The House met at 10 a.m. and was called to order by the Speaker pro tempore (Mr. BARTLETT).

DESIGNATION OF THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:


I hereby appoint the Honorable Roscoe G. BARTLETT to act as Speaker pro tempore on this day.

JOHN A. BORINER, Speaker of the House of Representatives.

PRAYER

Monsignor Stephen Rossetti, Associate Professor, The Catholic University of America, Washington, D.C., offered the following prayer:

Good and gracious God, it is Your spirit that guides us into all truth and leads us on the straight path. In these challenging days, may we be open to being led by this spirit. May we be so docile to Your divine guidance that all of us will work together with one heart for the betterment of all.

Finally, we know that one day Your spirit will lead us safely home. Buoyed up with this saving knowledge and guided by this same spirit, we now step forward into the future with confidence and hope. We make this prayer in Your holy name.

Amen.

THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the last day’s proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. The Chair will lead the House in the Pledge of Allegiance.

The SPEAKER pro tempore 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.

PUBLICATION OF BUDGETARY MATERIALS

REVISIONS TO THE ALLOCATIONS OF THE FISCAL YEAR 2013 BUDGET RESOLUTION RELATED TO LEGISLATION REPORTED BY THE COMMITTEE ON APPROPRIATIONS

Mr. RYAN of Wisconsin. Mr. Speaker, pursuant to section 314 the Congressional Budget Act of 1974 (Budget Act), I hereby submit for printing in the CONGRESSIONAL RECORD revisions to the aggregate budget levels and committee allocations set forth pursuant to H. Con. Res. 112, the Concurrent Resolution on the Budget for Fiscal Year 2013. The revision is for new budget authority and outlays for a provision designated as disaster relief, pursuant to section 251(b)(2)(D) of the Balanced Budget and Emergency Deficit Control Act of 1985, contained in a bill making appropriations for the Department of Homeland Security reported by the Committee on Appropriations. A corresponding table is attached.

This revision represents an adjustment for disaster relief, pursuant to section 302 and 311 of the Budget Act. For the purposes of the Budget Act, these revised allocations are to be considered as allocations included in the budget resolution, pursuant to section 101 of H. Con. Res. 112.

BUDGET AGGREGATES

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ALLOCATION OF SPENDING AUTHORITY TO HOUSE COMMITTEE ON APPROPRIATIONS

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<td>OT</td>
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ADJOURNMENT

The SPEAKER pro tempore. Without objection, the House stands adjourned until 10 a.m. on Friday, May 25, 2012.

There was no objection.

Accordingly (at 10 o’clock and 5 minutes a.m.), under its previous order, the House adjourned until Friday, May 25, 2012, at 10 a.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker’s table and referred as follows:

608H. A letter from the Acting Under Secretary of Defense, Department of Defense,
transmitting authorization of Colonels Roger L. Cloutier and Kristin K. French, United States Army, to wear the insignia of the grade of brigadier general; to the Committee on Armed Services.


6084. A letter from the Assistant Secretary for Export Administration, Department of Commerce, transmitting the Department’s final rule — Certain Persons on the Entity List: Addition of Persons Acting Contrary to the National Security or Foreign Policy Interests of the United States [Docket No.: 11102760-1743-01] (RIN: 0584-AP43) received April 16, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Foreign Affairs.

6085. A letter from the Associate General Counsel, Department of Agriculture, transmitting three reports pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

6088. A letter from the Director, Office of Surface Mining, Department of the Interior, transmitting the Department’s final rule — Oklahoma Regulatory Program [STAS Nos.: OK-603-FOR; Docket No. OSM-2011-0001] received April 27, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Natural Resources.

6090. A letter from the Director, Office of Surface Mining, Department of the Interior, transmitting the Department’s final rule — Iowa Regulatory Program [STAS Nos.: IA-016-FOR; Docket No. OSM-2011-0014] received April 27, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Natural Resources.

6091. A letter from the Acting Deputy Assistant Secretary for Regulatory Programs, NMFS, National Oceanic and Atmospheric Administration, transmitting the Service’s final rule — Endangered and Threatened Species; Range Extension for Endangered Central California Coast Coho Salmon [Docket No.: 10032316-2126-03] (RIN: 0648-XV30) received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Natural Resources.

6092. A letter from the Rules Administrator, Department of Justice, transmitting the Department’s final rule — Unlawful Internet Communication With Media: Removal of Byline Regulations [BOP-1149-F] (RIN: 1128-AB94) received April 18, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Judiciary.

6093. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department’s final rule — West Oahu Offshore Security Zone [Docket No.: USCIG-2011-1048] (RIN: 1625-AA87) received April 16, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6094. A letter from the Attorney, Department of Homeland Security, transmitting the Department’s final rule — Safety Zone; Sausalito Yacht Club’s Annual Lighted Boat Parade and Fireworks Display, Sausalito, CA [Docket No.: USCIG-2011-0970] (RIN: 1625-AA00) received April 26, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6095. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department’s final rule — Regulated Navigation Area, 10th Street Bridge Rehabilitation Project, Mystic River, MA [Docket No.: USCIG-2011-1125] (RIN: 1625-AA11) received April 26, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6096. A letter from the Chief, Border Security Regulations Branch, Department of Homeland Security, transmitting the Department’s final rule — Technical Amendment to Cuba Airport List: Addition of Recently Approved Airports (CBP Dec. 12-08) received April 16, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.


6098. A letter from the Chief, Publications and Regulations Branch, Internal Revenue Service, transmitting the Service’s final rule — Guidance under Section 267(f); Deferral of Loss on Transactions Between Members of a Controlled Group [TD 9583] (RIN: 1545-B192) received April 16, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.


6100. A letter from the Commissioner, Social Security Administration, transmitting a consolidated report of the Administration’s processing of continuing disability reviews for FY 2010; to the Committee on Ways and Means.

6101. A letter from the Secretary, Department of Health and Human Services, transmitting the Department’s report entitled, “Report to Congress on the Administration, Impact and Proposals for the Organization Program for Medicare Beneficiaries for Fiscal Year 2009”; jointly to the Committees on Ways and Means and Energy and Commerce.

6102. A letter from the Program Manager, Department of Health and Human Services, transmitting the Department’s major final rule — Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation (CMS-1559-F) and 0505-AQ08 received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); jointly to the Committees on Ways and Means and Energy and Commerce.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XXIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. ROGERS of Kentucky: Committee on Appropriations. Revised Suballocation of Budget Allocations for Fiscal Year 2013 (Rept. 112-490). Referred to the Committee of the Whole House on the state of the Union. Mr. ROGERS of Michigan: Permanent Select Committee on Intelligence. H.R. 5743. A bill to authorize appropriations for fiscal year 2013 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, the Central Intelligence Agency Retirement and Disability System, and for other purposes; with an amendment (Rept. 112-490). Referred to the Committee of the Whole House on the state of the Union.

PUBLIC BILLS AND RESOLUTIONS

Under clause 4 of rule XXII, memorials were presented and referred as follows:

219. The SPEAKER presented a memorial of the House of Representatives of the State of Idaho, relative to House Joint Memorial No. 7 urging the President to award Retired Sergeant Chris Tschida the Medal of Honor; to the Committee on Armed Services.

220. Also, a memorial of the House of Representatives of the State of Idaho, relative to Senate Memorial 1822 urging the Congress to repeal the Sarbanes-Oxley Act of 2002; to the Committee on Energy and Commerce.

221. Also, a memorial of the House of Representatives of the State of Idaho, relative to House Joint Memorial No. 8 urging the Congress to repeal the No Child Left Behind Act of 2001; to the Committee on Education and the Workforce.

222. Also, a memorial of the House of Representatives of the State of Idaho, relative to House Joint Memorial No. 14 recognizing and commending the ETA’s statement of a definitive cessation of its armed activity and end to terrorism; to the Committee on Foreign Affairs.

223. Also, a memorial of the House of Representatives of the State of Idaho, relative to Senate Memorial 65 urging the President, Executive Agencies and the Congress to work together to see that the Beyond the Border Action Plan on Regulatory Cooperation are carried out; to the Committee on Foreign Affairs.

224. Also, a memorial of the House of Representatives of the State of Florida, relative to Senate Memorial 63 urging the Congress to direct the Fish and Wildlife Service to reconsider the proposed rule to designate Kings Bay as a manatee refuge; to the Committee on Natural Resources.

225. Also, a memorial of the House of Representatives of the State of Florida, relative to House Memorial 83 petitioning the Congress to propose to the states an amendment to the Constitution of the United States to limit the number of consecutive terms which a person may serve in the Senate or the House of Representatives; to the Committee on the Judiciary.

226. Also, a memorial of the House of Representatives of the State of Idaho, relative to Senate Memorial 63 urging the Congress to authorize an additional United State District Court Judge and commensurate

MEMORIALS
staff for the District of Idaho; to the Committee on the Judiciary.

227. Also, a memorial of the House of Representatives of the State of Louisiana, relative to House Concurrent Resolution No. 57 memorializing the Congress to review the Government Pension Offset and the Windfall Elimination Provision Social Security benefit reductions; to the Committee on Ways and Means.

228. Also, a memorial of the House of Representatives of the State of Maine, relative to Joint House Resolution urging the President and the Congress to improve the process by which the United States trade agreements are developed and implemented; to the Committee on Ways and Means.

229. Also, a memorial of the Senate of the State of Maine, relative to Joint Senate Resolution urging the President and the Congress to support the continued and increased development and delivery of oil derived from North American oil reserves to American refineries; jointly to the Committees on Transportation and Infrastructure, Foreign Affairs, Energy and Commerce, and Natural Resources.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 7 of rule XII of the Rules of the House of Representatives, the following statements are submitted regarding the specific powers granted to Congress in the Constitution to enact the accompanying bill or joint resolution.

Mr. CUMMINGS: H.R. 5853.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8: "The Congress shall have Power to lay and collect Taxes, Duties, Imposes and Excises, to pay the Debts and provide for the common Defence and general welfare of the United States"

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 210: Ms. SUTTON, Ms. DEGETTE, and Mr. LEVIN.

H.R. 1244: Mr. LEWIS of Georgia and Mr. LATHAM.

H.R. 1873: Mr. HINCHRY.

H.R. 2499: Mr. WOLF and Ms. PINGREE of Maine.

H.R. 2569: Mr. HENSARLING.

H.R. 2730: Mrs. CAPPs.

H.R. 3015: Mr. CONNOLLY of Virginia.

H.R. 3040: Mr. HINOJOSA and Mr. BISHOP of New York.

H.R. 3096: Ms. CHU.

H.R. 3397: Mr. LANGEVIN.

H.R. 3435: Ms. MCCOLLUM.

H.R. 3444: Mr. FITZPATRICK.

H.R. 3895: Mrs. LUMMIS.

H.R. 4082: Mr. SMITH of Washington.

H.R. 4296: Mr. SCOTT of Virginia, Mr. WESTMORELAND, and Mr. DOLD.

H.R. 4971: Mr. POMPEO, Mr. MANZULLO, Mr. COSTELLO, Mr. ROE of Tennessee, Mr. LATTA, Mr. NUNNELEE, and Mr. LONG.

H.J. Res. 103: Mr. FLORES.

H. Con. Res. 125: Mr. REICHERT, Mrs. McMorris Rodgers, and Mr. SMITH of Washington.

H. Res. 220: Ms. LORETTA SANCHEZ of California.

H. Res. 659: Mr. CALVERT, Mr. LUETKEMEYER, Mr. McNERNEY, and Ms. WATERS.
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,

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 Nevada 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 shortages faced by many Americans battling cancer and other life-threatening illnesses.

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 about 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 that have come in 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 White House 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 does. It might require a little more work but it is what we need. It is time to lead.

I ask unanimous consent that 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 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. 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 thrashing out a bipartisan filibuster on energy.

“I think the reality is the current Congress is not constituted in a way that makes court—whether that’s Senate, OlympicSnowe, 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 that’s 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 term on issues like immigration and energy policy.

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

ECONOMIC CHALLENGES

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; $20 million of our tax money to promote a trillion dollar government program.

That’s $20 million of our tax money to promote a trillion dollar government program.

Moreover, Democrats argue that when Congress was trying to save $160 billion from 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 Senate Majority Leader Harry Reid that persuaded him to back down, Harkin told Politico.

“If you put two and two together, you can see what happened,” an aide 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 the Affordable Care Act and the Dodd-Frank financial services law.

The new gavel-holders on Capitol Hill, Democratic 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 Senate Majority Leader Harry Reid that persuaded Harkin to back off.

“While I 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.

But even with broad bipartisan support backing away to a catastrophic showdown last summer. But it’s only a matter of time before Congress will 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.

The president 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 during the Bush administration.
The $20 million contract was first reported efits to Medicare patients.
tive services available without a co-pay or
ance of prevention while also explaining
able Care Act and must describe the impor-
official said.
stay healthy and prevent illnesses, an HHS
signed to educate the public about how to
the Affordable Care Act.
ment has signed a $20 million contract with
inappropriate conduct as chairman re-
mission of Jaczko's offensive behavior first sur-
mine the mission of the NRC itself. But
virtuous leader. The fact
cause, as the Senator from New Hamp-
brating National Small Business Week,
nation of my colleagues that we are cele-
SBA could indeed be the advocate for
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 forward many initiatives that
help small businesses, and I think it
could make a huge difference as our econ-
omy 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
make small businesses feel that it
has made a huge difference as our econ-
omy is starting to recover. We are now
looking at 23 consecutive months of
continuous private sector job growth
where we have turned around the econ-
onomics. We are now growing at a large
time we act. Svinicki has served
as commissioner with distinction, is
enormously qualified, has bipartisan
support and deserves a speedy recon-
firmation. 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 fol-
lowing hour will be equally divided and
controlled between the two leaders or
designees, with the majority con-
trolling the first half and Republicans
controlling the second 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 or-
dered.
Mr. CARDIN. Madam President, I ask
unanimous consent to speak as in
morning business.
The ACTING PRESIDENT pro tempore.
Without objection, it is so or-
dered.
NATIONAL SMALL BUSINESS WEEK
Mr. CARDIN. Madam President, I
take this time to bring to the atten-
tion of my colleagues that we are cele-
brating National Small Business Week,
which is a very important occasion be-
cause, as the Senator from New Hamp-
shire 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 incredible large num-
er of patents per employee from small
companies than from large companies.
So the growth engine for America's
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 cybernetics and other technology 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 reauthorizations and predictability of funding under the SBIR Program and the increased amounts that are available will create, and has already created, new 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 tem. The Senator’s time has expired.

