a Presidential election year, we continue to confirm consensus district judge nominees. We have now confirmed 151 nominees of this President to the district and circuit courts. We also have confirmed two Supreme Court nominees during President Obama's term.

I have heard some Members repeatedly ask the question, ''What is different about this President that he has to be treated differently than all these other Presidents?'' I won't speculate as to any inference that might be intended by that question, but I can tell you that this President is not being treated differently than previous Presidents. By any objective measure, this President has been treated fairly and consistent with past Senate practices.

For example, with regard to the number of confirmations, let me put that in perspective for my colleagues with an apples-to-apples comparison. The last time the Senate confirmed two Supreme Court nominees was during President Bush's second term. And during President Bush's entire second term the Senate confirmed a total of only 119 district and circuit court nominees. With Ms. Rosenbaum's confirmation today, we will have confirmed 32 more district and circuit nominees for President Obama than we did for President Bush in similar circumstances.

During the last Presidential election year, 2008, the Senate confirmed a total of 28 judges—24 district and 4 circuit. Today, we will exceed that number, as well. We have already confirmed 5 Circuit nominees, and this will be the 24th district judge confirmed this year. Those who say this President is being treated differently either fail to recognize history or want to ignore the facts.

After graduating from the University of Miami School of Law in 1991, Judge Rosenbaum worked as a trial attorney for the Federal Programs Branch of the Department of Justice. Her practice involved defending the constitutionality of Federal statutes and agency programs. In September 1995, she joined the Independent Counsel Office's investigation of former U.S. Secretary of Commerce Ronald Brown. She served as staff counsel, participating in the criminal investigation and providing advice to other team members. Upon closure of the investigation, Judge Rosenbaum joined the law firm of Holland & Knight LLP as an associate. While there, from 1996 to 1997, she worked on a variety of civil matters, including Federal employment law. Judge Rosenbaum then accepted a position as a law clerk for Judge Stanley Marcus on the U.S. Circuit Court of Appeals for the Eleventh Circuit, where she worked from January to October 1998.

After her clerkship, Judge Rosenbaum became an assistant U.S. attorney. She specialized in criminal prosecutions such as securities fraud, bank fraud, identity theft, tax fraud, telemarketing fraud, health care fraud, internet fraud, and computer crimes. In 2002, she became the chief of the Economic Crimes Section for the Central Division, Fort Lauderdale, which gave her supervisory responsibilities over 8 to 10 other assistant U.S. attorneys. She held that title until her appointment as a magistrate judge in 2007.

In 2007, the U.S. district judges for the Southern District of Florida appointed Judge Rosenbaum to be a U.S. magistrate judge. As magistrate judge in the District of Southern District of Florida, she manages all aspects of the pretrial process in civil and criminal cases: conducting evidentiary hearings, ruling on nondispositive motions, making reports and recommendations regarding dispositive motions, and issuing criminal complaints, search warrants, and arrest warrants.

The ABA Standing Committee on the Federal Judiciary unanimously rated Judge Rosenbaum as ''well qualified.''

Mr. NELSON of Florida. Mr. President, our Nation faces an alarming judicial vacancy rate. I am grateful that today we will be voting to confirm U.S. Magistrate Judge Robin Rosenbaum to fill a judicial emergency in the Southern District of Florida for a Federal district judgeship. She earned her undergraduate degree at Cornell, her law degree from Miami. She began her legal career in the U.S. Attorney General's Honors Program where she worked as a trial attorney in the Federal Programs Branch of the Civil Division. She has worked in private practice at Holland & Knight and as a law clerk to Judge Stanley Marcus, U.S. Circuit Court Judge for the 11th Circuit Court of Appeals, and she has worked as an Assistant U.S. Attorney down in the Southern District of Florida.

Our State has a great tradition of bipartisan support for our Federal judicial nominees going back a couple of decades. Of course, through this judicial nominating commission, she has come forth with their stamp of approval. The two Senators from Florida agree. I am happy to recommend her to the Senate.

I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The question is, Will the Senate advise and consent to the nomination of Robin S. Rosenbaum, of Florida, to be U.S. District Judge for the Southern District of Florida.

The clerk will call the roll.

The assistant bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from West Virginia (Mr. ROCKEFELLER), the Senator from Colorado (Mr. UDALL), and the Senator from Virginia (Mr. WEBB) are necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Utah (Mr. HATCH) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 92, nays 3, as follows:

[Rollcall Vote No. 167 Ex.]

YEAS—92

Akaka	Feinstein	Merkley
Alexander	Franken	Mikulski
Ayotte	Gillibrand	Moran
Barrasso	Graham	Murkowski
Baucus	Grassley	Murray
Begich	Hagan	Nelson (NE)
Bennet	Harkin	Nelson (FL)
Bingaman	Heller	Portman
Blumenthal	Hoeven	Pryor
Blunt	Hutchison	Reed
Boozman	Inhofe	Reid
Boxer	Inouye	Risch
Brown (MA)	Isakson	Roberts
Brown (OH)	Johanns	Rubio
Burr	Johnson (SD)	Sanders
Cantwell	Johnson (WI)	Schumer
Cardin	Kerry	Sessions
Carper	Klobuchar	Shaheen
Casey	Kohl	Shelby
Chambliss	Kyl	Snowe
Coats	Landrieu	Stabenow
Coburn	Lautenberg	Tester
Cochran	Leahy	Thune
Collins	Levin	Toomey
Conrad	Lieberman	Udall (NM)
Coons	Lugar	Vitter
Corker	Manchin	Warner
Cornyn	McCain	Whitehouse
Crapo	McCaskill	Wicker
Durbin	McConnell	Wyden
Enzi	Menendez	

NAYS—3

DeMint	Lee	Paul

NOT VOTING—5

Hatch	Rockefeller	Webb
Kirk	Udall (CO)	

The nomination was confirmed.

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid upon the table, and the President will be duly notified of the Senate's action.

LEGISLATIVE SESSION

The PRESIDING OFFICER. The Senate shall resume legislative session.

RECESS

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

Thereupon, at 12:30 p.m., the Senate 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 OF 2012—Continued

The PRESIDING OFFICER. For the information of the Senate, cloture having been invoked on the motion to concur in the House amendment to S. 3187 yesterday, the motion to refer fell, being inconsistent with cloture.

Under the previous order, there will be 6 hours 15 minutes of debate, with 2 hours controlled by the Senator from Iowa, Mr. HARKIN; 4 hours controlled by the Senator from North Carolina, Mr. BURR; and 15 minutes controlled by the Senator from Kentucky, Mr. PAUL.

The Senator from Iowa.

Mr. HARKIN. Mr. President, again, we are on the Food and Drug Administration Safety and Innovation Act of 2012. As the chair just said, we have 6 hours 15 minutes of debate time. I am hopeful we don't utilize it all and that we can vote on this sometime later this afternoon.

We just considered this bill in the Senate a few weeks ago and passed it 96 to 1. Following the conference with the House, the House passed the bill unanimously last week. Today I trust that we will finish the job.

