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Senate

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

PRAYER

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

Let us pray.

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

PLEDGE OF ALLEGIANCE

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

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

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

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

The legislative clerk read the following letter:

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

To the Senate:

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

DANIEL K. INOUE,
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 bat-

ting cancer and other life-threatening illnesses.

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

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

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

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

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



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

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

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

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

RECOGNITION OF THE MINORITY LEADER

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

ECONOMIC CHALLENGES

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

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

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

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

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

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

[From Politico, May 22, 2012]

DEMS WAIT BY PHONE FOR OBAMA

(By Manu Raju)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

president since spring 2010 over energy policy.

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

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

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

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

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

[From The Hill, May 21, 2012]

HHS SIGNS \$20M PR CONTRACT TO PROMOTE HEALTHCARE LAW
(By Sam Baker)

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

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

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

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

JACZKO RESIGNATION

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

Jaczko's alleged behavior is unacceptable in any workplace. The fact that it was allowed to persist at a critical agency that oversees the safety of our Nation's nuclear power plants is astonishing. The White House must now move swiftly with a replacement for Jaczko and I urge the Senate to move quickly to reconfirm the nomination of Kristine Svinicki as NRC commissioner before her term expires on June 30th. The only reason her nomination was held up by the White House and the Democrat-led Senate in the

first place was because she had the courage to stand up to a hostile work environment, and to the bully who was responsible for it. Now that Jaczko has submitted his resignation, it's time for the Senate to move forward on Kristine Svinicki.

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

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

I yield the floor.

RESERVATION OF LEADER TIME

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

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

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

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

The legislative clerk proceeded to call the roll.

The ACTING PRESIDENT pro tempore. The Senator from Maryland.

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

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

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

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

NATIONAL SMALL BUSINESS WEEK

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

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

economy rests with our small businesses.

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

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

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

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

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

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

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

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

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

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

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

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

The ACTING PRESIDENT pro tempore. Is there objection?

Without objection, it is so ordered.

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

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

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

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

Taylor Made Transportation Services, which first qualified under the

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

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

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

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

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

With that, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arizona.

THE ECONOMY

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

This is a key discussion to have because how we view this so-called fiscal cliff defines our perspective on how an economy grows and prospers. Edward Lazear, who is a former Chairman of the President's Council of Economic Advisers, recently wrote an op-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 government spending cuts—in other words, austerity—and growth. Their perspective holds that growth is contingent on government spending.

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

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

He goes on:

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

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

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

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

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

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

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

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

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

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

The choice, in other words, between spending cuts and growth is a false choice. If the President is not truly concerned about boosting growth and reversing the trends of the last 3½

years, he should stop presenting this false choice, as he did, for example, at the G8 summit last weekend, where he actually encouraged German Chancellor Angela Merkel and other leaders to embrace what he called a "growth package" modeled in part after his own budget-busting stimulus spending. I hope Chancellor Merkel and other leaders around the world take a very close look at whether the Obama growth package is something they wish to bring home after observing the American economy for the last 4 years.

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

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

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

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

THREE VIEWS OF THE 'FISCAL CLIFF'

(By Edward P. Lazear)

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

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

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

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

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

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

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

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

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

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

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

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

The ACTING PRESIDENT pro tempore. The Senator from Iowa.

LIGHTSQUARED DANGER

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

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

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

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

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

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

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

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

you know me—I did not give up. The FCC's response to me is just another variation on what the Justice Department told me when I started asking questions about Operation Fast and Furious.

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

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

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

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

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

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

I trust the House committee will ensure that the FCC provides those 7,000 or so additional documents. I have al-

ways said if you are hiding something, it is best to get it out in the open, because the longer you stonewall—in this case the FCC—the worse you are going to look when those facts finally come out.

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

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

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

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

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

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

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

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

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, we are now on the motion to proceed, as you know, to the Food and Drug Administration Safety and Innovation Act of

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

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

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

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

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

Again—and I will be pointing out later also—FDA does a very good job of

getting products, both drugs and devices, to market quickly. In fact, of the 154 drugs approved in both the United States and Canada, in a study done by the *New England Journal of Medicine*, 132 were approved here first. So we have not been dragging our heels and FDA hasn't been dragging its heels in terms of getting the job done.

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

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

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

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

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

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

In this sector, as long as we preserve safety standards—which is, what is

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

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

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

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

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

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

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

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

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

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

The assistant legislative clerk proceeded to call the roll.

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

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

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

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

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

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

Nowhere is this approach more necessary than in addressing the drug shortage problem in this country. It is a problem, it is a crisis, it is an outrage. The United States should be embarrassed and outraged that the great-

est country in the history of the world, the strongest on the planet, having developed lifesaving medicines and devoted extraordinary research and development to make those medicines available to the people of this country, still has shortages, crisis shortages in those very pharmaceutical drugs.