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

The ACTING PRESIDENT pro tem. 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, I 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 the SBIR 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. This 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 made 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. 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.

With that, I yield the floor.

The ACTING PRESIDENT pro tem. 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, 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-ed 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 spending and taxes—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, transfers, 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, the 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 stimulus can revitalize a sagging economy that is not already dependent on 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. For a delay in 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, growth cannot happen. Consequently, the key to growing our country is policies that stimulate consumption targets the wrong side of the equation. In order to get the economy growing, we need to focus on the inputs—labor, capital, and technology. We also believe government spending, stimulative cuts are beneficial because they free up private capital and help align revenues with government spending.

Lazear argues that supply-siders stand on the firmer ground when it comes to the question of fiscal policy and economic growth. Here is what he writes:

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

The tax rate on long-term capital gains has not dipped below 15 percent for 39 months. As Lazear notes, we are experiencing a recovery in name only. So there is not much evidence that stimulus can revitalize a sagging economy that is not already dependent on 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:

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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 does—lowers 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—boom 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 cut where 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 drastically 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 $15 billion in spending and will reduce the deficit by over $222 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-balancing proposal. 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 emulate but also take a look at 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 to be printed in the RECORD, as follows:

From the Wall Street Journal, May 21, 2012

Three Views of the ‘Fiscal Cliff’

(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, knowing that increased taxes 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 “fiscal cliff,” the budget balancer thinks of this as “fiscal con-solidation.” Tax increases reduce the deficit, as do cuts in government spending. Both are austerity measures that make the government more responsive and, therefore, both are conducive to long-run economic growth.

Those who support the Simpson-Bowles plan subscribe 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 economy is 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-siders focus on the harmful effects of tax increases. Raising tax rates hurts the economy directly by giving taxpayers a reason 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 revenue and spending exceed revenues, then the government must borrow and this commits future governments to raising taxes in order to serve the debt. Those who support the Simpson-Bowles plan do so in 2013 primarily as a tax increase and fears what that will do to the economy. The spending cuts are a positive. Unlike the Keynesian and the budget balancer, who see 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 sees it one-and-one. The tax increases are harmful to 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, all monetary policy is 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 in—note the 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 the day of reckoning, we should keep spending at a higher level for each year that we want to postpone the negative consequences for growth. Given the state of the latest budget, this is not a likely event. 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 marginal taxes of 1% reduces 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 Henriksson (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 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 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.

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 has prevented their confirmations. It is my hope that Congress will cooperate with the FCC 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. 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 plans to provide a terrestrial network 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 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 have 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’s Committee, or any other Congress, the documents 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 the Chairman of the Justice Department’s feet to the fire to make sure they responded fully and re- orted. With LightSquared, it was another committee in the House of Representatives, the House Energy and Commerce Committee, Chairmen WILDEN, 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 what they are doing. They are afraid 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. So I 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 hold a couple weeks ago, so these nominations can 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 obtain 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.

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 because more time, even if 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 bio-similar 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. Those working groups completed their work earlier this year. Those working groups completed their work earlier this year.

We also called in all the stakeholders—the prescription drug manufacturers, the pharmaceautical industry, the drug stores, 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 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 now we 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 gone faster and the 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 effectiveness. 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, 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 now we have a bill that is broadly supported.

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Again—and I will be pointing out later also—FDA does a very good job of 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 going to 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 systems and improves the FDA’s role in 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 noun 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 not 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 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 expediously 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 pass this bill before we go home for the summer.

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
We are talking about people of great stature, 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 several others to improve 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 KIORI.

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 drug shortages in this country. If 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 medicines that are essential than in addressing 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, 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, is an example of a drug used in an emergency are sometimes in shortage 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.

I am pleased to say this 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 several others to improve 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 KIORI.

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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, Doxil 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 in Connecticut, 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 has 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 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 the drugs they need 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 generally, 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 there are 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 evidence of fraud is there. The markets are not working, therefore now a gray market that involves mark-ups 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 mark-up with Senators PLANAltinho, 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. It is a starting point, 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 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 work 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. I gave 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. 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 important, but let us start as Chairman BAKIN 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.

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 are able to steal from the government. 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 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 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.

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 be somewhere 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, a few hundred thousand.

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 that 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 were seeing significant numbers of children being paid as a result of the Individual Taxpayer Identification Number, or ITINs. The House has acted and we should get it fixed.

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 to live and 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 ability to work that they 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 who 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 enforcing 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 the Senate should 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. There is another way folks in Louisiana 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.

According to the Senate 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. Thank you for 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 in 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 plan 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 less than $4 billion 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 saying ‘‘pass legislation 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 do 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 the House focused on this, we may be able to get the Senate to pass it. 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 responses 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 illegal aliens 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 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 President 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 “Flying Swordsmen” of the National Flier Flighter 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 burning fuel and 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 on 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 shoulders.

And what adults 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 our 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.

The time being 12:30 p.m., Senate recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. Webber).

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

Mr. REID. Mr. President, I ask unanimous consent that the Senate remain in recess until 3:18 p.m., 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 free-for-all 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 any 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. Tuberculosis 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 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 1922. Typhoid and polio were common. 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 anti-microbial 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 fees. The important programs that the Food and Drug Administration needed resources to review new medically necessary products.

There is another program 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 study 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 adults. That would mean 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. 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 Senator Enzi 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 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 legislation 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 to promote 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 very ill, then 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 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 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 direction we hope the world has 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 Tennessee in 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 Senator Enzi 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 FDA 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 mean that it will put lives of many Americans at risk while they wait for potentially lifesaving medicine.

Now 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 a new 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 importance 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 HARKIN, as well as 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 that will allow 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 morning be dispensed.

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

Mr. DURBIN. Mr. President, I ask unanimous consent to speak as in no other 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 was 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 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 previous 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 flag, and they knew the words. 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 the children of parents who committed an illegal act. 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, to 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 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 DREAM Act has had 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.

Sharon called me about a young girl. 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 have her knowledge, in any other country 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 92- 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 voted down, and 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 made it clear that 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 of people. 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 receive something that they are entitled to. 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 clinic in Wayne County 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 under 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 passed. 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 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. 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. Barbara Bush once said 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 all 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. 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 their hard work made possible. It is the right thing to do, and it will make America a stronger Nation.”
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 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 compete for business based on the fees they charge, 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. 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. 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 consumers—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 low, a few pennies. But the banks, looking for more revenue, exploited the swipe fee system to charge far more than they could ever charge. The banks then claimed that small banks and credit unions have actually thrived since this reform took effect. Why? Because 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 think 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 end competition. That is not the case. Consumers are also benefitting from debit cards, with almost all institutions offering debit card discounts for items such as gas, furniture, and clothing.

USA Today also pointed out that despite the banks that charge 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 can 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 the Senate to set a swipe fee cut 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 will now be able to charge even more for their services than before.

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 small 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 how dangerous it is to water 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 cannot be tolerated.

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 enforcer of competition that 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’s 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 credit and debit card systems have competition, transparency about their choices, 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 reasonably that we can 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 involved discretionary spending caps—not nearly enough to balance our budget over 10 years but a step in the right direction. That legislation said we would raise the debt ceiling $2.1 trillion but we will cut spending $2.1 trillion. Congress was supposed 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—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 this 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, 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.

So I have sent a letter to Chairman CONRAD expressing my chairmanship and refiling 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.

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) 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 levels from 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 $13 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 of the BCA requires that the mandatory spending allocations to Senate authorizing committees be consistent with the CBO baseline. The CBO March 2012 baseline for the Committee on Finance for fiscal year 2013 is $1,328,356 million. But the allocation filed on March 20 ($1,329,474 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 and authorize 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 Congress 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 are completely bought out by the constituency, and we have to see how they can defeat, get around, and spend more money than they are allocated.

The American people are being misled. 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.

Governments 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, with inevitable jokes 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 three-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, heads who can stand 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 is to be honest and actually come up with 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 hard-earned American budgets 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 steally increase discretionary outlays today 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.

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 Chamber. Senator 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 Senate floor. 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 Senator 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. First, I currently draft amendments. In fact, 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 and see it as 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 red color are the areas 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, dikes, 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 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 wiggie 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—that people who are currently paying for flood protection. In most cases, they do it, 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 wiggie room—what they would be required to do is make sure that only people who 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 bodily all over the country, but it is over 1,200 in every 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 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 know 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 have a good 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 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 100-year flood, 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 if 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 House bill. I think the reason it is not— I can’t speak for the Corps of Engineers—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 the 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 one of the charts that 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, Indiana, Illinois, and Kentucky. Illinois is in there as well. This large blue area is what they call the historic floodplain. Before man came, before people started building levees, before they started drainage 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 also 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 not to meddle with it.

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 problem we 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. I 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.

The floods 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 not everyone will be able to purchase flood insurance. They can’t get a mortgage. It has to do with 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 floodplain should be sent 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 maps. Therefore, I am opposed.

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 ask my Federal Emergency Management Agency (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. Every year they spend $2 billion.

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 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 lose 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 precedence over policy. That is not right then and it is certainly not right now. Our Nation faces serious problems—immediate problems—and action today, 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 of conscience for 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 “fiscal cliff” is an election year is not excuses 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 I wish to commend 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 of reforming our tax systems to have a single-minded focus on his re-election. 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 cause harm 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 growth 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, 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 a temporary 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 on buying a home, saving for college, investing in a new business, or hiring a new worker. Will pass-through 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 found the 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. Federal Reserve Vice Chairman William Dudley further commented that the Federal Reserve’s policy-making does not have the capability for offsetting the resulting decline in economic growth. 

This morning 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 ausing 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 to the point of self-inflicted harm.

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 what gets what. They don’t want politicians spreading the wealth around. They don’t want self-appointed 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 villified for engaging in free enterprise. They want a job. And nothing is more fair than giving every American the chance to make something of themselves and acquire Washington getting out of the way, not getting more involved.

Second, the American people seem to understand that the President’s promise to address the so-called tax hikes of the rich while 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 paying more spending.

There is only one other option available to President Obama and it is one that he has shown so far 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 danger. We certain 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 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 policy about what 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 facing. 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 afraid. We certain put this discussion off any longer. It is time for our President to lead.

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. We cannot wait until next year or even a lame duck 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.

Mr. REED. I yield the floor.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. 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 industries, the resources and expertise 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.

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 to a quorum call, and then I will be recognized for such time as I may take to address the Senate.
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 MURPHY, and Senator ROBERTS, another bipartisan effort to improve the health of children throughout this country.

Until 1997—15 years ago—80 percent of drugs sold 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 family—plan and earlier treatments 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 that FDA plans for continuing 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 timelines to the FDA or approval or failing to complete a required study once they are pricing 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, create a reasonable and sensible law for the development of 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 that 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 come 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 within a year when tanning device use 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 and tanning label warnings 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 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.
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 would like 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. 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 is important for the Senate to be here 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 at the wording of this amendment, as we did yesterday, and come to their final decision.

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 SHEEROD 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, AFSAE, National Legislative Association on Prescription Drug Prices, the Alliance for Relieved 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 deny 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 prices.

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. As a result of a settlement in response of companies that would have been able to pay much less for those same drugs.

Ensuring access to affordable medication is an essential aspect of addressing the high cost of 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 2006, 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-third the price of the price of the 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 the 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. In other words, the original intent of Hatch-Waxman was to reward 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 from monopoly companies for delaying market entry, extended patent life, 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 companies who get the cash reward 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 another way, there is no penalty 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 drugs 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 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

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.
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 first filer has a right to seek 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 filers 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 clarity and eliminates 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 offer interferes 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 Hatch-Waxman Act’s structural flaw is 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, 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 these drugs is: Altace, 2 years; Lipitor, 2 years; and Propranolol—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 are billions 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 and taxpayers. The second drug was Lipitor. In 2007, Lupin was granted 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 successfully litigated 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 2006 New York Times report, Pfizer and generic manufacturer Randoxy 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 very week in late 2011.

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—that 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 Georges Act, been the law—and we have introduced it as a stand-alone bill—that had the Fair Georges Act been the law, generic versions of Provigil would very likely have been available 6 months after 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 address 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, the Noes 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 across Massachusetts, and Americans’ access to the most groundbreaking, state-of-the-art medical devices which people need.

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 bill 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 that will 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 billions in revenue 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 23 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 totally stunned by how much 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, 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 disheartening 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 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 Massachussets, and it should concern every Member of this body.

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

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

The ACTING PRESIDENT pro tempore. The clerk will 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 to the public and no one apparently knows how many 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 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 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 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 common sense 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 make 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 instance—there needs to be a mechanism for it to be known what is in it and that it wouldn’t harm somebody. This amendment would require dietary supplement manufacturers to report serious adverse events, and it would require the FDA to keep track of the 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 immediate 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 about it.

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 consumed seven grams 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 her, her grandfather Dick and grandparents. They have been here today because they are hoping the Senate will hear about this amendment and that we can take it up and pass it.