I am genuinely proud of this legislation. It will ensure that the FDA has the resources to speed market access to drugs and devices while continuing to ensure patient safety. For the first time, it will make new resources available to allow the FDA to clear its backlog of applications for generic drugs, which will help ensure that patients have access to less expensive medications. It will make sure the FDA has the funds to prevent there ever being a backlog in applications for biosimilars. These resources are vital to FDA's ability to do its job, to the medical products industry's ability to make these products and, most importantly, to patients who need both access to drugs and devices, and assurances that they are indeed safe.

This legislation has benefited from input from a diverse range of interested parties, Senators on both sides of the aisle, our colleagues in the House, industry stakeholders, consumer groups, and patient groups.

Over 1 year ago the parties started bringing policy ideas to the table. We worked together in bipartisan working groups to reach consensus on these policy measures. Where we could not achieve consensus, we didn't allow those differences to distract us from the critically important goal of producing a bill that could be broadly supported. As a result of this bipartisan process, we have a bill that advances our shared goals of patient safety, patient access, a well-functioning FDA, and strong and viable American businesses. We streamlined the device approval process while also enhancing patient protections. We modernized FDA's authority to ensure that drugs and drug ingredients coming to the United States from overseas are safe and to ensure that our domestic companies compete on a level field with foreign ones. We addressed the critical problem of drug shortages. We helped spur innovation and incentivized drug development for life-threatening conditions. We reauthorized and improved the incentives for studying drugs in children.

Finally, we increased accountability and transparency at FDA. So the bill strikes a balance. It will help keep our regulatory system in pace to adapt to technological and scientific advances. It will create the conditions to foster innovative advances in medical technologies. Again, it will do all of this without losing sight of the most important function of the FDA—ensuring patient safety.

So it has been a long road leading up to this moment. We have been working on this bill for well over 1 year and 3 or 4 months with the help of Senators on and off the committee.

Again, I thank my colleague, the ranking member of the Health Committee, Senator ENZI, for all of his diligent and hard work and that of his staff for helping to bring all the different parties together and making sure we had a consensus bill that responded to all of those inputs.

So we have had a great collaboration. I think we have an excellent bill. Again, I am hopeful we can have our comments and discussions this afternoon, but I urge all my colleagues to vote today to pass the FDA Safety and Innovation Act. It is critically important to the agency, the industry, and to the patients we get this done. This will be the final step.

As I said, the House passed it unanimously. If we pass it today, it can go to the President for his signature as soon as we pass it this afternoon.

Mr. President, I yield such time as he may consume to my good friend and colleague and ranking member, Senator ENZI.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the chairman of the committee. I thank him for his kind words, but I also thank him for his leadership on this issue. We have had a great teamwork effort both between the Senators and between the staff. This isn't something that just came together a couple of weeks ago. This is something that has been worked on for about 1½ years, with pretty constant meetings on Fridays of all of the interested groups and then stakeholders. It takes a tremendous amount of work to put something like this together and have it be in a bipartisan way like this. It is largely because it came to committee.

In committee we took a look at all of the amendments that were suggested, we got the people together who had very similar amendments, and they usually were able to work out something to satisfy everybody in that instance, and we came up with a bill. As Senator HARKIN mentioned, it passed 96 to 1. Anytime we get something to pass, it is kind of a landmark success. But when we get something that bipartisan, it is even more landmark.

We have been trying to get this bill wrapped up before the Supreme Court decision came out on health care. The reason we have been trying to do that is, who knows what it is going to say or what kind of ideas people will come up with when that happens. This is a group of 100 idea generators, so we wanted this cleared up by that time. We are on a path to get that done right now and a path that will keep the people employed who are taking a look at new drugs and devices and generics and biosimilars and continue to get those on the market so people will have the latest innovations.

One of the things we included in the bill was some use of foreign clinical trials if they were approved by the FDA, and that should even speed up the process. Of course, when we went to conference there were a lot of things people wanted to have that they brought up as amendments. It is very critical in the bill, and we get some of them and we don't get others.

I know Senator ALEXANDER played a huge role; he had seven items in the bill and we got six of them. Senator BURR had 12 items in the bill, and we got 11 of them. I have to mention, of course, that the one we did not get is a particularly important but particularly difficult issue that is going to take more time to get worked out. It is one that deals with drug distribution security, and that is something we cannot avoid. We have to do it. But it is going to take longer to work that out. It deserves some extra time and some more understanding on both sides of the aisle on that one and in a number of different States. It doesn't just involve the Senate; it doesn't just involve the drug companies; it also involves the whole chain that these things have to go through, including the local pharmacist whom we don't want to overload with work, and the people who have to transport these drugs whom we don't want to overload with work or make it extremely complicated when they cross different State lines and have to do different kinds of reporting.

Senator ISAKSON had four amendments, and we were able to get three of them. Senator PAUL had two, and we got one. Senator HATCH had six, and he got all of them. Senator MCCAIN had two, and we got one. Senator ROBERTS had two, and we got both of those. Senator MURKOWSKI had two, and we got both of those. Senator KIRK had two, and we got one of those. Senator GRASSLEY had two, and we got one of those. Senator PORTMAN had two, and we got both of those. And Senator COBURN had two, and we got one of those. Senator CORKER had two, and we got both of those.

So there are a lot of things we did on the Senate side that became possible on the House side. There are a number of things they did on the House side that we couldn't agree with on this side either. But we did reach agreement—and we reached it in pretty much record time. We now have a bill that can go ahead and be passed and go to the President for signature to assure that the level of safety we have in our drugs not only continues but improves, and drugs can get on the market faster than they had before by streamlining the process and also making sure there are better foreign inspections so the ingredients that go into the drugs don't cause problems.

So this legislation reauthorizes the Food and Drug Administration's user

fee program, and it ensures that Americans get better access to safe innovative medicines and medical devices. It will make significant changes. It will improve the FDA's review and approval of new drugs and devices.

Unfortunately, FDA's current process for reviewing and approving medical devices too often creates delay and unpredictability. This in turn threatens patient access to the best possible treatments for their conditions. In some cases, this has forced American patients to travel overseas to obtain access to lifesaving new devices that FDA has not approved in the United States.

The bill goes a long way toward solving these problems and makes the most significant changes to the law of governing FDA's review of devices in decades.

This bill will speed the approval of devices by reducing the redtape associated with the ''least burdensome'' standard that FDA uses to approve such devices. The bill will also make it easier for FDA to approve devices for patients with rare diseases who might not otherwise be able to have their conditions treated most effectively. It will also enable FDA to expedite safety determinations, to resolve appeals, and to improve their postapproval surveillance activities to detect problems as they occur. It is not good enough to get them approved, we also want them watched after they are approved, and this will do it.

The bill also contains important reforms to foster drug innovation and patient access to new therapies. It modernizes the accelerated approval pathway for drugs to reflect advances in science over the past 20 years. It formalizes a new process to expedite the development and approval of breakthrough therapies. These changes are particularly important for patients with rare diseases where there are no therapies available, and it is not feasible or ethical to require large conventional clinical trials.

Nobody wants to be the one who is a test case when there might be something that would work for them, and there aren't the sizes of the populations to do the conventional clinical trial anyway. The patient community strongly supports these improvements because these will save lives.