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

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

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

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

We are talking about people of great courage and fortitude, such as Susan Block. She is just illustrative. I have her picture here. My office helped her to get a drug called Doxil to treat her cancer because halfway through her chemotherapy treatments for ovarian cancer she arrived at the hospital one day to learn from her doctor that Doxil would no longer be available. She called my office in a panic upon learn-

ing that information. Ovarian cancer causes more deaths than any other cancer of the female reproductive system and Susan was unwilling to settle for half a treatment. She was right, and her doctor supported her and my office supported her in securing an emergency delivery of Doxil for Susan, allowing her to complete treatment.

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

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

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

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

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

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

and across the country because the markets are not working and the government, the FDA, is failing in its responsibilities—under great pressure, perhaps with good intentions, but still not working effectively enough. The President of the United States recognized it when he issued an Executive order that required the FDA to use its current powers of notification more effectively and to refer price-gouging cases to the Department of Justice when there is evidence of them. The markets are not working so there is now a gray market that involves 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 markup, along with Senators FRANKEN, SCHUMER, CARDIN, and KLOBUCHAR, to impose penalties, tough penalties for manufacturers who fail to notify. Notification is fine but it will be less effective if there are no penalties for failure to notify. We may try to walk a balance between enforcement and incentives, but enforcement in this area is critical, and this measure imposing penalties for failure to notify is critical as well.

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

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

Market manipulation must be addressed more effectively and I have proposed an amendment that will stop the gray market so far as it is possible to do, to prohibit market manipulation of drugs that are in shortage and prohibit the distribution of false information. It gives the FTC authority to assess penalties for these actions. I thank my colleagues on the Commerce Committee, Chairman ROCKEFELLER, and

also thank Senator SCHUMER for his leadership, because he has shown a similar commitment to addressing these issues.

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

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

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Louisiana.

CHILD TAX CREDIT

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

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

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

In March of 2009, the Treasury Department said:

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

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

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

I urge all of us to come together in a straightforward, commonsense, bipartisan way to fix this problem. The IRS and the Treasury Department have told us that the fix is simple, and it is clear. We simply need to mandate that folks applying for the credit use valid

Social Security numbers. That will cut off the fraud, and that will cut off \$4.2 billion going improperly to illegal alien families. It will not cut off the benefit going to anyone who deserves it under the law.

UNANIMOUS CONSENT REQUEST—S. 577

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

The PRESIDING OFFICER. Is there objection?

The majority leader is recognized.

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

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

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

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

The PRESIDING OFFICER. Objection is heard.

The Senator from Louisiana.

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

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

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

If I could bring that point up through the Chair.

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

The PRESIDING OFFICER. The Senator from Louisiana.

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

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

The PRESIDING OFFICER. The Senator from Alabama.

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

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

In fact, he said in his report:

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

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

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

people who work in America end up not paying income tax, but they still get a check from Uncle Sam for \$1,000 per child.

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

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

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

The PRESIDING OFFICER. The Senator from Louisiana.

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

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

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

Again, in March 2009 the Treasury said:

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

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

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

In fact, this is what we do with regard to the earned-income tax credit.

We require a valid Social Security number for that separate tax credit. We are simply applying that valid fix to this different tax credit.

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

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

The PRESIDING OFFICER. The Senator from Alabama.

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

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

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Louisiana.

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SESSIONS. Mr. President, to conclude, I think the American people are unhappy with their leaders. They feel as though the money they have sent here is not being well spent, is not being watched closely enough. We have a big judicial conference for the second year—since 2010, the second time—to go spend \$1 million on a resort conference in Maui. We have the Solyndra loans going out to cronies that are not being paid back in any way. We have the General Services Administration

having a big party out in Las Vegas with hot tubs and magicians and so forth. We have no budget for three consecutive years in the U.S. Senate. And what are we hearing from many of our leaders here in Washington? Well, we have a problem, American people. We have too big a debt. Send us more money. Send more money. We don't have enough. We are borrowing 40 cents of every dollar we spend. Send more money.

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

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

TRIBUTE TO THOMAS HUDNER

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

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

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

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

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

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

Just a few years after the racial integration of the U.S. military, Hudner

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. President, I yield the floor.

RECESS

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, I thank the majority leader for bringing up this bill. He and the Republican leader have put on the floor a piece of legislation that affects nearly every American family. This will not have the fireworks some things we do have, because we have a lot of agreement on it, which is one reason it is on the floor. It has gone through the com-

mittee. Senator HARKIN and Senator ENZI have worked carefully with all of the Republicans, all of the Democrats on the committee, and many other people on a complex piece of legislation for a year, to bring to the floor the Food and Drug Administration Safety and Innovation Act—a bill that is likely to succeed.

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

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

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

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

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

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

We are reauthorizing two user fees. These things have absurd names. The

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

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

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

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

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

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