Anas case is not the only one. Emergency room visits due to energy drink 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 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 the energy drink 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 not find this is being characterized and described as a dietary supplement. Democrats, 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, I recommend 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 few 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 different requirements. So my first message today is to the conference, 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 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 this legislation agreed to include 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 begin 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 safe 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 and industry. We need legislation under which medical gases that have stood the test of time remain available for use; and brand new medical gases reviewed for medical use; and brand new medical gases.
gas products that have never been test-
ed through an appropriate FDA re-
view—which is what the original bill envisioned.

I once again thank the chairman and ranking member for all of the hard work to move this tit-
ure bill forward in such a bipartisan manner. The way the Committee has ap-
proached this important legislation has resulted in a good bill that de-
serves everyone’s support. I also want to express my appreciation for the in-
clusion of the Chemical Gas Safety Act in this bill. Senator BLUMENTHAL de-
serves credit for the work he has done in this area.

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

Supply chain compliance and safety is currently a patchwork of inconsis-
tent State requirements and licensing which potentially jeopardizes the safety and welfare of millions of Amer-
icans. Federal legislation 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. Adapting to the ever-changing landscape of Federal policy, when the Federal policy covering all pharmaceutical supplies 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.

Third Party Logistics Providers, or 3PLs, are playing a growing and impor-
tant role in making sure medicines reach their destination safely and se-
curly. The term “third party logistics provider” refers to an entity that pro-
vides or coordinates warehousing, dis-
tribution, or other services on behalf of a manufacturer, wholesaler, or dis-
penser, but does not buy, sell, or direct the sales of those products.

Currently, Federal law does not rec-
ognize 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 enforce-
ment more difficult and there is added cost without a safety benefit.

Failure to uniformly and define 3PLs in Federal language is simply wrong. Rec-
ognizing the role of 3PLs is a strong first step towards the development of uniform Federal standards for a 3PL li-
cense. Ensuring that all entities are properly licensed within the pharma-
caceutical supply chain not only makes sense, but it is one of the most effec-
tive deterrents to dangerous counter-
faked drugs entering the supply chain.

I thank my colleagues Senator BEN-
NET and BURR, and their staff, for their leadership to enhance supply chain safety by working with all industry stakeholders. I also express my grati-
tude to Ranking Member ENZI, Chair-
member 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 de-
fining 3PLs, 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 com-
mand the chairman and ranking mem-
ber on their service and their fine work on the FDA bill.

I yield the floor, and I suggest the ab-

The ACTING PRESIDENT pro tem-
porum. 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 statement
of Mr. CASEY. Without objection, it is so or-
dered.

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

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

Katie’s first job was at a music store in a local mall. She got the job, as any
other high school student would, because she wanted to hear music and
make some money. She worked hard, was a good employee, and her man-
agers respected her. She was a hard worker and a good employee. She
worked hard, was a good employee, and her managers respected her.

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

I am proud to say that Katie was a
native Iowan. She was born in March
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 dam-
gage 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. Slow-
ly, 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 inten-
sive 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 for nursing home in order to be
covered.

Katie’s predicament began to receive
attention thanks to the intervention of

many people, including then-Congress-
man Tom Tauke, who was Katie’s Con-
gressman 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
President Reagan was so concerned
about this and a national 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 chil-
dren. 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 in-
stitutional bias in Medicaid and per-
mitting children with significant dis-
abilities to receive their support and
services in their own homes rather than in a hospital, nursing home, or other
institution.

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?

Katie’s story is one of hope. Before the Katie Beckett Waiver, her
fellow students considered her different because of her medical condition, she
never needed special education serv-
dices. At an early age she became a pas-
ionate advocate for home- and com-
munity-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 Ex-
ceptional Parent magazine while living
in Boston. That summer between her
junior and senior year of high school,
Katie learned to manage her own med-
cal care, directing nurses who pro-
vided her treatment and managed her
ventilator.

Katie considered advocacy to be her
vocation and chosen path—in par-
ticular, to raise the consciousness of
other young people about disability
issues. Even though she found this
work rewarding, she sometimes felt un-
comfortable in those pre-ADA days—
the pre-Americans with Disabilities
Act days—and being singled out be-
cause 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
Katie’s home. She could only receive care in a hospital for nursing home in order to be
covered.

Katie’s predicament began to receive
attention thanks to the intervention of


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 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 recommendations 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 was one of those people with disabilities showing that any 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 for which her name, the Katie Beckett Waiver, 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 Beckets 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. 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 and 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.

But Katie's story doesn't end there. As Katie grew up, 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 of 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 was inspired by 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 the Money Follows the Person Act, 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 Katie is not alive, it will remain that inspiration for many people for a long time to come.

Thank you very much. I yield the floor.

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

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 will live on 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 exchanged 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 undertook 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 away from medical VISN headquarters.

Currently, VA office would have been made to the medical facilities and the women veterans who are present at veterans, OIF–OEF–OND veterans, application are coordinators for homeless management staff over 17 years is expected, 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 field 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 polices 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 posture by the 1995 reorganization to a total of 1,340 staff for the 21 VISN 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 oversight of the Centers for Medicare and Medicaid Services’ impact of 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 structure 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, and, in the simplest terms, 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 VHA central office or an assignment in the 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, and, in the simplest terms, 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 VHA central office or an assignment in the 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, and, in the simplest terms, budget, management, and planning duties that they were originally tasked with in the 1995 original reorganization.

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.

Just as the Veterans Affairs bill, 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 support this effort to 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 not able to get it to a vote today. I am hopeful that tomorrow we will be able to because of the importance of this bill, 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 town hall meetings 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 Senate 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 can treat the 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. The number of committee members who worked on it, 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 10 years ago 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. That is unacceptable that 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 when they can see their foreign counterparts do not have to worry about FDA visiting them for a decade, if ever, because they can delay or request 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 an FDA 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 can 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 working 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 bill should operate.

I yield the floor.

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

Mr. SHAHEEN. I applaud my colleague from Colorado, Senator Bennet, and his efforts on the 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. 219

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. 3218, 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 off-label conditions.

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.

I wish to make one final observation. The 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 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 specifically cited by the FDA. Moreover, it showed that more than half of the 1.4 million claims for 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 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 extend a special thank you to Senator Harkin and Ezzii 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 senator from Ohio has yielded the floor.

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.

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 heard 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 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. Some estimates say it is not possible 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 deals 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 meant, 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 breaks, went overseas, 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 surge 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 2010 to early 2013, we have 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 made in 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 Parma, 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.
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, they 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 of course important to rescued, 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 our 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 about to collapse.

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.

These 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 terror 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 development 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.

TAINW’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 challenge 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 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 com-
merce 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—will launch 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 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. 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 support. In 2009, the Benedictine School launched a campaign for capital projects and endowment. Sister Jeannette has been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has never been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has never been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has never been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has never been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has never been her lifetime dream to provide a complete and total program that will meet the needs of individuals with developmental disabilities. She has

I hope my colleagues will join me in thanking Sister Jeannette Murray—the “little woman with the huge heart” as 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 on 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 to the family and friends 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 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 Hartford 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.

TRIBUTE TO SISTER JEANNETTE MURRAY

Mr. CARDIN. 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 1798, 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 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 for 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 provide for 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. 3212. An original bill making appropriations for 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 (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. CARDIN (for himself and Ms. LANDRIEU):

S. 3215. An original bill making appropriations for military construction and 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. MORA (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. BERNICH):

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. CAHN, Mr. CARDIN, Mr. CUBBINS, Mrs. FEINSTEIN, Mrs. GILLIBRAND, Mrs. HAGAN, Mr. HARKIN, Mr. LEAHY, Mr. LEVIN, Mrs. MCCASKILL, Mr. MENDELL, Mrs. MURR, Mr. REID, Mr. SANDERS, Mrs. SHAHEEN, Mr. UDALL of New Mexico, Mr. WHITEHOUSE, Mr. KERRY, Ms. LANDRIEU, Mr. BENNET, Ms. KLOUCHIN, 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 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 Authenticity, 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. 3215. An original bill making appropriations for military construction and 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 (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. CARDIN (for himself and Ms. LANDRIEU):

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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
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.

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 former 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. 1522
At the request of Mr. Cardin, the name of the Senator from Washington (Ms. Cantwell) was added as a cosponsor of S. 1522, 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. 1523
At the request of Mrs. Gillibrand, the name of the Senator from Maryland (Mr. Cardin) was added as a cosponsor of S. 1523, a bill to amend title 10, United States Code, to prohibit the Secretary of Defense from using funds to provide for the commercialization of military aircraft.

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 during the Holocaust.

S. 1899
At the request of Mr. Barrasso, the name of the Senator from Alaska (Ms. Murkowski) was added as a cosponsor of S. 1899, 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 of 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. 2002
At the request of Mr. Durbin, the name of the Senator from California (Mrs. Feinstein) was added as a cosponsor of S. 2002, 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. 2122
At the request of Mr. Begich, the name of the Senator from New Hampshire (Ms. Shaheen) was added as a cosponsor of S. 2122, 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. 2194
At the request of Mr. Blumenthal, the name of the Senator from New York (Mrs. Gillibrand) was added as a cosponsor of S. 2194, a bill to amend title 10, United States Code, to provide for certain requirements relating to the retirement, addition, care, and recognition of military working dogs, and for other purposes.

S. 2198
At the request of Mr. Inhofe, the name of the Senator from Kansas (Mr. Roberts) was added as a cosponsor of S. 2198, a bill to amend the Toxic Substance Control Act relating to lead-based paint renovation and remodeling activities.

S. 2199
At the request of Mr. Begich, the name of the Senator from Delaware (Mr. Coons) was added as a cosponsor of S. 2199, 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. 2199
At the request of Mr. Moran, the name of the Senator from Kansas (Mr. Roberts) was added as a cosponsor of S. 2199, 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.
BEGiNH 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.

At the request of Mr. Moran, the name of the Senator from New Hampshire (Ms. Ayotte) was added as a cosponsor of S. 2206, a bill to prohibit funding to negotiate a United Nations Arms Trade Treaty that restricts the Second Amendment rights of United States citizens.

At the request of Mr. Nelson of Florida, the name of the Senator from Nebraska (Mr. Hekler) 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.

At the request of Ms. Inhofe, the name of the Senator from Delaware (Mr. Coons) was added as a cosponsor of S. 2292, 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.

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.

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.

At the request of Mr. Rubin, the name 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 certain nonresident alien individuals.

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.

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.

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 Fort Myer's 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.

At the request of Mr. Brown of Massachusetts, the name of the Senator from Nevada (Mr. Hekler) was added as a cosponsor of S. 3210, a bill to amend title 38, United States Code, to modify the treatment under contract with 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.

At the request of Mr. Rubino, 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.

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’.

At the request of Mr. McCaín, 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.

At the request of Ms. Murkowski, the name of the Senator from Washington (Mrs. Murray) was added as a cosponsor of amendment No. 2106 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 non-profit 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 are-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 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 schools. 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” in 2012. 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 youth 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 some of these programs. 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 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:

SEC. 1. SHORT TITLE.

This Act may be cited as the “Today’s Entrepreneurs Act” or the “TEAM Act.”

SEC. 2. DEFINITIONS.

In this Act—

(A) the term “Administration” and “Administrator” mean the Small Business Administration and the Administrator thereof, respectively; and

(B) 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) Office of Entrepreneurial Education.—

(1) In General.—The Small Business Act (15 U.S.C. 631 et seq.) is amended—

(A) by redesignating section 45 (15 U.S.C. 631 note) as section 45;

(B) by inserting after section 44 (15 U.S.C. 655), the following:

SEC. 45. ENTREPRENEURIAL EDUCATION.

(1) Office of Entrepreneurial Education.—

(A) Office of Entrepreneurial Education—

(i) the terms “Administration” and “Administrator” mean the Small Business Administration, which shall develop and provide innovative entrepreneurial information, education, and resources, to promote prospective entrepreneurs and successful small business concerns; and

(ii) the Office of Entrepreneurial Education shall have such duties and powers as the Administrator determines is necessary.

(B) Director.—The Office of Entrepreneurial Education is the Director of the Office of Entrepreneurial Education, who shall carry out this Act.

(2) 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; and

(B) coordinate with other entrepreneurial programs of the Administration, including—

(i) online resources for youth entrepreneurs; and

(ii) coordination and outreach with entrepreneurial development services providers that offer counseling and training to youth entrepreneurs desiring to start or expand small businesses.

(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 other dignitaries visiting the United States who are interested in issues relating to entrepreneurs and small business concerns.

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 agree to provide to the Administrator information relating to the use and result of the assistance provided and (C) each student receiving a scholarship under subsection (a) has a mentor to help the student develop an academic course of study or a small business concern or entrepreneur project.

(b) REQUIREMENTS.—The Administrator shall—

(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 institutional projects (including virtual projects); and

(C) each student receiving a scholarship under subsection (a) has a mentor to help the student develop an academic course of study or a small business concern or entrepreneur project.

2. IDEAcorps is an MBA service learning program that assists youth entrepreneurs by working with local partners to launch the IDEAcorps ‘2008, 15 national business schools and 596 MBA students have participated in IDEAcorps. Participating universities include: Stanford, Harvard, HBS, Wharton, Duke, Berkeley, DePaul, MIT, Columbia, Tulane, Loyola, University of Pennsylvania, University of Chicago and Xavier Law 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. IDEAcorps 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. IDEAcorps Participating universities include: Stanford, Harvard, HBS, Wharton, Duke, Berkeley, DePaul, MIT, Columbia, Tulane, Loyola, University of Pennsylvania, University of Chicago and Xavier Law Relations Institute in India.

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There are authorized to be appropriated to the Administrator $200,000 for each of fiscal years 2013 through 2015 to carry out this section.