The bill also contains important reforms that will help mitigate the problems associated with drug shortages. It will require better coordination within FDA as well as the other Federal agencies such as the DEA. It will also allow FDA to move faster, to take actions, and to address shortages through expedited reviews and approvals.

The bill also makes important changes to how FDA uses Risk Evaluation and Mitigation Strategies, REMS. REMS play a critical role in protecting patients and public health and this bill includes a provision that clarifies the process for modifying REMS—especially with regard to minor modifications.

The provision in the bill being passed today does not change Congress' expectation that a non-minor modification will generally be based on the best available science including an assessment demonstrating that the modification is necessary or appropriate. Nor does the clarification indicate that a modification should be approved if it would reduce the REMS' effectiveness in addressing the drug's known risks.

The bill follows what I call the 80 percent rule. When we focus on 80 percent of the issues on which we can reach agreement rather than focusing exclusively on the parts and the issues we can never resolve, we can achieve amazing results. Over 1 year ago staff began to work on identifying the 80 percent. A group of staff from Republican and Democratic offices on the Health, Education, Labor, and Pensions Committee began a series of standing meetings and proceeded to meet every week for several months. They met with stakeholders and discussed policy solutions that each member thought would solve the problem.

After much discussion of the benefits, costs, and possible unintended consequences, members agreed on a list of policy concepts. If there was not a consensus on a particular policy, it wasn't included. This is the 80 percent rural in action.

As this process has progressed, my staff also met with the Republican staff on the Health Committee for at least 2 hours every week to keep them informed and to seek their input. I also personally met with the members of the committee before markup to ensure I understood their priorities.

This bill reflects the work of every member of the Health, Education, Labor, and Pensions Committee. All of them have at least one provision included in this legislation. Many members of the committee worked with us to find consensus measures that addressed their priorities as well.

As I mentioned, not everyone got everything they wanted. We did, however, find the 80 percent of each solution that we could all agree would help solve the problem, and the bill passed the committee by a voice vote. This legislation could be a model for how the process can and should work regardless of the political environment. We followed this model as we transitioned from the committee process to the Senate floor. We worked with members who filed amendments in committee to address some of the concerns in the manager's amendment. We also worked with Members who filed amendments on the Senate floor.

We did the same thing in our discussions with the House. You can see that the results are very positive. We preserved and we improved policies to foster drug innovation and patient access, and to promote accountability and transparency at the FDA. We also made significant improvements to the Senate's medical device reforms for startup and emerging growth companies, and with respect to the 510(k) process.

We thank Senator HARKIN for his tireless effort on this bill. I know he spent countless hours and attended dozens of meetings, working with Senators and stakeholders and advocates to address their concerns. This bill would not have had such broad bipartisan support without all of his work.

Senator HARKIN's staff has also worked tirelessly on this bipartisan bill. Their knowledge, professionalism, their graciousness were instrumental in addressing all of the issues in this bill. They worked many late evenings, they worked through weekends, they worked through countless working group discussions to be able to get the bill where it is today.

Specifically, I want to recognize Elizabeth Jungman, Bill McConagha, Kathleen Laird, and Kate Wise for all their work. I thank Pam Smith, Senator HARKIN's staff director, for her leadership getting this bill to the finish line. I especially want to recognize Jenelle Krishnamoorthy, whose organization and diplomatic skills helped us resolve the most difficult challenges and made sure that the priorities of all the members of the committee are reflected in the bill.

I also wish to thank the staffs of the Legislative Counsel, the Congressional Budget Office, and the Federal Drug Administration for all of their technical assistance. Again, there are people in those groups who had to work through the weekends when we were finishing up.

Finally I would thank my staff—Keith Flanagan, Melissa Pfaff, Grace Stuntz, Katy Spangler, Rob Walton, and my health policy director, Chuck Clapton.

I would be really remiss if I didn't thank my staff director Frank Macchiarola for his work on this bill, especially as the bill progressed through the HELP Committee, the Senate floor, and discussions with the House. My staff has been working around the clock for many days, for weeks, and for months. I sincerely appreciate their dedication to getting this bill passed and for helping to work with the 80-percent rule.

I urge my colleagues to support this bipartisan bill that makes important changes to the FDA and I ask them to support this process that expedites getting the conference done. We will have a real and meaningful impact on millions of American patients.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. Mr. President, I wish to start off by thanking the chair and the ranking member for the great work they have accomplished with what has always been a very delicate piece of legislation. Their staffs have been tireless on both sides, trying to work out differences, and we would not be here today if it were not for their commitment to this legislation.

Let me say to the chair and the ranking member, I plan to go on for some time. If I were you, I would take the opportunity to leave for a while because I will go for an hour or two or maybe three. And it is not all going to pertain specifically to this legislation, but I have a lot to say because I have heard some of the opening statements. I have heard statements such as ''our goal is to finish before the Supreme Court.'' I have a question: Why? Why a crucial piece of legislation that affects so many Americans and so many patients around the world—why did it have to be done before the Supreme Court? I am not sure anybody can give an answer, but somebody started that as a goal and it sort of was adopted.

I heard the legislation was accomplished at record speed. I don't see that as something to herald. Speed is indicative of something that we rushed our way through. I know on behalf of the chairman's staff and the ranking member's staff, they have been working on this for a long time. So has my staff. But from a standpoint of when we marked up the legislation and came to the floor—how fast we went to the floor—we did it because there was an understanding that we were going to try to hold the Senate product together.

I don't want to take issue with the numbers. I had two amendments that were dropped in conference so I am not sure how I had 12 and got 11 but, regardless, the question we are here to answer, the purpose of this legislation, is that this is supposed to drive innovation in America and bring lifesaving drugs, devices, and biologics to patients—here in America first, but around the country, around the world. That is the goal behind this legislation.

I have to take issue with my ranking member. I don't think the 80-percent rule applies to health care. I can't look at a patient and say: If we can get 80 percent of the right policy, I am going to feel good. If I am in the 20 percent that is left out, I am going to be really pissed off.

One of the reasons our health care costs are so high today is that we have been able to innovate as a country to where we maintain disease extremely well. But we are right on the cusp of being able to cure things such as breast cancer and diabetes. It is not going to be cheap. It is not going to be fast. You are not going to find it in the 80-percent category. You are going to find it in the 20-percent category. It is going to take a while. It is going to take people investing capital and companies that are committed to their shareholders that they are not going to have the returns because they are invested in something important and that is the long-term future of our country and our country's health.

That is what I see in a 5-year PDUFA bill. This is not a 1-year reauthorization of something. Granted, this is not a piece of legislation that this committee drafted from scratch. It is important that everybody understands that for this legislation, in the negotiations between drugs, devices, biologics, generics industry with the Federal Drug Administration, there is not a Member of Congress and no staff of Congress in the room as they negotiate what fees they are going to pay to the FDA to actually process their applications. So the focus of this committee was to look at what happened in the negotiations and try to figure out how could we make this bill better—how could we assure ourselves there was a level of transparency we could understand, that the negotiations they had entered into in fact benefited American patients.

