p.m., adjourned until Wednesday, May 23, 2012, at 9:30 a.m.