3. IDEAcorps has been a success story. Since participating universities include: Stanford, Harvard, HBS, Wharton, Duke, Berkeley, DePaul, MIT, Columbia, Tulane, Loyola, University of Pennsylvania, University of Chicago and Xavier Law Relations Institute in India.
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 small-person, invite-only annual Summit for the entrepreneurship education industry at the U.S. Chamber of Commerce, White House, and Capitol Hill featuring the 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 these efforts, our company has seen the large unmet need in exposing today’s youth to entrepreneurship as a viable career path. We’re 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 needed.

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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 needed.

Finally, the TEAM Act requires the SBA to conduct outreach and mentorship in K-12 schools. Sincerely,

Michael Simmons, Co-Founder & CEO.

May 21, 2012.

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 ‘Young Entrepreneurs are Americas’ 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 field 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 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 young 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 demands of loan payments can be a significant barrier for young adults when they’re trying to get their business off the ground.

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 formally 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 for students and aspiring entrepreneurs 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 Entrepreneurs Council (YEC) in the U.S. Senate, I support the TEAM Act, the YEC can continue to speak out, educate, and develop entrepreneurial competencies. We look forward to working with you and the Senate Committee 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 the most challenged and under-resourced communities across the nation, and we’ve seen firsthand how this type of intensive, experiential programming can change the relevant lives of 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 can 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.

Chairwoman Landrieu: Today there are over 540,000 students enrolled in 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 funding for entrepreneurship education provided by the Small Business and Entrepreneurship Committee. We also encourage the committee to
consider language in the bill that would di-
rect, incentivize and enable the Small Busi-
ness Administration to work with other agen-
cies such as USDA, Department of Edu-
cation, HHS, Department of Labor developing an inter-
agency working group that can develop a more comprehensive plan and approach to k-
12 Entrepreneurship Education. To the de-
gree we can, I am proposing in this legislation that collaboration and planning we would be
happy to do so.

Thank you for your leadership in recog-
nizing the importance of this issue and for
putting forward legislation that will increase
the visibility and effectiveness of Entrepre-
nurship Education. It is important to young people, our communities, our nation and the world.

Sincerely,
COUNCIL OF GRADUATE SCHOOLS,

Chairman MARY LANDRIEU,
Chair, Committee on Small Business and Entrep-
nrepreneurship, U.S. Senate, Russell Senate Office Building, Washington, DC.

I am writing in support of Today’s Entrepreneurs are Amer-
ica’s Mentors (TEAM) Act, legislation that is in-
tegrated in the U.S. entrepreneur ecosystem by empowering the Small Business Administration’s Office of Entre-
preneurial 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 stu-
dents. Scholarship recipients would provide free technical assistance, financial planning and sustainable business practices to local small business owners and start-up companies. This provision recognizes the increasing im-
portance of graduate education in providing the highly skilled talent the nation needs to be successful in the 21st century global econ-
y. The role of graduate education in pre-
paring a highly skilled workforce is ad-
dressed 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.fge
report.org.

A recent report, Pathways Through Grad-
uate School and Into Careers, proposed in-
creased collaboration among business lead-
ers and university leaders to develop and support the next generation of entrepreneurs and innovators and is available at http://
pathwaysreport.org/. Both reports were pro-
duced 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 on your legislation on ex-
ploring additional ways that U.S. graduate education, a strategic national asset, can sup-
port our nation’s entrepreneurial enter-
tprise. Thank you for your leadership in in-
roducing this important legislation.

Sincerely,
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 Entre-
preneurs are Mentoring (TEAM) Act. This legislation would strengthen the federal enter-
prise education outreach to our na-
tion’s K–12 student population. It is our hope that this legislation will encourage the SBA Office of Entrepre-
nurial Education (OEE) to work with exist-
ent entrepreneurial outreach organizations, including Junior Achievement. I believe the legislation is necessary to make a significant impact for small businesses.

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 organiza-
tion. Along with financial literacy and work readiness, teaching students about entrepre-
nurship through hands on activities that promote an entrepreneurial spirit is woven into JA’s programs. Since 1919, the JA Com-
pany Program has taught millions of students about the responsibilities needed to start and run a business.

Given JA’s history and scope of impact in the entrepreneurship space, 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,
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 significant experience in its growth and ability to help small businesses. 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 well together. It 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 States. I introduced an amendment intended to harmonize, 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. I believe that we need to improve our coordination and work better 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 colleagues from New Hampshire, Senator SHAAHEEN, 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 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 expands 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, supra; which was ordered to lie on the table.

SA 2131. 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 Mr. 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 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. ALLEN, 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. KOHL (for himself, Mr. GRASSLEY, Mr. BROWN of Massachusetts, Mr. BURR, Mr. COBURN, Mr. CORNYN, Mr. LUGAR, Mr. ROBERTS, Mr. HOBUS, Mrs. HUTCHISON, Mr. LIE, Mr. WICKER, Mr. COATS, Mr. BAHRAMO, Mr. TOOMEY, Mr. MORAN, Ms. COLLINS, Mr. INHOFE, Mr. BLUNT, Mr. PORTMAN, Mr. ALLEN, Mr. AYOTTE, and Mr. CRAFUT) 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, 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.

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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 OF 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(i) of the Public Health Service Act (42 U.S.C. 282(i));

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

(3) 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(i) of the Public Health Service Act (42 U.S.C. 282(i)) (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(i).

(c) 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.

(1) Approved by GAO.

(2) IN GENERAL.—Not later than 2 years after the issuance of the final rule under section (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 Representa-

ators a report on the development of the registration and reporting requirements for applicable drug and device clinical trials

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CONGRESSIONAL RECORD — SENATE

May 22, 2012

within classes of medications in order to avoid patient confusion and harm; and

(4) 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.

(5) Publishing 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 2128. Mrs. GILLIBRAND (for herself 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 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. 350d) is amended by adding at the end 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 506(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 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;

(i) 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
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) IMPACT.—The report under paragraph (1) shall include—

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of site, level of project 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 Commissioner of General determines useful) with the requirements of—

(i) registering applicable clinical trials under section 402(j);

(ii) reporting 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 basis of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Commissioner of General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the initial registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Commissioner General may consult with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative and 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 VII, add the following:

SEC. 7. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall conduct an evaluation of the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documentation, corrective and preventive action, management, and best practices for conducting comprehensive assessments, 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 contract timelines; and

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

(b) 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 and contractor 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 shall establish a performance award program for each employee described in subsection (b) (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 and performance standards described in section 101(b), 301(b), or 401(b), as appropriate.
Food and Drug Administration (21 U.S.C. 366(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.

(b) Prohibition on Market Manipulation.—(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (b) shall be treated as an unfair or 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. 57(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 subject themselves to the penalties and priviledges 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 action 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 this subsection (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).
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 expand 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—
"(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) 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 to the Congress a report on the evaluation conducted under this subsection.

(b) CRITICAL REINFORCEMENT.—To carry out this section, the Secretary may—
"(1) for the rapid production of a critical reinforcement drug;
"(2) that the qualified manufacturer will maintain production of a critical reinforcement drug;
"(3) that would allow the Secretary to purchase supply of a critical reinforcement drug;
"(4) that the qualified manufacturer will not use any confidential, trade secret, or proprietary information of any other entity without such entity’s consent.

(c) QUALIFIED MANUFACTURERS.—To be a qualified manufacturer for purposes of this section—
"(1) an entity shall be a drug manufacturer;
"(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) currently produces a critical reinforcement drug or a similar product and can increase production immediately to address the shortage with no regulatory approvals required;
"(C) 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 the shortage;
"(D) 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.—The Secretary shall—
"(A) negotiate a manufacturing contingency plan with the manufacturer to meet an identified critical reinforcement need in subsection (c). The Secretary may—
"(B) expedite the review of any abbreviated new drug application submitted under paragraph (1) by the qualified manufacturer for a drug that is vulnerable to shortage as identified pursuant to the criteria established under subsection (a); and
"(C) 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, the Secretary may retroactively assess the application fees withheld under paragraph (1) for an abbreviated 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 approval 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. FEINGOLD, 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 506C (21 U.S.C. 356c) is amended—
"(1) in subsection (b), by inserting "or (subparagraph (h) of section 409 of the Federal Food, Drug, and Cosmetic Act)" after "(9)" each place such term appears; and
"(2) in section 509A(b) 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 monetary penalty 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. —S. 3505 (21 U.S.C. 355) is further amended by adding at the end the following:
striking ‘‘In this section’’ and inserting ‘‘In under such subsection (j)(5)(B)(iv).’’.

180-day exclusivity with respect to such drug marketed, sold, or distributed—

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)(6)(B)(iv); or

(ii) after expiration or forfeiture of any 180-day exclusivity with respect to such drug under subsection (j)(6)(B)(iv).

(b) CONFORMING AMENDMENT.—Section 505(c)(3) (21 U.S.C. 355(c)(3)) is amended by striking ‘‘In this section’’ and inserting ‘‘In this subsection’’.

SA 2138. Mr. VITTER submitted an amendment introduced to be proposed by him in the bill S. 337, 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.

TITLES—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 $200,000,000 annually, and that the Federal Emergency Management Agency has indicated that it will be unable to pay back this debt;

(4) the National Flood Insurance Program must be strengthened to ensure it can pay future claims;

(5) while flood insurance is mandatory in the 100-year flood plain, substantial flooding occurs outside of existing special flood hazard areas;

(6) events throughout the country involving actual and potential 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 equalled 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 equalled 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.).

(b) WRITING YOUR OWN.—The term ‘‘Write Your Own’’ means the cooperative underwriting between the insurance industry and the Federal Insurance Administration which allows participating casualty and insurance companies to write and service standard flood insurance policies.

(c) 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.

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(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 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 1306 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’’;

(2) by adding at the end the following:

‘‘(g) 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, and with the cumulative amount of such claims payments exceeding $20,000; or

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall become effective 90 days after the date of the enactment of this Act.

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; or

(B) any repetitive loss property; or

(C) any property that has incurred flood-related damage in which the cumulative amounts of payments under this title exceeded or exceeded the fair market value of such property; or

(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

(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 properties insured 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; or

(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 insurer who refuses to accept any offer for mitigation assistance by the Administrator (including an offer to relocate), including an offer of mitigation assistance that—

(A) following a major disaster, as defined in section 105 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5129); or

(B) in connection with—

(i) a repetitive loss property; or

(ii) a severe repetitive loss property.

(2) 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.’’.
(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 (i), by striking “and” at the end;

(2) in clause (ii), 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—

(1) an estimate of the expected value of future losses;

(2) all costs associated with the transfer of risk, and

(3) 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 1306(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(e)) is amended—

(1) by striking “under this title for any property” and inserting the following: “under this title for any properties with any single” and inserting the following: “under this title for any properties with any single”; and

(2) described in subparagraphs (A) through (I) of section 1307(f)(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 such properties described under paragraph (1).”;

(d) PREMIUM PAYMENT FLEXIBILITY FOR NEW AND EXISTING POLICYHOLDERS.—Section 1306 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016) 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 two equal 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) RESIDENTIAL RISK AREAS.—The regulations required by subsection (a) shall require the expansion of areas of special flood hazards to include—

(1) in general.—Any area described in subsection (b) shall be subject to the mandatory purchase requirements of section 102 and 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a, 4016).

(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 special flood hazards 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 such structure.

(4) 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 1306 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:

“(b) 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 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 in such area under 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 the increase, 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 located in 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 other change in the flood insurance map, and in 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) by striking the second sentence.

SEC. 110. 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;

and

(2) by adding at the end the following:

“(12) ‘State entity for lending regulation’ 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 106(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, in accordance with the regulations and Modernization Act of 2012, lending institution to 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 provide consistent supervision and coordination with the Federal Financial Institutions Examination Council, 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 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.

“(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 any provision of this Act.”
“(1) 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 property taxes, insurance premiums, fees, or any other charges in an escrow account for 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 a mobile home; and

“(2) in 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

“(b) by adding at the end the following:

“(2) 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 any 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 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 on or before December 31, 1974, or on the effective date of any 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 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) $2,500, 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 “, along with input from the public and other stakeholders;”;

“(2) in subsection (b), by striking the comma after “a” and inserting a semicolon; and

“(A) in paragraph (4), by striking the period and inserting “; and”;

“(B) 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;”;

“(6) in subsection (c), by adding at the end the following:

“(B) rules of construction.—For purposes of this section, the calculation of an “average historical loss year” includes catastrophic loss years; and

“(C) any other factor that 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.

SEC. 114. RESERVE FUND.

Chapter I of the National Flood Insurance Act of 1968 (42 U.S.C. 4001 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’) that 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 section 112.

“(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 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, 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 required under subsection (b), the Administrator shall place in the Reserve Fund an amount for that fiscal year an amount equal to not less than 7.5 percent of the reserve ratio required under subsection (b).

“(e) RESERVE RATIO.—In any 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 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 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 association or other company 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);
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(B) a member of a recognized professional
surveying association or organization; and

(C) a member of a recognized professional
mapping association or organization; or

(D) a member of a recognized professional
government association or organization; or

(E) a representative of a State geographic
information association; and

(F) a representative of a State geographic
information organization; and

(G) a representative of the Administration; and

(H) a representative of a State recognized
professional association or organization;

(I) a member of a recognized professional
organization; and

(J) a member of a recognized geographic
information association or organization; and

(K) the Secretary of Agriculture (or the
designee thereof);

(L) a member of a recognized regional flood
and storm water management organization; and

(M) a representative of a State agency that
has entered into a cooperative 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; and

(P) a member of the Council's risk manage-
ment association or organization; and

(Q) a State mitigation officer.