If this doesn't benefit the health care costs and the health care of Americans, then we have missed the mark. The whole objective is to put America in a better position after the passage of this bill.

I will be boring because some of what I am going to talk about a lot of people in this institution know. But I am not sure the American people understand the background that is here. The Federal Drug Administration is responsible for assuring the safety and efficacy and the security of human and animal medical products. One element of FDA's statutory mission is to promote the public health and the FDA accomplishes this mission in part by timely—timely—approving lifesaving, life-enhancing innovations that make medicine safer, more effective and in many cases more affordable.

FDA's broad regulatory authority crosses a range of products and has resulted in the agency overseeing products that amount to 25 cents of every dollar of the U.S. economy. Let me say that again. The FDA regulation extends to 25 cents of every dollar spent in the U.S. economy. Therefore, the FDA's review and decision process not only impacts our Nation's patients and innovators, their work has a significant impact on many sectors of our Nation's economy. As consumers and patients, the American people have serious interests in assuring that the FDA is accountable, transparent, efficient, and making sound decisions in as timely a fashion as possible.

You see, that is why I am on the floor today. If the goal is to have transparent, efficient, sound decisions in a timely fashion, you don't rush through it. You make sure that there is a matrix in place—not one that was designed by the agency and not one that was designed by the industry, but one that is designed by the body that is responsible to do oversight over Federal agencies, the Congress of the United States, the HELP Committee. It is our job. That is why concerns about timeliness and predictability of FDA's regulatory process must be taken seriously and they must be addressed.

Unfortunately, too often Congress is guilty of not paying close enough attention to how well things are working or not working at the FDA on behalf of the patients, the very people for whom the most is at stake. Every 5 years, drug and device industries negotiate their user fees that are then sent to Congress with the expectation that we will quickly act upon them to ensure the continuity of the agency. Let me assure you, this year is no exception. They dropped these agreements on Congress's lap and said: Would you pass these as quickly as you can with no changes? And to their credit, the chair and the ranking member said: No, Congress has a role to play. And staff has had tremendous input into what the final product was.

Unfortunately, rushing the bills through the House and the Senate has resulted in bipartisan track-and-trace provisions not being included in the bill we have before us today. As the ranking member said, I am very disappointed that these important bipartisan provisions were sacrificed as the expense to attain speed. I understand the difficulty of the lift. I acknowledge that to my colleagues and to their staff. But I also question how hard we tried, on an issue that we knew going in was tough. There is no such thing as spending too much time when it comes to getting something as important as drug distribution security right.

I assure all my colleagues that my friend from Colorado, Senator BENNET, and I will continue to work together to get these important provisions done. I might add, I have had the commitment from the chair and the ranking member to work with us on other legislation to try to address this.

But let me say today, it will not be any easier than it is right now. It may be tougher then because this was a vehicle that had to go, therefore people would have swallowed a lot more that is in this bill.

As my colleagues know, FDA and industry tell us not to make any changes because it would ''open up the agreement.'' Think about that. The industry and the FDA told Congress don't put anything else in here because we would consider that as opening up our agreement.

When did Congress become so irrelevant that a Federal agency would suggest that we not get involved? Yet it requires our passage for this to go in statute.

I have explained before, Congress is told to tiptoe around the agreements and we focus our efforts on the belt-and-suspenders policies to complement the agreement. This does not make for the most consistent and deliberative process in considering how Congress can work with FDA and industry to strengthen and improve FDA's drug and device work on behalf of our Nation's patients, but this is the process Members have to work within, which is why it is so important to assure that the right policy riders, including transparency and accountability, are included in the final package.

One thing that has been made quite clear over the past few years is the importance of FDA reporting on the right

matrix. I can predict with some confidence, since this is a 5-year bill, we will be here 5 years from now and hopefully there will be at least one Member of the Senate who steps up and says: How did the FDA hold up against what they said they were going to do in the agreements?

That is at the heart of transparency and accountability. If we do not have a matrix established that everyone understands here is where we are and here is where we promised we would get to, then how in the world 5 years from now do we measure this? How do you know then that if you raise the user fees, that it is justified, that the beneficiary of it is the American patient? I am going to say that is candidly obvious to everybody listening. When drug companies, device companies, biologic companies, generic companies pay more money to get their application approved, who pays for it? The consumers. The people who buy the drugs, use the devices, and buy the generics. This is the first time we have ever had a user fee for generic pharmaceuticals. Generics were called that because generics were created after the patent life expired so we could bring low-cost products to the market.

What are we doing? We are creating generic user fees which will raise the generic price for the American people. It may alter the fact whether it is cheaper for a person to pay for their generic prescription or whether it is cheaper to have their copayment do it on their insurance card. That is the reality of what we are dealing with. I am not suggesting it is bad, but why would we rush through it without understanding what the impact is? That is where we are today.

Reporting only on the negotiated user fees performance goals agreed to by the industry and the FDA has not provided a complete picture of how well the FDA is working to fulfill its mission on behalf of patients. The bottom line is what gets measured gets done. So it has to be measured.

In the Wall Street Journal op-ed earlier this year, former FDA Commissioner Andy von Eschenbach highlighted what is at stake if Congress does not get the user fee reauthorization package right and fix the underlying problems at the FDA. He writes:

> The stakes couldn't be higher for our health. The U.S. biomedical industry is one of the crown jewels of the American economy. It employs about 1.2 million people directly and over five million throughout its supply chain, with a total output of $519 billion in 2009 . . . Many of the firms are among the world's most innovative: From 2001 to 2010, the Milken Institute report shows, U.S.-based companies produced nearly 60% of the world's new medicines, up from 42% the previous decade.
>
> But U.S. firms won't continue to lead unless the FDA retains its role as the world's ''gold standard'' for evaluating new medical products.

Many people establish the gold standard as being the hurdle they have to pass in order to be approved. The gold standard is also how difficult the process is that they have to go through, and will the capital be there to finance the research and development so approval is something they see as a light at the end of the tunnel. These all have to be weighed in the policies they put in place, and I will say we have come up somewhat short.

Last year the National Venture Capital Association released a report that underscores America's risk of losing its standing as the world leader in medical innovation. Their survey clearly showed that the FDA's regulatory challenges, the lack of regulatory certainty, the day-to-day unpredictability, and unnecessary delays are stifling investment in the development of lifesaving drugs and devices. Instead of deterring investment and innovation in lifesaving treatments such as cardiovascular disease, diabetes, and cancer, we should accelerate it. Instead of deterring that capital to come in, we should be finding policies to accelerate that capital to chase cures in heart disease, diabetes and cancer and work with America's innovators on behalf of patients who are depending on the next breakthrough drug or device.

Our Nation's health care system is unsustainable. We all agree we must lower health care costs in America. Predictable regulatory pathways that facilitate innovative medical products that reach patients in as timely a manner as possible is key for lowering our health care costs. This survey is another serious call for the need to restore regulatory certainty and predictability at the FDA.

As we comb through this bill, we see the two amendments that were voted and accepted in the Senate markup of the bill were dropped and discarded because somebody was too concerned with requiring too many reports. There is a reason we get granular with what we put in legislation and, more important, what we require an agency to produce. Predictable regulatory pathways that facilitate innovative medical products reaching patients in a timely manner will lower our health care costs.