(2) QUALIFICATIONS.—Members of the Counci-
shall be appointed based on their dem-
strated knowledge and competence regard-
ing surveying, cartography, remote sensing,
geographic information systems, or the tech-
nical 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 dissemination of flood insurance rate maps and risk data; and

(B) identification of flood activities on
Federal properties required to
effectively and efficiently map
flood risk areas in the United States;

(2) recommend to the Administrator mapp-
ing standards and guidelines for—

(A) flood insurance rate maps; and

(B) data accuracy, data quality, data cur-
rency, and data eligibility;

(3) develop best practices that the Admin-
istrator how to maintain, on an ongoing basis, flood
insurance rate maps and flood risk identifica-
tion; and

(4) recommend procedures for delegating
mapping activities to State and local map-
ping partners;

(5) recommend to the Administrator how to
coordinate, on an intergovernmental basis,
the activities of the Council with the Admin-
istrator and the United States Geological
Survey; and

(6) submit an annual report to the Admin-
istrator that contains—

(A) a description of the activities of the Coun-
cil;

(B) an evaluation of the status and per-
formance of flood insurance rate maps
and mapping activities to revise and update flood
insurance rate maps, as required under sec-
tion 118;

(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 commu-

nities to—

(A) develop recommendations on how to—

(i) ensure that flood insurance rate maps
incorporate available climate science to assess flood risks; and

(ii) ensure that the Federal Emergency
Management Agency uses the best available
methodology to estimate the impact of—

(I) the rise in the sea level; and

(II) future development on flood risk; and

(ii) not later than the date of the enact-
ment of this Act, prepare written
recommendations in a future conditions risk
assessment and modeling report and to sub-
mit such recommendations to the Admin-
istrator.

(2) RESPONSIBILITY OF THE ADMINIS-
TRATOR.—The Administrator, as part of the
ongoing program to review and update Na-
tional Flood Insurance Program rate maps
under section 118, shall—

(1) incorporate any future risk assessment
submitted under paragraph (1)(B) into any
version or up or updated version of the
Council’s map; and

(2) establish or update flood-risk zone data
and models to—

(i) identify flood insurance rate maps that
are protected by levees, dams, and other
flood control structures; and

(ii) identify flood insurance rate maps that
could be inundated as a result
of the failure of a levee, dam, or other
flood control structure; and

(iii) identify the location of flood-risk zone
data; and

(iv) utilize the most accurate topography
and elevation data available.

(b) MAPPING.—

(1) IN GENERAL.—In carrying out the pro-
gram established under subsection (a), the Adminis-
trator 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 possi-
ble 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; and

(iv) areas that could be inundated as a re-

sult of the failure of a levee, dam, or other
flood control structure;

and

(B) 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 (2 U.S.C. 4011 et seq.), the most accurate topography and ele-
vation data available.

(c) FUTURE CONDITIONS RISK ASSESSMENT
 AND MODELING REPORT.—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 dissemination of flood insurance rate maps and risk data; and

(B) identification of flood activities on
Federal properties required to
effectively and efficiently map
flood risk areas in the United States;

(2) recommend to the Administrator mapp-
ing standards and guidelines for—

(A) flood insurance rate maps; and

(B) data accuracy, data quality, data cur-
rency, and data eligibility;

(3) recommend to the Administrator how to
maintain, on an ongoing basis, flood
insurance rate maps and flood risk identifica-
tion; and

(4) recommend procedures for delegating
mapping activities to State and local map-
ping 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 co-
ordinate budgets and expenditures across
Federal agencies; and

(6) submit an annual report to the Admin-
istrator that contains—

(A) a description of the activities of the Coun-
cil;

(B) an evaluation of the status and per-
formance of flood insurance rate maps
and mapping activities to revise and update flood
insurance rate maps, as required under sec-
tion 118;

and

(C) a summary of recommendations made
by the Council to the Administrator.
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science and the potential for future inundation from sea level rise, increased precipitation, and increased intensity of hurricanes due to global warming; and

(E) provide the best available 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) any other local governments in managing development to reduce the risk of flooding; and

(B) comply with the open publishing and data exchange standards established by the Open Geospatial Consortium; and

(C) ensure that flood elevation data defined by the National Geodetic Survey are used.

(d) COMMUNICATION AND OUTREACH.—

(1) IN GENERAL.—The Administrator shall:

(A) work to enhance communication and outreach to the residents of 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) any such changes may have on flood insurance purchase requirements; and

(B) engage with local communities as part of consistency 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) conform to standards of data quality and official data defined by the National Geodetic Survey.

(e) GENERAL DETERMINATION.—

The Administrator shall make a determination with respect to the appeal in accordance with subsection (c) within 60 days after the issuance of the determination, unless the Administrator determines that implementing the determination of the Scientific Resolution Panel pursuant to subsection (a)(2), is in favor of the Administrator by waiver, to pass the end of the appeal period; or

(B) that has received an unsatisfactory ruling under the map revision process established pursuant to section 1396(f).

(f) APPEALS BY OWNERS AND LESSORS.—If a community and an owner or lessee of real property within the community appeal a proposed determination of a flood elevation under section 1396(b), upon the request of the community—

(A) the owner or lessee shall submit scientific and technical data relating to the appeal to the Scientific Resolution Panel; and

(B) the Scientific Resolution Panel shall make a determination with respect to the appeal in accordance with subsection (c).

(4) 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 unreasonable 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. Members 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 make a determination with respect to the appeal in accordance with subsection (a).

(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), is in favor of the owner or lessee of real property in the community; and

(B) data provided by the Administrator.

(3) NO ALTERNATIVE DETERMINATIONS PERMITTED.—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 by waiver, to pass the end of the appeal period; or

(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 have—

(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).

(f) MAPS USED FOR FLOOD INSURANCE AND MANDATORY PURCHASE REQUIREMENTS.—With respect to any community that has a dispute that is being considered by the Scientific Resolution Panel pursuant to this subsection, the Federal Emergency Management Agency shall ensure that for each such community—

(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’’ and inserting ‘‘the Scientific Resolution Panel provided for in section 1363A’’.

(2) JUDICIAL REVIEW.—The first sentence of section 1363(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(e)) is amended by striking ‘‘Any appellant’’ and inserting

“Any appellant”.
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 10 years.

SEC. 121. REMOVAL OF LIMITATION ON STATE CONTRIBUTIONS FOR UPDATING AVAILABILITY OF FLOOD MAPS.

Section 102 or 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4102(a) and 4106).

"(b) DUTIES OF THE ADMINISTRATOR.—In carrying out subsection (a), 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 availability 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. 4157 note; relating to the National Spatial Data Infrastructure) for the implementation of and compliance with such standards;

(3) coordinate with, leverage, and coordinate funding of, to the maximum extent practicable, the current flood mapping activities of each unit of State and local government; and

(4) integrate, leverage, and coordinate, to the maximum extent practicable, the current geospatial activities of other Federal agencies and units of State and local government.

SEC. 122. 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 of flood mapping, including a funding strategy to leverage and coordinate budgets and expenditures; and

(2) 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 agencies.

SEC. 123. NOTICE OF FLOOD INSURANCE AVAILABILITY UNDER RESPA.

Section 5(b) of the Real Estate Settlement Procedures Act of 1981 (12 U.S.C. 2605(b)) is amended by adding after subsection (a) the following:

"(A) a member in good standing of the State bar in the State in which the mediator participated 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 mediator participated in State-sponsored mediation under this section shall be—

(2) a retired trial judge from any United States district court.

SEC. 124. NONMANDATORY PARTICIPATION IN STATE DISASTER CLAIMS MEDIATION PROGRAMS.

(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 200 or 204 of the Flood Insurance Act of 1968 (42 U.S.C. 4102(a) 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) LENDER REQUIRED NOTICE.—

(a) REGULATED LENDING INSTITUTIONS.—Each Federal or State agency entity for lending regulation (as consultation and coordination with the Federal Financial Institutions Examination Council) shall, by regulation, require regulated lending institutions, as a condition of providing new or renewing any loan secured by property located in an area within the 500-year floodplain, to notify the purchaser or lessee (or any person exercising a benefit of the property 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.

(b) FEDERAL OR STATE AGENCY LENDERS.—Each Federal or State agency lender shall, by regulation, require notification 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 1020(f)(5) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 41202).

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"(4) Qualifications of Mediators.—Each State mediator participating in State-sponsored mediation under this section shall be—

(a) be a member of the bar of the State in which the mediation takes place, and shall have at least 2 years of practical experience; and

(b) be a retired trial judge from any United States district court.

"(5) mediation proceedings and documents developed pursuant to participation, all statements made and documents produced pursuant to State-sponsored
medication involving representatives of the Administrator shall be deemed privileged and confidential settlement negotiations made in anticipation of litigation.

(1) The final rules established pursuant to subsection (h), (k), and (m); and

(2) 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 claims associated with a State-sponsored mediation program in which such representative of the Administrator participates.

(i) Exclusion.—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 an emergency declaration under 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) and the regulations issued pursuant to such section.

 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 under a standard flood insurance policy obtained under the program that was subject to a flood.

(b) Type of Information To Be Collected.—All 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;

(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.—

(1) To the Administrator.—Not later than 20 days after the date of the enactment of this Act, each property and casualty insurance company participating in the Write Your Own program shall submit to the Administrator a biennial report under section 205 of the Bunning-Bereuter-Blumenauer Flood In-
"(3) 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 separate claims 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 following: "; and

(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 PROVED 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 PERFORMANCE.—The Administrator shall give priority for funding to activities, to develop grant applications, and to implement grants awarded under this Act that 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 recommendations of the Administrator.

(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 community;"

(vi) in subparagraph (H), as so redesignated, by striking "at the end"; and

(vii) by adding at the end the following new subparagraphs:

"(1) 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 established by the Administrator 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 a timely manner, to communities to identify eligible activities, to develop grant applications, and to implement grants awarded under this Act that 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 recommendations of the Administrator.

(b) ELEIMINATION OF PILOT PROGRAM FOR REPEATED INSURANCE CLAIMS—

(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).

(c) NATIONAL FLOOD MITIGATION FUND.—

Section 1367 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017a) 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 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);";

(2) in subsection (c), by striking “section 1366(1) and inserting “section 1366(1);" the

(3) by redesigning 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 used to offset collections from premium rates for flood insurance coverage under this title.

"(e) ELIMINATION OF PROJECTION FOR LOAN REPAYMENT.—Any amounts made available pursuant to subsection (d) of this section shall be used to repay the National Flood Insurance Fund for assistance provided under this title.

(f) INCREASED COST OF COMPLIANCE COVERAGE.—Section 1304(b)(4) of the
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 ACREDITATION 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 40, Code of Federal Regulations, for levee systems to be recognized on maps created for purposes of the National Flood Insurance Program;

(2) the term ‘‘flood protection structure accreditation requirements’’ means the flood protection structure accreditation requirements established under subsection (b);

(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, 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).

(c) Implementation.—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.

(d) 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.

(e) 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), 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.

(f) 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) Reports—

(1) Review.—The Administrator shall review—

(A) the processes and procedures for determining that a flood event has commence or is in progress;

(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 for determining that a flood event has commenced or is in progress;

(D) 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.

(2) Effective Dates.—Notwithstanding section 136(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, that was purchased or made during the period beginning May 1, 2011, and ending June 6, 2011.

(b) 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, that was purchased or made during the period beginning May 1, 2011, and ending June 6, 2011.

(c) Effective Dates.—Notwithstanding section 136(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, that was purchased or made during the period beginning May 1, 2011, and ending June 6, 2011.

SEC. 132. CLARIFICATION OF RESIDENTIAL AND COMMERCIAL COMMERCE 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 more than one family’’; and

(B) by striking ‘‘shall be made available to every insured upon renewal and every applicant for flood insurance, in respect to any single building, up to an aggregate liability (including such limits 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 to every insured upon renewal and every applicant for flood insurance, in respect to any single building, up to an aggregate liability for contents 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 flood 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 to every insured upon renewal and every applicant for flood insurance, in respect to any single building, up to an aggregate liability for contents of $250,000’’;

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 Assistant 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 become designated as an area having special flood hazards for purposes of the National Flood Insurance Program, unless the determination is made on the basis that—

(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 conditions and guidelines of the Federal Insurance Administration shall be made available so as to enable such information to be used for accuracy at the 95 percent confidence level.

(b) 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 136(d) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(d)) 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 the requirements under section 136(c) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(c)) for flood elevation determinations have been satisfied.
(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 (3), the Administrator shall—

(i) calculate the difference between the reduced risk premium rate and the risk premium rate that was in effect for the area on the date of enactment of this Act; 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 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 apply to a project for which the Administrator has made all reimbursements required under subsection (b)(4).

SEC. 134. ELIGIBILITY FOR FLOOD INSURANCE COVERAGE 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 shall be eligible for flood insurance coverage under the National Flood Insurance Program if—

(A) 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 current risk premium rate that would be chargeable if the flood protection system had been completed.

(2) ADVANCED 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) more than 90 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 as finally determined by the Administrator, or

(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 community has made adequate progress under paragraph (1), the Administrator shall—

(1) take into account—

(A) an estimate of the amount of Federal funds the Administrator has made available under section 61.6 of title 44, Code of Federal Regulations, to or for the community; and

(B) a requirement that, if the Administrator determines that the flood protection system of the community would not 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 determined that a community has 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 project schedule for the reconstruction or improvement of the community is completed, 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 determined that the community has made adequate continuing progress on the reconstruction or improvement of a flood protection system if—

(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 for which the Administrator determined that a community has made a determination under paragraph (1), the Administrator shall—

(A) take into account the losses attributable to repetitive loss structures; and

(B) determine an appropriate risk premium rate for policies that had been issued under the National Flood Insurance Program that are in force.

(5) 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 policyholders currently insured under the National Flood Insurance Program that would be required to increase their risk premium rates in order to reduce the risk to the National Flood Insurance Fund and the Federal National Mortgage Association; and

(2) what effect, if any, the proposed risk premium rates would have on the financial condition of the National Flood Insurance Program.

(6) REPORT ON THE NATIONAL FLOOD INSURANCE PROGRAM.—Not later than 5 years 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 policyholders currently insured under the National Flood Insurance Program that would be required to increase their risk premium rates in order to reduce the risk to the National Flood Insurance Fund and the Federal National Mortgage Association; and

(2) what effect, if any, the proposed risk premium rates would have on the financial condition of the National Flood Insurance Program.
(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. 4016(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 an assessment 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, calculated by theAdministrator as the original 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 foregone premiums 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 INVESTIGATE FOR 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;

(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 terms and conditions 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 such properties;''; and

''(ii) nonhurricane related damage;''; and

''(ii) by striking “;” and inserting “Other-''; and

''(ii) by striking the semicolon at the end and inserting a period;

(E) by redesigning paragraph (4) as paragraph (5);

(F) in paragraph (5), as so redesignated, by striking “;” and inserting “Other-''; and

(G) by inserting after paragraph (3) the following new paragraph:

(4) Placing reinsurance coverage on insurance provided by such program:”;

and

''(4) in section 1366(c)(4) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016);

(E) describes fluctuations in historical reinsurance rates:”;

(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 1355(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. 4051a(a)(2)), by inserting “; including as reinsurance 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 “; after flood insurance coverage”; and

(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

(2) by adding at the end the following:—

(2) PRIVATE REINSURANCE.—The Administrator is authorized to assume a portion of the insurance risk of the National Flood Insurance Program to pay claims.

(3) The Administrator shall conduct an assessment of the ability of the National Flood Insurance Program to pay claims.

(ii) the results of the assessment available to the public.

and

(iii) the results of the assessment available to the public.

and

(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 1335(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 PERSONAL LIVING EXPENSE COVERAGE.

(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;
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 prices such optional coverage at true actuarial rates; 
(4) the impact such optional coverage would have on participation in the National Flood Insurance Program; and 
(5) the fiscal impact such optional coverage would have upon the National Flood Insurance Program.

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 containing the results of the study under subsection (a).

(a) 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, and all conditions, exceptions, and other limitations pertaining to coverage under the subject policy, regardless of the unique insurance product, in plain English, in boldface type, and in a font 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. 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 Federal Government's role in reducing flood-related damages to property;
(3) methods for establishing an affordability framework for the National Flood Insurance Program, including methods to aid individuals who exceed established premium limits 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 costs and benefits to the Federal Government of a flood insurance program with full risk-based premiums, combined with means-tested Federal assistance to reduce the costs to individuals who cannot afford coverage, through an insurance voucher program.

(c) Study Conduct and Submission.—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.

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 in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

(b) Findings.—Congress finds that participation 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) includes an analysis of the study 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(c)(3) (42 U.S.C. 4012a(c)(3)), and inserting "Administrator";
(2) in section 201(b) (42 U.S.C. 4105(b)), by striking "Director's" and inserting "Administrator's";
(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. 4104(e)) is amended by striking "Director's" each place that term appears and inserting "Administrator".

SEC. 143. PRIVATE FLOOD INSURANCE POLICIES.
(a) Definitions.—In this section the following definitions shall apply:

(b) Guidance.—The term "guideline" means, with respect to a State entity, the program, guidelines, or regulation, or guidance.

(c) 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.

(d) Amendments Required.—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, 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 policy to satisfy the mandatory purchase requirements under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4002a), if the private primary flood insurance policy—
(1) is available for sale under the laws of the State in which the private primary flood insurance policy is to be written;
(2) complies with applicable Federal regulations;
(3) State law considerations.—Neither the Guidelines nor the amendments to the Guidelines shall be construed to preempt State insurance law, regulation, or guidance.

(e) Notification.—To the Federal and State Entity 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. Congress finds that the Administrator shall provide the information required under subsection (c), the Federal entities for lending regulation shall train employees to understand and assess the Guidelines under subsection (b).

SEC. 144. TREATMENT OF SWIMMING POOL ENCLOSURES OUTSIDE OF HURRICANE SEASON.

Notwithstanding any other provision of law, the Federal and State entities for lending regulation shall provide the information required under subsection (c) to the Federal entities for lending regulation shall train employees to understand and assess the Guidelines under subsection (b).

TITLES 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. HISTORY OF NATURAL CATASTROPHES.

Congress finds that—

(1) Hurricanes Katrina, Rita, and Wilma, which struck the United States in 2005, caused an estimated $200,000,000,000 in total economic losses; and

(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; and

(5) some insurers are not renewing insurance policies to cover losses from natural catastrophes, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(6) the inability of property and business owners to obtain and afford property and casualty insurance coverage endangers the national economy and public health and safety;

(7) National Flood Insurance Program and other Federal programs to cover losses inflicted by natural catastrophes in the uninsured section of the United States are at risk of a natural catastrophe, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes; and

(8) building codes and land use regulations play an indispensable role in managing catastrophe risks and for paying for losses caused by natural catastrophes, including assessing—

(A) the condition of the property and casualty insurance market and the capacity for providing protection in all regions of the country; and

(B) the costs of natural catastrophes to Federal and State taxpayers;

(9) several amendments to the Flood Disaster Protection Act of 1973 (42 U.S.C. 4021a)

(2) TO LENDERS.—The Administrator and each Federal and State entity for lending regulation shall include the notification required under paragraph (1) in any publication that the Administrator or Federal entity for lending regulation provides to lenders in the United States, published after the date of enactment of this Act.

(3) 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. 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 individuals—

(A) who 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 catastrophe risk, meteorology, seismology, environmental issues, or other pertinent qualifications;

(B) who are 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 Congress in which such member is first appointed.

(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 by a majority vote of all the members of the Commission.

(e) CHAIRPERSON.—The Commission shall, by a majority vote of all 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 market and the capacity for providing protection in all regions of the country; and

(2) the current condition of, as well as the outlook for, the availability and affordability of insurance in all regions of the country; and

(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 catastrophe 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, pooled, reinsurance 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 sections of the American population;

(9) approaches for implementing a public or private reinsurance 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, and residual property and casualty 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 noninsured communities; 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 of 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 risks, 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, payers, 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 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 flood risk mitigation efforts.

SEC. 206. REPORT. (a) In general.—Not later than 9 months after the date of the enactment of this Act, the Council shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representa- tives a final report containing— (1) a detailed statement of the findings and assessments conducted by the Commission pursuant to section 205; and (2) 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 any of 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 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 file any document or record with the Secretary of the Treasury by a vote of a majority of all of the members of the Commission. (c) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—Staff of the Commission may be— (1) appointed without regard to the provi- sions of title 5, United States Code, govern- ing appointments in the competitive service; and (2) paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, for services rendered by members of the Commission or agents of the Commission in their capacity as agents of the Commission.

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(17) the appropriate role, if any, for the Federal Government in stabilizing the property and casualty insurance and reinsurance markets; and

SEC. 205. STUDY AND REPORT.

(1) In general.—The Commission shall study the adequacy of current and proposed rates, the adequacy of rates for the United States as a whole and for insured losses caused by natural catastrophes, including an estimate of the probability of the occurrence of natural catastrophes, and methods that would foster the development of financial products designed to cover natural catastrophe risks, such as risk-linked securities; and

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 mem- bers of the Commission to such subcommit- tees 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 file any document or record with the Secretary of the Treasury by a vote of a majority of all of the members of the Commission.

(4) COVERED DATA.—The term ‘covered data’ means, with respect to a named storm or loss of civil service status or privi- lege.

(2) STORMS OVER COASTAL STATES. (a) Assessing and Modeling Named Storms Over Coastal States. (1) The term ‘coastal state’ in section 304 of the Coastal Barrier Resources 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. 301. SHORT TITLE.

This title may be cited as the ‘Consumer Option for an Alternative System to Allo- cate 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 Pub- lic Health and Quality Care 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.

(2) the appropriate role, if any, for the Federal Government in stabilizing the property and casualty insurance and reinsurance markets; and (3) the level of Federal assistance necessary to the discharge of its duties and responsibili- ties.

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 Allo- cate Losses Act of 2012’ or the ‘COASTAL Act of 2012’.

SEC. 302. ASSESSING AND MODELING NAMED STORMS OVER COASTAL STATES.

(a) Assessing and Modeling Named Storms Over Coastal States. (1) The term ‘coastal state’ in section 3301 of the coastal zone management Act of 1972 (16 U.S.C. 1451 et seq.) means— (A) any coastal state; (B) any coastal waters; and (C) any coastal zone.

(b) Extensions.—Subject to the provi- sions of this section, the term ‘coastal state’ shall include any coastal state, any coastal waters, and any coastal zone.

SEC. 303. ESTABLISHMENT OF THE COASTAL MODEL.

(1) 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 of 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 risks, 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, payers, 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 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 flood risk mitigation efforts.

SEC. 206. REPORT.

(a) In general.—Not later than 9 months after the date of the enactment of this Act, the Council shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representa- tives a final report containing— (1) a detailed statement of the findings and assessments conducted by the Commission pursuant to section 205; and (2) 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.
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 winds in excess of 64 kilometer (40 miles) per hour that develops in the area of the United States National Hurricane Center of the National Oceanic and Atmospheric Administration, or any successor thereof.

(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)(2)(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 using the reported damage, climate, timing, and spatial variations of winds, rainfall, and storm surges associated with a specified 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.

(11) 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 Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall develop and maintain, and the Secretary of Homeland Security may receive consideration for the use of, a computerized model, developed by the Administrator in consultation with the Office of the Federal Coordinator for Meteorology—

(i) to determine the degree of accuracy of a post-storm assessment produced by the Administrator under subsection (a)(7); and

(ii) to subject the Administrator to judicial review.

(B) POST-STORM ASSESSMENT REQUIRED.—

(1) IN GENERAL.—Not later than 540 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall, to the extent practicable, permit other public and private entities to place sensors on such structures to collect—

(i) meteorological data;

(ii) navigation-related data;

(iii) hydrographic data; or

(iv) such other data as the Administrator considers appropriate.

(2) USE OF ACQUIRED STRUCTURES.—

(A) IN GENERAL.—If the Administrator acquires a structure for the placement of a sensor pursuant to subsection (b), and the Administrator shall, to the extent practicable, permit other public and private entities to place sensors on such structures 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).

(3) IN-KIND CONTRIBUTION.—Consideration received under subparagraph (B) may be received in any form the Administrator determines to be appropriate.

(4) USE OF OTHER DATA.—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 paragraphs (1) and (2) with the United States Army Corps of Engineers, the National Oceanic and Atmospheric Administration, or any successor thereof, the United States Geological Survey, or any other public, private, and academic sector entities as the Administrator considers appropriate for purposes of carrying out the protocol established under subsection (a).

(6) 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 Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall, to the extent practicable, permit other public and private 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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall provide information to 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—

(i) such other matters as the Administrator considers appropriate.

(E) The Office of the Federal Coordinator for Meteorology, the National Oceanic and Atmospheric Administration, the United States Army Corps of Engineers, the National Oceanic and Atmospheric Administration, or any successor thereof, the United States Geological Survey, or any other public, private, and academic sector entities as the Administrator considers appropriate for purposes of carrying out the protocol established under subsection (a).

(F) The Director of the United States Geological Survey.

(G) The Office of the Federal Coordinator for Meteorology.

(H) Such public, private, and academic sector entities as the Administrator considers appropriate for purposes of carrying out the protocol established under subsection (a).

(1) IDENTIFICATION OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—

(1) IDENTIFICATION OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—

(A) carry out a survey to identify all Federal, State, and local efforts 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, identify any gaps in the ability of the systems identified under paragraph (1) and 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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services 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—

(i) such other matters as the Administrator considers appropriate.

(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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall provide information to 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—

(i) such other matters as the Administrator considers appropriate.

(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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall provide information to 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—

(i) such other matters as the Administrator considers appropriate.

(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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall provide information to 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—

(i) such other matters as the Administrator considers appropriate.

(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 required for post-storm assessment under subsection (b)(3).

(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Protection, and Domestic and Community Meteorological and Oceanographic Services Act of 2012, the Administrator shall provide information to 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—

(i) such other matters as the Administrator considers appropriate.
(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, 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. 1357. 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 301 of the Coastal Zone Management Act of 1972 (36 U.S.C. 1453).

(4) INDETERMINATE LOSS.—

(A) IN GENERAL.—The term "indeterminate loss" is 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) LIMITATION.—An insurance claims adjuster certified under the national flood insurance program shall only determine 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.

(C) NAMED STORM.—The term "named storm" means any organized weather system with surface 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.

(6) POST-STORM ASSESSMENT.—The term "post-storm assessment" means the post-storm assessment required 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 the Treasury.

(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 Deputy Secretary of Commerce for Oceans and Atmosphere, in consultation with the 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 of the enactment of this Act, the Administrator shall determine and allocate by mathematical formula the property damage caused by flood or storm surge associated with a named storm; and

(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(c)(1) of the Omnibus Public Land Management Act of 2009; and

(B) use relevant data provided on the National Flood Insurance Program Website for each coastal State for which the 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 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 under subsection (B), the Administrator, each time the Act amends 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) 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, as so modified, in 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.

(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, as so modified, in 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.