It is clear the FDA's global leadership in innovation is at risk. A 2011 report by the California Healthcare Institute and the Boston Consulting Group highlighted this point. The report found that in recent years the environment for medical innovation has deteriorated and the most critical factor has been the FDA, the Food and Drug Administration. Let me repeat that. The report found the environment for medical innovation has deteriorated and the most critical factor has been the Food and Drug Administration. The report states:

> . . . for the Agency's policies and activities exemplify President Obama's critique of a regulatory system whose ''rules have gotten out of balance, placing unreasonable burdens on business—burdens that have stifled innovation and have had a chilling effect on growth and jobs.''

Now, all of a sudden, we are talking about a piece of legislation we have rushed through the process because we wanted to beat the Supreme Court decision on Thursday. We did it at an accelerated pace, faster than we have ever done through the Senate, and we realize this legislation affects the economy and jobs. It is not just about health care. It is not just about patients. It is about jobs.

Dr. David Gollaher, president and CEO of the California Healthcare Institute, raises a clear alarm in his report we should all heed. He concludes:

> The result of uneven performance of the Agency has been to increase the risk associated with regulation, dampening investment in companies whose products face FDA regulation. Meanwhile, as global competition in high-tech industries has intensified, other nations have adapted their regulatory systems to out-compete the FDA. The flight of medical technology product launches to European Union countries should be a serious cause of concern for policymakers and patient advocates alike.

What does that mean in layman's terms? We are losing them here and the EU is attracting them there. Why? Because their policies are easier to understand. It is not that their threshold for safety and efficacy is any lower, but they carry on an honest partnership with the applicants, and most will say dealing with the FDA is akin to inviting your worst relative to spend the week with you in your house.

Exporting lifesaving innovation overseas—and the jobs that come with it—will not help patients or our economy here at home. It erodes our Nation's standing as the global leader in medical innovation and results in America's patients having to wait longer for lifesaving therapies or jeopardizing their access to them at all.

I am not sure in America we ever thought we would go to another country where they had approved a new therapy we couldn't get in the United States, but I would be willing to bet that every family in America knows somebody who has gone outside the country to get some type of treatment or some type of dosage of something we haven't approved here, and one might think they are not safe or effective. The likelihood is that those products have never even applied for FDA approval. Why? Because the process has become so unpredictable and so expensive that a company has to justify the potential sales of a product to meet the billion-dollar cost just to get through the FDA application process.

Exporting lifesaving innovation overseas and the jobs that come with it will not help our patients and will not help the economy. It erodes the Nation's economy and results in America's patients having to wait longer. I just said it.

The FDA is supported by both user fees and taxpayer dollars, so Congress has a critical oversight role in ensuring that the FDA is meeting its requirements under the law. Moreover, as elected representatives of the American people, Congress institutionally has a duty to ensure that the FDA is

broadly fulfilling its statutory mission and promoting the public health through its review and regulation on a range of medical products.

The reauthorization of the drug and device user fees agreement is an important opportunity for Congress to ensure that the FDA is fulfilling its mission. Why would we in any way water down the accountability and transparency if, in fact, we are the ones to ensure the FDA is fulfilling its mission? But closely examining these issues once every 5 years is not going to help address the underlying problems at the FDA that we all know must be fixed. The only way that is going to happen is with the FDA, Congress, patients, and innovators consistently working together with the right data points. The bottom line is we don't know what we don't measure. If we don't know it, how can we ensure that it is right?

Another report by the California Healthcare Institute and the Boston Consulting Group in 2012 underscores the importance of reliable data at the FDA and how FDA performance is a function of management. The report finds there would be great value in regularly gathering and analyzing the best possible data and updating performance metrics during this PDUFA cycle in order to track performance consistently and longitudinally with the goal of the most accurate possible measures of agency performance.

Do you sense a trend that every outside evaluation—not industry, not FDA, not Congress—of the user fee agreement is basically saying: Hey, Congress, don't miss this opportunity. If we want to track performance, then we have to set up the metrics and collect the data. Why in the world would we drop from the bill the transparency and accountability provisions that get the granular data we need to make this assessment? I guess we will never know.

Congressional oversight can help highlight the processes that are working well at the FDA, as well as reveal areas where the FDA needs to make improvements to ensure timely and predictable regulatory decisions on behalf of America's patients. Recently, the GAO reports over the past year have underscored these points and why the right metrics must be reported on to paint a full and complete picture. Now all of a sudden we have the General Accounting Office, the GAO, saying the same thing that all these third parties have said. Why? Because they are the ones we turn to when we want to ask them to do an evaluation of the FDA, and they are telling Congress: Hey, don't miss this opportunity to get this stuff in there. You actually can get the data we can't get because it is not in the statute.

Every 5 years when we pass the final user fee package, FDA's authority and responsibilities grow. Think about that. With more employees and higher costs, it seems like things would be getting better, but without the metrics, without the accountability, without transparency, we don't know. This bill is no exception. The FDA is going to get an unprecedented level of user fees and more new authority, billions in user fee dollars. With this unprecedented level of user fees, there must be unprecedented transparency, oversight, and accountability. It does not exist.

Let me be clear. There are good provisions in this bill that should help to improve transparency, accountability, and regulatory certainty. However, throughout the committee's work on various issues, I repeatedly raised the point that if we did not fix the underlying issues at the FDA, the new responsibilities and expectations we are going to create with this bill would not achieve the desired outcome. Quite simply, that is why I am disappointed that some key transparency and accountability provisions included in the Senate bill did not survive the final bill. While key GAO reporting provisions may have been removed from the final bill, I wish to take this opportunity to inform my colleagues and the FDA that I personally intend to pursue this oversight analysis outside of this bill. Just because it is not in this bill does not mean I am going to go away.

What has happened is that speed has trumped policy—the attempt to speed through this bill, the attempt to get it done before the Supreme Court announces its decision on ObamaCare. I have yet to have anybody explain to me why we are benefited by moving this before the Supreme Court ruling. If somebody has a concern that there is something in the bill that might be affected by what the Supreme Court ruling is, would we not be smart to delay this until after the ruling to see if there is some adverse reaction to what we have done? If I thought there was any reason to do that, I would be on the Senate floor pleading with my colleagues today. But the truth is that there is nothing that will come out in the Supreme Court decision that will affect the user fee relationship between drugs, devices, biologics, generics, and the Food and Drug Administration. But somebody wanted to finish it, and they set that as the goal that everybody could see.

(Mr. FRANKEN assumed the chair.)

Mr. BURR. Because of the hard work of my colleagues on both sides of the aisle, the final bill includes new incentives intended to help spur the next generation of lifesaving antibiotics. This is a good thing, and my colleagues should be commended for their bipartisan work on this important issue.

Unfortunately, the requirement for the FDA to submit a strategy and implementation plan that would have helped to ensure greater regulatory certainty and predictability regarding FDA's work with antibiotics was not included in the final bill. Yet we have all watched stories on TV about a young lady who was attacked by a virus that has eaten her hands and her feet—an infection. What does she need? She needs a breakthrough in antibiotic therapy.