(C) FUNDING.—Notwithstanding section 12312 of the National Flood Insurance Act of 1968 (42 U.S.C. 4051 et seq.), 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 1213(b)(2)(C) of the National Land Management Act of 2009, for each indemnity loss for which the COASTAL Formula is used pursuant to subsection (c)(2), the Administrator shall notify the policyholder that makes a claim relating to the indemnity loss—

(1) that the Administrator used the COASTAL Formula with respect to the indemnity loss;

(2) a summary of the results of the use of the COASTAL Formula;

(3) CONSULTATION.—In carrying out subsection (b) and (c), the Secretary shall consult with—

(1) the Under Secretary for Oceans and Atmosphere;...

SEC. 1141. SUBTITLE D—Theft of Medical Products

SEC. 1141. SUBTITLE D—Theft of Medical Products

SEC. 1142. SUBTITLE E—Theft of Medical Products

SUBTITLE D—Theft of Medical Products

Subsection (a) applied with respect 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.

Subsection (b) is amended by inserting at the end the following:

"$670. Theft of medical products"

(a)(1) 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 taketh, 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 has expired or been stolen;

(4) with intent to defraud, buys, or otherwise obtains, a pre-retail medical product that has expired or been stolen;

(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; or

(B) involves the use of a deadly weapon;

(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; and

(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 20 years, or both, and if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 20 years; and

(d) If the offense under this section 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.''

Subsection (b) is amended by inserting at the end the following:

"(c) CIVIL PENALTIES.—Whoever violates subsection (a)—

(1) if the offense is a violation of 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.

(b) CIVIL PENALTIES.—Whoever violates 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.

(c) BREAKING OR ENTERING CARRIER FACILITIES.—Section 2117 of title 18, United States Code, is amended by inserting 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 subsection (a) is greater.''

Subsection (d) is amended by inserting 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 section is greater.''

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 Does 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)(1) 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 taketh, 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 has expired or been stolen;

(4) with intent to defraud, buys, or otherwise obtains, a pre-retail medical product that has expired or been stolen;

(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; or

(B) involves the use of a deadly weapon;

(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; and

(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 20 years, or both, and if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 20 years; and

(d) If the offense under this section 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) CIVIL PENALTIES.—Whoever violates 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.

(c) BREAKING OR ENTERING CARRIER FACILITIES.—Section 2117 of title 18, United States Code, is amended by inserting 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 subsection (a) is greater.''

(d) CIVIL PENALTIES.—Whoever violates 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.

SA 2139. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the
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 biologicals, 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 23. 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."
(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 retailer 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 shall be in effect for a period of not more than 3 years.

(c) IN GENERAL.—Any market shortage declared by the President in accordance with this title shall be in effect for a period of not more than 3 years.

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 and proven 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. 12. 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:

(2) by striking subparagraph (3) and inserting the following:

(3) DISCLOSURES NOT AFFECTED.—Nothing in this subsection authorizes any official to withhold, or to authorize the withholding of, any information that is required to be disclosed under paragraph (1).
“(1) names the specified food or dietary supplement sold by the person causing the publication to be distributed;
(2) represents that the specified 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 WARRANTLESS ENRAINTS WITHOUT WARRANTS.

Section 702(e) (21 U.S.C. 372(e)) is amended—

(1) by striking paragraph (1);
(2) by redrafting 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. 111. 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 refuse’’ and inserting “The knowing and willful refuse’’;
(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 “violation’’;
(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 “disclosure’’;
(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’’;
(C) in paragraph (3), by inserting “knowing and willful” before “receipt’’;
(25) in subsection (aa), by inserting “knowing and willful” before “violation’’;
(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 “falsification of a report’’;
(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 “falsification’’;
(38) in subsection (nn), by inserting “knowing and willful” before “falsification’’;
(39) in subsection (oo), by inserting “knowing and willful” before “disclosure’’;
(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 “Forging’’ and inserting “Knowingly and willfully forging’’;
(42) in subsection (rr), by inserting “knowing and willful” before “chasteur’’;
(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 (uu), 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. BURB, 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:

“(O) 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 a 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 shall 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 that changes 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 MDS 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
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May 22, 2012

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 and the DEA, 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 mechanisms as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;
(3) support communications 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.
(b) USE OF ENHANCEMENT GRANT FUNDS.—A recipient of an enhancement grant under the Harold Rogers Prescription Drug Monitoring Program shall provide the databases of the State to comply with the national interoperability standards established under section 1143(a).

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 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.
(b) COST—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; and
(3) a direction of how State prescription monitoring programs could increase the production and distribution of unsolicited reports to prescribers of controlled substances, law enforcement officials, and health and professional licensing agencies, including the enhancement of such reporting through interoperability with other States and related agencies’ 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 1144. 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.—Section 7, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812) is amended by adding at the end the following:

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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. 12. REPEAL OF MEDICAL DEVICE EXCISE TAX.

Subsection (a), (b), and (c) of section 1465 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. ENGEL, Mr. RICHARDSON, Mr. SMITH of Ohio, Mr. INGALA, 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 GENERIC ACT

SEC. 01. SHORT TITLE.

This title may be cited as the “Preserve Access to Affordable Generic 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) As of 2008, 19 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.

(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 (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. PRECISION ACCESS TO AFFORDABLE GENERICs.

"(a) IN GENERAL.—The Federal Trade Commission shall have jurisdiction over any proceeding initiated 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.

"(b) PREJUDGMENT.—

"(1) 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 anti-competitive effects of the agreement.

"(c) 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 relevant patent or statutory exclusivity that would prevent the marketing of such drug,

"(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 entry of the ANDA product 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.

"(d) LIMITATIONS.—In determining whether the ANDA filer has 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 infringes a patent, prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder’s determination under this section.

"(e) 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.

"(f) REGULATIONS AND ENFORCEMENT.—

"(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 593 of title 5, United States Code, regulations implementing and interpreting this section. These regulations shall attempt to prevent 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 in paragraph (2), is located. The filing of such petition 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.

"(g) 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, limit or repeal the authority of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws on other laws relating to unfair competition.

"(h) PENALTIES.—

"(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of any provision of this title 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 and the NDA holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to an agreement under section 1 of the Sherman Act or any provision under subsections (a) and (b) 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, other remedies provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

(b) DEFINITIONS.—In this section:

(1) AGREEMENT.—The term ‘agreement’ means an agreement not to sue, to settle, or to enter into any provision under subsection (a), and the amount of commerce affected; and

(2) 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, the consequences of doing business, and the amount of 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.

(3) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, other remedies provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

(b) DEFINITIONS.—In this section:

(1) AGREEMENT.—The term ‘agreement’ means anything that would constitute an agreement not to sue, to settle, or to enter into any provision under subsection (a), and the amount of commerce affected; and

(2) 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, the consequences of doing business, and the amount of 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.

(3) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, other remedies provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

SEC. 54. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 112(b)(2) of the Prescription Drug User Fee Act (21 U.S.C. 355 note) is amended by—

(1) inserting “the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug User Fee Act and Modernization Act of 2003 (21 U.S.C. 355 note).”.

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Improvement Act, as added by section 30, 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 User Fee Act 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 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 OBSTETRICIAN — GYNECOLOGISTS FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING ANTI-PSYCHOTIC DRUG.

(a) CERTIFICATION.—Section 1121 of such Act is amended by adding at the end the following:

(2) 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 II of the Medicare Prescription Drug User Fee Act (21 U.S.C. 355 note) in June 2003 were submitted as required by section 28 of the Federal Trade Commission Act, as added by section 30, 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 User Fee Act and Modernization Act of 2003 (21 U.S.C. 355 note).
SEC. 399V–7. 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) 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 such payments from the amounts in the covered funds 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 the funds provided 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.

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 a comprehensive 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 such payments from the amounts in 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 the funds provided 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.

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 1 p.m., to conduct a committee hearing entitled ‘‘Implementing Derivatives Reform: Reducing Systemic Risk and Improving Market Oversight.’’

Mr. BROWN of Massachusetts. Mr. President, I ask unanimous consent that the Senate Committee on Intelligence 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.

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.

Mr. HARKIN. Mr. President, I ask unanimous consent that the Senate Committee on Energy and Natural Resources be authorized to meet during the session of the Senate on May 22, 2012, at 12:00 p.m.

Mr. HATCH. Mr. President, I ask unanimous consent that the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 3:30 p.m.

Mr. CARDIN. Mr. President, I ask unanimous consent that the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 3:00 p.m.

Mr. CARDIN. Mr. President, I ask unanimous consent that the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 1:30 p.m.

Mr. CARDIN. Mr. President, I ask unanimous consent that the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 12:30 p.m.

Mr. HARKIN. Mr. President, I ask unanimous consent that the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 11:00 a.m.
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 22; 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.
IN OPPOSITION TO THE VIOLENCE AGAINST WOMEN ACT

HON. SAM FARR
OF CALIFORNIA
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 22, 2012

Mr. FARR. Mr. Speaker, I am sad to rise today in opposition to H.R. 4970, the Violence Against Women Reauthorization Act of 2012.

VAWA has never been a partisan issue until this Congress, and I am disappointed that the safety of women in this country is now a political game to those in charge.

Mr. Speaker, I am a brother, a father and a grandfather.

I want to be a part of a country that believes in protecting and preventing violence towards all people, especially our most vulnerable.

When women and girls feel threatened or are at risk of experiencing violence, it interferes with their ability to pursue an education, employment, or community involvement.

For this reason, I have been a strong supporter of past Violence Against Women bills.

The Violence Against Women Act has been an essential tool in helping to protect victims of domestic and sexual violence and to allow women and girls to pursue the American dream.

First passed in 1994 and reauthorized in 2000 and 2005, VAWA has successfully strengthened enforcement of state and federal anti-violence laws and implemented effective prevention and victim support programs.

Since VAWA was first signed into law, annual incidents of domestic violence have dropped by more than 60 percent.

It has been one of the best tools law enforcement, prosecutors, and community service providers have to help protect and support women who have experienced gender violence. The law also streamlines these community programs, saving states and the federal government billions of dollars.

Unfortunately, the version of the bill before us today reverses many of the modest protections in the original bill.

Even worse, some changes go a step further and outright excludes vulnerable populations such as Native American women, non-citizen women, and LGBT individuals.

Tragically, H.R. 4970 subjects many women to even greater risks of violence and makes it even harder for them to receive the services and programs that should be readily available to them.

Once again, House Republicans are choosing confrontation over compromise.

This Republican bill is opposed by hundreds of groups including law enforcement, civil rights, and faith-based groups and many, many, many of my constituents.

I want only the best for the women in my family and for all of the women in this country.

This bill fails far, far short of the mark.

It does not deserve to be called the “Violence Against Women Act” because it fails to protect the people it claims to serve.

I will be voting against this bill and I urge my colleagues to support all women and reject this terrible legislation.

CONGRATULATIONS TO PRESIDENT MA YING-JEOU ON THE OCCASION OF HIS INAUGURATION

HON. PETE OLSON
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 22, 2012

Mr. OLSON. Mr. Speaker, I want to extend warm congratulations and best wishes to President Ma Ying-jeou for his inauguration on the occasion of the Republic of China’s Centennial National Day. This national holiday commemorates the 1911 Wuch’ang uprising that ended centuries of monarch rule and led to the birth of the Republic of China (Taiwan).

Taiwan and the United States enjoy an important relationship that reflects our two countries’ historical, cultural, and economic ties over the last century. While there is a formal relationship between the two countries, the United States and Taiwan continue to be strong partners in trade, cultural and educational exchanges, as well as cooperation in many other areas. In the last three and a half years, the relationship between the United States and Taiwan has grown even stronger.

Taiwan’s cooperation with the United States in combating global terrorism has earned the trust of the American people and improved our exchanges and enhanced the friendship between our two nations. These relations also include discussions about Taiwan’s military needs. A strong Taipei-Washington relationship is in the best interests of both and the stability of East Asia. Last year, we celebrated the 31st anniversary of the enactment of the Taiwan Relations Act, the cornerstone of the U.S.-Taiwan relations.

Recently, there has been good news about Taiwan’s rapprochement with mainland China. Taiwan has concluded 16 agreements with mainland China and each one is based on the principles of parity, dignity, and reciprocity and ensures that Taiwan comes first for the benefit of its people. I sincerely hope that Taiwan and China will continue to work together and cultivate a future based on respect, democracy, and freedom. Again, congratulations to President Ma Ying-jeou on his second inauguration.

IN HONOR OF THE FAMILIES OF THE ARMED SERVICES

HON. PETE SESSIONS
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 22, 2012

Mr. SESSIONS. Mr. Speaker, I rise today to recognize Albert “Bert” Caswell and the men, women, and families of our Nation’s Armed Services.

Bert has worked as a United States Capitol tour guide for over twenty-five years. He is known throughout the Capitol for his extraordinary work and selfless attitude. After hours, Bert volunteers his time offering Capitol tours to wounded veterans and participants of the Make-A-Wish foundation. He also visits and writes poems for wounded soldiers at Walter Reed National Military Medical Center to lift their spirits and celebrate their heroic nature.

Mr. Speaker, I submit to you a poem, on behalf of Albert, who penned this tribute in recognition of the extraordinary sacrifices and courage of the men, women, and families of our Nation’s Armed Services.

THEY MAKE US WHO WE ARE
(By Albert Caswell)

They make us who we are!
They make us who we are!
For they are the greatest of all shining stars!
As they so make us who we are!
Our loved ones and families
They are the one and all!
The ones who so live with such heartache and pain ...
And such worry, wondering if they shall ever so see us all again ....
Oh yes, they make us who we are!
Quiet Heroes, out across our heartland one and all!
The ones who so live with such heartache and pain . . .
And so face so all of this!
For all of them it is so very hard!
The ones who never had the chance to so say goodbye!
The ones for whom our Lord’s love shall never die!
As they so make us who we are!
The ones who now at our bedside who have so traveled so very far . . .
As we come home from war, half dead and so full of scars . . .
Carried, now upon us all!
Missing arms and legs in all places, as somehow they must face this!
For all of them it is so very hard!
As they so help us to beat down death, and so face so all of this!
As they bless, because they are all in it for the long haul!
Oh how they so make us who we are!
Providing us with the hope and courage, and not letting us so get discouraged!
Where, would we and our nation all so be?
If it were but not for such all of these, who so make us who we are?
Yes, all of our loved ones and families . . .
Who all in us do so believe!
And so make us who we are!
Shining ever so brightly, our nation’s most courageous of all stars!
All with such dignity and faith, as they shine from sea to sea!
As one day up in heaven, they will all so be!
For these are the ones, who have so sent!
So sent, all of their most beloved daughters and sons off to war!
Husbands and Wives, who live with such deep pain so deep down inside!
And all our children who so lie awake at night, and so begin to cry!

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

Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.
Who must live with such fear, day in and night after night!
And all of that death and destruction, that which war does so make!
Unrelenting . . . . our loved ones helping us to rebuild what war has so taken away!
To once again, To So Make Us What We Are!
Just look at those heroes standing there, with such honor and such faith and tears who so care!
Wearing that uniform, with those most courageous hearts that which beat so warm!
Who were so raised by those loved ones, who their souls have so formed!
To make them who they are!
Just, look at all of those husbands and wives, and children who now must so cry
. . . . . . .
Who so sent their loved ones off to die . . . .
For they all so make this Nation, and our Country Tis of Thee who we are!
America’s Shining Stars!
They . . . Make . . . Us . . . . Who . . .
We . . . Are!

NATIONAL BLUE ALERT ACT OF 2012

SPEECH OF

HON. JON RUNYAN
OF NEW JERSEY
IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 15, 2012

Mr. RUNYAN. Madam Speaker, I rise today to offer my support for a bi-partisan piece of legislation that I am a co-sponsor of, H.R. 365, the National Blue Alert Act of 2012.

The Blue Alert system, similar to the “Amber Alert” system used for abducted children, would operate throughout the United States to quickly disseminate information to law enforcement organizations advising them of when an officer has been seriously injured or killed in the line of duty.

Currently, there is no national alert system to distribute this valuable information to law enforcement. In implementing H.R. 365, we can speed up the apprehension of criminals and ensure rapid broadcasting of information to enhance public safety for all of our constituents.

This piece of legislation is deficit neutral and is funded using previously appropriated dollars from the COPS Program. This bill is supported by the Fraternal Order of Police, the Sergeants Benevolent Association, the National Sheriffs’ Association, the National Association of Police Officers, and the Federal Law Enforcement Officers Association.

In observance of National Police Week, I urge my colleagues to support H.R. 365.

HONORING COLIN KANTOR OF THE CARROLL SENIOR HIGH LATIN CLUB

HON. KENNY MARCHANT
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 22, 2012

Mr. MARCHANT. Mr. Speaker, it is with great pride that I recognize Colin Kantor, a member of the Latin Club at Carroll Senior High School, who took first place in the Classical Geography and Monuments competition (Level IV) at the Texas State Junior Classical league convention.

As part of the Junior Classical League, Kantor is among 50,000 students in this worldwide organization. Twenty-two students from the Carroll Senior High Latin Club travelled to participate in the convention held by the Texas chapter in San Antonio in March. The convention hosts a variety of competitions, both academic and cultural, that relate to the ancient Greek and Roman civilizations.

A fourth year student of Latin, Colin entered two Level IV competitions at the convention, one in Roman History and another in Classical Geography and Monuments. He demonstrated excellence and studiousness and took home first place in the Geography category. We are very proud of Colin and thankful to Terra Windham for so ably sponsoring him and leading the Latin Club. I am told that the Latin Club at Carroll Senior High is growing in popularity as a result of its successes, and it impresses me that these young people are taking such an astute interest in a language and culture that has such a venerable heritage.

Mr. Speaker, on behalf of the 24th Congressional District, I ask that my distinguished colleagues to join me in congratulating Colin Kantor on his earning a state title.

IN RECOGNITION OF MR. KENNETH CAPSHAW

HON. SILVESTRE REYES
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 22, 2012

Mr. REYES. Mr. Speaker, I rise today to recognize Mr. Kenneth Capshaw, a fellow El Pasoan and high school band director who has spent his life educating El Paso’s young people and children and instilling in them an appreciation for music. He has also been a member of the El Paso Symphony Orchestra for 30 years, not only extending his knowledge of music to younger generations, but the entire community as well.

Mr. Capshaw has been a band director for over 20 years, 15 of which were spent at Coronado High School. Under his leadership, the Coronado High School band has become one of the most successful band programs in the State of Texas.

Capshaw has been recognized many times for his achievements in music education, including receiving the Lifetime Achievement Award from the John Philip Sousa Foundation and the Meritorious Award from the Texas Bandmasters Association.

Not only is he recognized nationally in the field of music education, but he is highly respected and admired by the music community and scores of young people in El Paso.

Mr. Capshaw has touched the lives of many students in his career. They could be the custodian’s daughter or the surgeon’s son, or have a physical disability. His sole focus was always to develop each student’s musical talents and character, teaching them the values of hard work, responsibility and working together to achieve excellence.

Fine Arts is a subject very important to our children’s education, and many studies demonstrate that students of musical education programs often have higher academic achievement. Music education, particularly when directed by a dedicated and caring music director like Kenneth Capshaw, encourages motivation and teamwork among participating individuals.

Today I recognize Mr. Capshaw and thank him for the many years he has spent educating our children and making beautiful music.
for our community, and I wish him and his wife the best of luck in retirement. God bless you, Mr. Capshaw.

PERSONAL EXPLANATION

HON. BLAINE LUETKEMEYER
OF MISSOURI
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 22, 2012

Mr. LUETKEMEYER. Mr. Speaker, on roll-call No. 254, due to a constituent meeting that went long, I wasn’t able to make this vote.

Had I been present, I would have voted “yea.”

HONORING THE CARROLL SENIOR HIGH SCHOOL WINTERGUARD CHAMPIONS

HON. KENNY MARCHANT
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 22, 2012

Mr. MARCHANT. Mr. Speaker, it is with great pride that I recognize the members of the Carroll Senior High School winterguard for winning first place in the Scholastic Triple-A Purple Division on March 30 in Forney, Texas. In Texas when the members of the colorguard finish their duties with the high school football season, their own season is just beginning as they transition to winterguard competition. From November through March the winterguard practices most days of the week, often hours per day, perfecting the team’s choreography. This year, their centerpiece dance and performance was set to Eva Cassidy’s cover of “Bridge Over Troubled Waters.”

Capping off a season of commendable dedication and hard work, the Carroll winterguard took home first place in the Scholastic Triple-A Purple Division, with a competition in Forney, Texas, where they earned 71.7 points. The students who carried on their school’s strong tradition this year were Captain Nicole Elledge, Lieutenant Captain Mikaela Heming, Lieutenant Captain Mallory Wyatt, Gabrielle Allen, Nick Conard, Ann Dahl, Gabrielle Earley, Maher Gill, Caitlin Gillum, Emma Harding, Kim Hardy, Savanna Hensley, Morgan Howell, Haley Hurlburt, Olivia Jolley, Paige Lepp, and Amy Rasmussen. They were led by director Pam Randall and assisted by Amy Keller.

Mr. Speaker, on behalf of the 24th Congressional District of Texas, I ask all of my distinguished colleagues to join me in honoring the young people of the Carroll Senior High varsity winterguard on their accomplishments in Scholastic Triple-A Purple Division competition.
Chamber Action

Routine Proceedings, pages S3389–S3458

Measures Introduced: Eleven bills were introduced, as follows: S. 3212–3222.

Measures Reported:
- S. 3215, making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2013. (S. Rept. No. 112–168)

Measures Considered:

FDA User Fee—Agreement: Senate continued consideration of the motion to proceed to consideration of S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars. Pages S3389–S3400, S3400–20

A unanimous-consent agreement was reached providing that at 11 a.m., on Wednesday, May 23, 2012, the motion to proceed be agreed to; that a Harkin-Enzi substitute amendment, which is at the desk, be agreed to; and the bill, as amended, by the Harkin-Enzi substitute be considered original text for the purposes of further amendment; and that the Majority Leader be recognized. Page S3422

Measures Read the First Time:

Additional Cosponsors:

Statements on Introduced Bills/Resolutions:

Additional Statements:

Amendments Submitted:

Authorities for Committees to Meet:

Privileges of the Floor:

Adjournment: Senate convened at 10 a.m. and adjourned at 6:27 p.m., until 9:30 a.m. on Wednesday, May 23, 2012. (For Senate’s program, see the remarks of the Acting Majority Leader in today’s Record on page S3458.)

AUTHORIZATION: DEFENSE

Committee on Armed Services: Subcommittee on Airland met in closed session and approved for full committee consideration those provisions which fall within the jurisdiction of the subcommittee, of the proposed National Defense Authorization Act for fiscal year 2013.

AUTHORIZATION: DEFENSE

Committee on Armed Services: Subcommittee on Personnel met in closed session and approved for full committee consideration those provisions which fall within the jurisdiction of the subcommittee, of the proposed National Defense Authorization Act for fiscal year 2013.

IMPLEMENTING DERIVATIVES REFORM

Committee on Banking, Housing, and Urban Affairs: Committee concluded a hearing to examine implementing derivatives reform, focusing on reducing systemic risk and improving market oversight, after receiving testimony from Mary L. Schapiro, Chairman, U.S. Securities and Exchange Commission; and Gary Gensler, Chairman, Commodity Futures Trading Commission.

AMERICAN ENERGY INNOVATION COUNCIL REPORT

Committee on Energy and Natural Resources: Committee concluded a hearing to examine the report produced by the American Energy Innovation Council titled “Catalyzing American Ingenuity: The Role of Government in Energy Innovation” and related issues, after receiving testimony from Norman R. Augustine, American Energy Innovation Council, Bethesda, Maryland; Ethan Zindler, Bloomberg New Energy Finance, Washington, DC; and Jesse D. Jenkins, Breakthrough Institute, Oakland, California.

BUSINESS MEETING

Select Committee on Intelligence: Committee ordered favorably reported an original bill entitled, “FAA Sunsets Extension Act of 2012”.

House of Representatives

Chamber Action

Public Bills and Resolutions Introduced: 1 public bill, H.R. 5853 was introduced.

Additional Cosponsors:

Reports Filed: Reports were filed today as follows:

Revised Suballocation of Budget Allocations for Fiscal Year 2013 (H. Rept. 112–489) and H.R. 5743, to authorize appropriations for fiscal year 2013 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes, with an amendment (H. Rept. 112–490).

Speaker: Read a letter from the Speaker wherein he appointed Representative Bartlett to act as Speaker pro tempore for today.

Chaplain: The prayer was offered by the guest chaplain, Monsignor Stephen Rossetti, Associate Professor, The Catholic University of America, Washington, DC.

Quorum Calls—Votes: There were no Yea and Nay votes, and there were no Recorded votes. There were no quorum calls.

Adjournment: The House met at 10 a.m. and adjourned at 10:05 a.m.

Committee Meetings

No hearings were held.

Joint Meetings

No joint committee meetings were held.

COMMITTEE MEETINGS FOR WEDNESDAY, MAY 23, 2012

(Committee meetings are open unless otherwise indicated)

Senate

Committee on Appropriations: Subcommittee on Department of Defense, to hold hearings to examine the fiscal year 2013 Guard and Reserve budget overview, 10 a.m., SD–192.

Committee on Armed Services: Subcommittee on Strategic Forces, closed business meeting to markup those provisions which fall under the subcommittee's jurisdiction of the proposed National Defense Authorization Act for fiscal year 2013, 9:30 a.m., SR–232A.

Full Committee, closed business meeting to markup the proposed National Defense Authorization Act for fiscal year 2013, 2:30 p.m., SR–222.
Committee on Banking, Housing, and Urban Affairs: Subcommittee on Security and International Trade and Finance, to hold hearings to examine reviewing the United States-China strategic and economic dialogue, 2 p.m., SD–538.

Committee on Finance: to hold hearings to examine progress in health care delivery, focusing on innovations from the field, 10 a.m., SD–215.

Committee on Foreign Relations: to hold hearings to examine The Law of the Sea Convention (Treaty Doc. 103–39), focusing on the United States National Security and Strategic Imperatives for Ratification, 10 a.m., SH–216.

Committee on Homeland Security and Governmental Affairs: to hold hearings to examine the Secret Service, focusing on trust and confidence, 10:30 a.m., SD–G50.

Committee on the Judiciary: Subcommittee on Administrative Oversight and the Courts, to hold hearings to examine protecting our children, focusing on the importance of training child protection professionals, 10 a.m., SD–226.

Committee on Veterans' Affairs: to hold hearings to examine seamless transition, focusing on a review of the Integrated Disability Evaluation System, 10 a.m., SD–562.

House

No hearings are scheduled.

Joint Meetings

Commission on Security and Cooperation in Europe: to hold hearings to examine democratization in the Caucasus, focusing on elections in Armenia, Azerbaijan, and Georgia, and how far free and fair elections have come in the Caucasus, and what the United States can do to promote progress in upcoming elections, 2 p.m., 2203 Rayburn Building.
Next Meeting of the SENATE

9:30 a.m., Wednesday, May 23

Senate Chamber

Program for Wednesday: The Majority Leader will be recognized. The Majority Leader intends to continue consideration of the motion to proceed to consideration of S. 3187, FDA User Fee, and at 11 a.m. the motion to proceed will be agreed to.

Next Meeting of the HOUSE OF REPRESENTATIVES

10 a.m., Friday, May 25

House Chamber

Program for Friday: The House will meet in pro forma session at 10 a.m.

Extensions of Remarks, as inserted in this issue

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