This was a real opportunity for us to send a message out there that not only are we committed to doing it, we are committed to setting up a regulatory structure that allows it to happen.

Carefully drafted GAO reporting requirements intended to help FDA and Congress identify progress against regulatory challenges in this space have also fallen away. This had nothing to do with RICHARD BURR or MICHAEL BENNET, this was the General Accounting Office. Unfortunately, the reporting requirement that remains is not nearly as robust as the language passed by the Senate earlier this year. These requirements were intended to help identify and root out the regulatory challenges in this space to ensure that the incentives included in the final bill are as meaningful as possible and ultimately do achieve the goal of the next generation of novel antibiotics reaching patients. I cannot think of anything more important than for us to make sure.

I know the Presiding Officer comes from a State where devices are a key part of the economy.

Another reporting requirement that fell away is one my colleagues have heard me talk about a lot over the past year. The medical device user fee agreement includes reporting on the total time to decision in calendar days, not FDA days. This sounds a little bit like Disney World. What in the heck are FDA days? I know what calendar days are. Tomorrow is going to be one number higher than today, and yesterday was one number lower, and every 28 to 31 days, we switch and it becomes a new month and we start counting again. Not at the FDA. That is why it was important that calendar days be substituted for what we call FDA days at the FDA. Patients do not care about FDA days; patients care about how long it takes in calendar days for safe and effective products to reach them.

My colleagues may recall that last year the final Agriculture appropriations bill included a requirement for the FDA to report on calendar days because knowing the average number of calendar days it is taking FDA-approved therapies to reach patients is important for ensuring that we see the full picture of how well the FDA is working in a metric that the American people understand.

Last year, when the Senate considered the issue of counting calendar days for medical products, Dr. Paul Howard, a senior fellow and the director of the Manhattan Institute's Center for Medical Progress, described the importance of counting calendar days. He wrote:

> The PDUFA clock stops when the FDA requests more information from the sponsor . . . so repeated requests for information from the FDA can significantly draw out the time before a product reaches the market, even if the agency completes its review within the specified PDUFA timeframe. . . .

knowing actual calendar days that elapse from between the time that a sponsor submits an application to the time it is approved should give Congress some sense of how efficient—

How efficient—

the review process is. If the FDA is repeatedly asking for more information and lots of time is added to the approval process, it has important implications for patients (who wait longer for new therapies) and investors (who may perceive the regulatory process as arbitrary and time consuming).

Here again, another independent analysis of what should be important to the American health care system and an assessment that calendar days are absolutely vital to Congress's ability to understand how long it really takes at the FDA. And we are not even the person trying to finance the breakthrough.

I appreciate that the final bill will now require more granular reporting with respect to the prescription drug user fee agreement, which is a good thing, but I am baffled that a reporting requirement which Congress has supported in the past and which was included for generic drugs was not included in the final bill.

Talking about calendar days, how in the world could calendar days be important enough to put in the generic bill part and dropped from everything else? Why? Because FDA did not want it. FDA has gotten used to that little stopwatch they have. When they ask you for a little more information, they reset it, so they get to start again.

My dear colleague TOM COBURN and I both are disappointed that a provision offered by him, and which I supported, was removed from the final bill.

I have talked about a number of things removed from the final bill. I am not sure how the ranking member gave me a number at the beginning that I had interest in 12 things and that I had 11 accepted. I cannot count them as I am going through my presentation, but I think I am on three or four that have been dropped.

The medical device user fee agreement includes the requirement for an independent assessment of FDA's management of devices. Unfortunately, the assessment included in the prescription drug user fee agreement and final bill will look at only one-third of the FDA's work with drugs. Let me say that again. The medical device user fee agreement includes the requirement for an individual assessment of FDA's management of devices. Unfortunately, the assessment included in the prescription drug user fee agreement and final bill will look at only one-third of the FDA's work with drugs. Calendar days apply in one section. Generic drugs do not apply, and devices, drugs, biologics. Now, all of a sudden, we have an independent assessment of FDA's management of the devices industry where we are only applying that to one-third of the area of drug evaluation and not to generics and not to biologics.

Senator COBURN's provision, which was first introduced in a bill Senator COBURN and I introduced, the PATIENTS' FDA Act, would have ensured an independent assessment of all of FDA's drug work. Upon introduction of the PATIENTS' FDA Act, Dr. Paul Howard wrote that this provision was ''perhaps the most important provision'' because ''the outcome of that review may or may not be welcome by the FDA—but it will force Congress to pay attention and highlight the FDA's importance as the gateway for medical innovation not just in the U.S., but for the world.'' Paul Howard is no relation to me. This is, again, an independent doctor who makes a comment on a provision in an obscure bill that was introduced in Congress, and he says ''perhaps the most important provision.'' Yet it only applies now to one-third of the drug area, and all we wanted to do was to apply it to the whole thing. Not including this independent assessment is a missed opportunity for Congress, consumers, and patients to have a complete, independent, and objective look at FDA's management of its mission and resources with respect to drugs.

I understand that some of my colleagues are concerned about overreporting, but I would come back to the basic point that you do not know what you do not measure. This is about how Congress and the FDA prioritize, and, given what is at stake, not including targeted reporting requirements that will help FDA to better achieve their mission on behalf of patients is a huge, huge missed opportunity. Why? Speed over policy.

I would also like to talk about a key provision in the Senate's upstream supply chain provisions that is not included in the final bill.

As many of my colleagues know, the globalization of the drug supply chain presents unique challenges in ensuring the safety of the drugs American patients receive. Quite a bit of time has understandably been devoted to this issue. Unfortunately, while the bill includes many bipartisan provisions that will help FDA better target inspections of drug facilities based on risk, the final bill falls short in addressing end-to-end supply chain security. That is sort of important. I think the American people sort of take for granted that we have that in place now.

In addition to not including bipartisan downstream provisions, the final bill does not include the Senate's bipartisan provision to accredit third-party auditors to conduct drug safety audits of drug establishments. To be clear, these third-party drug safety audits would not have replaced official FDA inspections, but they would have been an important risk-based tool for the FDA to leverage in taking steps to ensure a safer global prescription drug supply chain. I actually believe that America thinks we have that in place right now. Who could be opposed to such a commonsense solution? It was a bipartisan initiative. Was it the House that kicked it out? Was it the FDA that kicked it out? It really does not matter. This was smart to have in the bill. The only conclusion I can come to is that speed trumps policy, that our quest to get this done quickly meant we did not look closely enough at the things we should have done and could have done and we did not do.

Now, the ranking member talked about my disappointment and his disappointment on the downstream drug distribution security. I want to take a brief moment and comment on downstream. I thank Senator BENNET, from the other side of the aisle. We worked together. And because of his hard work and dedication to this issue, I think I can say that we are both disappointed that the final bill does not include bipartisan provisions that we have been working on together for the past few months.

My colleagues all know why this is an important issue. It is important for America's patients and consumers.

I remain committed to establishing a workable and reasonable traceability system that strengthens the integrity of the pharmaceutical distribution supply chain. It is critical that we replace the current patchwork of inconsistent, inefficient, and costly State laws with a predictable, workable, and appropriate Federal standard. I am committed to getting this done.

As I said to the ranking member and the chair, it is not going to be easy. We knew that when we took this on. You can't do it fast. I did not know we had a stopwatch on how quickly we could get this bill through the Senate and how quickly we could get through conference and how quickly we could get it passed. I remind my colleagues that the current user fee agreement does not expire until later this year. It did not have to be done now, but it was. And for now 45 minutes I have pointed out things we could have done, should have done, and did not do, and it is embarrassing. This could have been done. This was the right vehicle to put this in because it was a must-pass piece of legislation.

Now let me, if I could, talk about some of the provisions Senator COBURN and I introduced in the PATIENTS' FDA Act. I am pleased we were able to find a bipartisan path forward on some of these provisions which will put in place an unprecedented level of transparency and accountability at the FDA.

While FDA should have already done many of the things that will now be explicitly required of them, by ensuring that we hold FDA accountable to measures and reports on specific requirements, there is a greater chance that they are going to actually get done. There is no certainty without congressional oversight. Greater transparency and accountability provisions included in the package today will help to ensure greater regulatory certainty and timely decisions on behalf of America's patients, which is key to ensuring that America maintains its role as a world leader in medical innovation and that

our patients have access to the most cutting-edge therapies in as timely a fashion as possible.

FDA will be required to develop a regulatory science strategy and implementation plan with clear priorities and report on the progress made in achieving these priorities in fiscal year 2014 and fiscal year 2016. The current FDA Commissioner has acknowledged that the FDA is relying on 20th-century regulatory science to evaluate 21st-century medical products.

Let me read that again. The current FDA Commissioner has acknowledged that the FDA is relying on 20th-century regulatory science to evaluate 21st-century medical products. Let's stop. Let's get this right. Even the Commissioner of the FDA is saying: You know what. We are not even in the same century in how we do what we are trying to accomplish. In other words, the products the FDA is required to regulate are advancing faster than the agency's ability to regulate them. I will be honest. That is a big problem.

Former FDA Commissioner von Eschenbach was right when he said that the FDA must be capable of ensuring that its reviewers know just as much about advances in emerging sciences as the creators of the products they regulate.

Listen, I will be the first to say that at the Food and Drug Administration we have some of the best and the brightest. They are some of the most dedicated Federal workers. They are some of the smartest folks I have ever seen. But they process approvals. They are not on a bench doing research and development. They do not understand how medicine and science have changed since they themselves left the bench. There is every reason to believe that people should be required to go back and be innovators and not necessarily make a lifetime of work as a reviewer at the FDA.

There has been much talk about regulatory science, but it is hard to tell if these efforts are targeted and achieving the desired results of helping the FDA to apply the most cutting-edge scientific tools in their research and their review of medical products. The agency must have clearly defined goals and metrics against which their progress will be tracked. This is the only way to ensure that the advances in regulatory science are being applied and that FDA is prepared to regulate the most novel and cutting-edge medical products ever created.

GAO has well documented FDA's management challenges. The user fee agreement included in the final bill will further increase these challenges by adding more than 1,200 new FDA FTEs, or employees, and further growing the scope of the agency's mission and regulatory responsibilities.

Many of the concerns about the lack of predictability and uncertainty at the FDA are symptoms of unaddressed, systemic management issues. This is the agency that regulates 25 cents of every dollar of our economy.

A February 2010 GAO report found that FDA does not fully use established practices for effective strategic planning and management. FDA agreed with the GAO recommendation to take several actions to improve FDA's strategic planning and management, such as the development of a strategic management plan and working to make FDA's performance measures more results-oriented. I cannot think of a business in America that does not do that today. However, 2½ years later, FDA has failed to adopt many of the key recommendations.

To address this concern, the final bill requires the FDA to submit to Congress a strategic integrated management plan with specific accountability metrics as recommended by the GAO. Even though the FDA admitted to the GAO, based on their recommendations, that they needed to do this and that they would do it, 2½ years later we are now putting it in statute in the user fee bill.

GAO has well documented FDA's challenges to sufficiently and successfully utilize its information technology process. GAO has also noted how these challenges undermine FDA's ability to use accurate and timely information to augment its regulatory mission. GAO reports in 2009 and 2012 found that the FDA has made mixed progress in establishing the IT management capabilities essential to supporting the FDA's mission. That is the information technology. So an agency that is on the cutting edge of medical approval in this country in 2009 and 2012 was found to have made mixed progress in establishing the management capabilities essential through technology to complete its mission.

A comprehensive IT strategy plan is vital for guiding and helping to coordinate the FDA's IT activities. A comprehensive IT strategy plan, including results-oriented goals and performance measures, is vital for guiding and helping to coordinate the FDA's IT activities, especially since the user fee agreement includes specific IT goals. The final bill requires the FDA to report on their progress in developing and implementing the comprehensive IT package called for by the GAO. To ensure further congressional oversight, GAO will report on the progress FDA makes on meeting the results-oriented goals and performance measures set out in the IT plan they submit to Congress.

Enhanced reporting requirements with respect to biosimilars and generic drugs include key reporting on clearing the backlog of generic applications and will also provide important transparency in the FDA's work and serve as an early-warning indicator if the agreements are not being fulfilled.

I am also pleased we were able to find a path forward on important pro-patient provisions from the PATIENTS' FDA Act and provisions that will also reduce unnecessary regulatory burdens for innovators. I wish to thank my colleagues, Senators MIKULSKI, ALEXANDER, and HAGAN, for working with us to ensure that the unnecessary redtape does not get in the way of meeting patients' unique medical device needs.

The custom device provision in the bill provides an important path forward to ensure that doctors are able to meet patients' most unique medical device needs in as timely a manner as possible. The risk-benefit framework included in the user fee agreement and codified by the final bill will facilitate the balanced consideration of benefits and the risks of FDA's drug decisionmaking.

As innovators have increasingly turned to global markets and opportunities overseas, FDA's work with its global peer regulators has taken on an even greater significance. FDA's work with its global regulatory counterparts to encourage uniform clinical trials standards will optimize global clinical trials to ensure that the need to conduct duplicative clinical trials is minimized while FDA maintains the gold standard for approval.

I wish to thank Senator PAUL. I thank Senator PAUL for working with me to ensure that we have optimized global clinical trial work and that FDA works with global peer regulators as much as possible to reduce unnecessary regulatory hurdles.

Senator PAUL was a champion in the committee to say: Why don't we accept the data we get from trials in Europe for applications that are under review for approval in the United States? And the answer I gave him was that in 1997, when we wrote the food and drug cosmetic modernization bill, we gave FDA the authority to do that. And now some 15 years later it has never, ever, ever been used. As a matter of fact, the FDA will not even consult with a company that says: Tell us how we need to design our trial in Europe so you will accept our data. That has not happened. But you know what. It has to happen in the future if we want drugs to be cost-effective so people can afford them, if we want innovation to happen here as well as over there. If innovation and the place where it is ultimately approved is determined by whether you can recover the costs of your investment, I will assure you we are all going to shop somewhere else for our drugs, our devices, our biologics, and even our generics. It will not be here unless we learn how to share that data from continent to continent.

I wish to highlight some specific medical device regulatory improvements. There may be any number of reasons a sponsor wants to conduct certain clinical studies that are not directly to the classification or approval of medical devices by the FDA. However, some sponsors have noted the tendency of the FDA to effectively prejudge the approval of a medical device by basing its decision related to a request to conduct clinical investigations of a device on whether the FDA

believes the clinical study will be adequate to support the ultimate classification or approval of a device. If the FDA approves the investigational use of a device only using the more narrow regulatory standard of device approval or classification, clinical research in the United States could be unduly restricted. The final bill would return the investigational device exemption approval process to the standard authorized by the statute, which is a good thing for both patients and for innovators.

The final bill will also improve regulatory certainty, transparency, and accountability with respect to medical devices by requiring FDA to provide a substantive summary of the scientific or regulatory rationale for significant decisions.

As many of my colleagues know, section 510(k) of the Food, Drug, and Cosmetic Act requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance.

Medical device manufacturers are required to submit a pre-market notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, or manufacturing process. There are legitimate concerns about recent guidance issued by FDA that could significantly increase the regulatory burden related to 510(k) modifications without clear benefit to patients. The final bill will go a long way in restoring regulatory certainty and balance with respect to the 510(k) modification process by making it clear that the 1997 guidance remains the standard until FDA issues new guidance, with appropriate input from stakeholders, on this subject.

While I wish that we could have gone further to strengthen and improve the device third-party review and inspection programs, the final bill does reauthorize these programs and includes a provision from the PATIENTS' FDA Act to set forth a process for reaccreditation and reauthorization of third-party reviews. This is a first and important step in enhancing the third-party review program.

Another thing we placed in the 1997 act is the hope that we would see academia in America actually be approved as third party evaluators—not for heart stints or that class of device, but how about things such as Band-Aids? How about those things on which we should not waste an FDA reviewer's time? Couldn't the company contract with an academic institution to reapprove and recredit? FDA chose to do that in-house. This is the first important step to enhance the third party review program.

Next is affirming the ''least burdensome'' requirements.

Also, the final bill underscores the importance of the ''least burdensome'' requirements we put into the 1997 law to streamline the regulatory process and reduce burdens to improve patient access to medical devices.

A central purpose of the FDA Modernization Act of 1997, or FDAMA as I like to call it, was to ensure the timely availability of safe and effective new products that will benefit the public and that our nation continues to lead the world in new product innovation and development. The goal was to streamline the regulatory process and reduce burden to improve patient access to breakthrough technologies. This law required FDA to eliminate unnecessary burdens that may delay the marketing of beneficial new products, but the statutory requirements for clearance and approval remained the same. The sections of the statute that capture these provisions are commonly referred to as the ''least burdensome'' provisions.

For years, FDA included ''least burdensome'' language in guidance documents and letters. Yet, toward the end of 2009 the ''least burdensome'' language disappeared only to reappear after Congress expressed significant concern regarding FDA's failure to consistently apply these requirements in its work with medical devices.

The lack of consistent application of the ''least burdensome'' requirements has added to regulatory uncertainty and unnecessary regulatory burden in a manner completely inconsistent with the law. It is sad that Congress needs to reaffirm a provision that has been the law since 1997, but I thank Senators KLOBUCHAR and BENNET for working with me to underscore the importance of affirming the ''least burdensome'' requirements in the final bill.

The final bill restores a more appropriate balance to FDA's conflicts of interest rules. This is an issue on which many patient groups have weighed and many members have worked because of its importance to patients and, ultimately, overall confidence in FDA's Advisory Committees. Ensuring that the FDA has access to the most qualified experts is vital to ensuring FDA's scientific capabilities and confidence in its regulatory decisions. It is critical that patients have the benefit of the very best expertise when weighing decisions that impact patient access to lifesaving products. Unfortunately, since 2007, increasingly complex and restrictive conflicts of interest rules have often resulted in the Agency being unable to consult with leading experts and difficulty in filling key advisory committee positions. These challenges are compromising the quality and timeliness of FDA's decision-making. The final bill should help to address these concerns and ensure FDA can draw upon the most knowledgeable experts.

Lastly, I'd like to highlight the Advancing Breakthrough Therapies for Patients Act, bipartisan legislation I was pleased to join Senators BENNET and HATCH in supporting because it will ensure patients have access to targeted, life-saving therapies as efficiently as possible. As former FDA Commissioner Von Eschenbach has rightly stated, ''breakthrough technologies deserve a breakthrough in the way the FDA evaluates them.'' This legislation is supported by Friends of Cancer Research and the National Venture Capital Association.

Earlier this year, an op-ed penned by former FDA Commissioner, Dr. Mark McClellan, and Ellen Sigal of Friends of Cancer Research, noted how the sequencing of the human genome has helped to unlock an even greater understanding of disease at the molecular level, helping to make personalized medicine become a reality. They note two main goals of the breakthrough legislation: First, to reduce the total development time and cost of the most promising ''breakthrough'' treatments; and second, to minimize the number of patients that would be given a ''control'' regimen or a currently available treatment that doesn't work well. They are right to underscore that in order to fulfill the promise of ''breakthrough'' therapies and this legislation, the regulators at FDA must be fully engaged, working with sponsors early on in the development and review process once a product has received the breakthrough designation.

More than 45 organizations representing patients, advocates, physicians, caregivers, consumers and researchers have weighed in with Congress urging the Advancing Breakthrough Therapies for Patients Act to be included in the final user fee package because they recognize that employing such an ''all hands on deck'' approach at FDA for these therapies will ultimately result in the most efficient development program and help to ensure that the most promising new treatments reach patients as safely and efficiently as possible.

Many would argue that the modernization of the accelerated approval and fast track pathways have been a long time coming since Congress has not significantly updated either pathway since 1997. Earlier this year, Dr. Paul Howard in writing about the breakthrough legislation noted that, ''the most important section of the legislation may be the clause that requires the Secretary of HHS to commission an independent entity to assess the 'quality, efficiency, and predictability' of how FDA has applied the directives in the legislation no later than four years after the bill passes.'' He goes on to say ''that may be the best way to ensure that we won't have to wait another 15 to 20 years to understand how well the FDA is utilizing the authority granted to it by Congress.'' Unfortunately, this independent assessment did not make it into the final bill. Speed trumps policy.

FDA faces unprecedented challenges today—challenges we could not have

envisioned a generation ago. Yet FDA still regulates a decade ago, based on the commission. The agreements and many of the provisions in the final bill are intended to help address these challenges. Unfortunately, the final bill does not bring to bear all of the tools that could have been included to ensure the greatest certainty, transparency, and accountability for patients and taxpayers. This is a missed opportunity.

I ask my colleagues where we will be if the provisions enacted as part of this bill—like the breakthrough therapy provision—do not achieve their stated purposes? Where will we be if Congress does not do our part to ensure accountability on the part of the Agency by carrying out consistent Congressional oversight?. Where will America's patients be in five years? Will FDA's regulatory standard still be the global gold standard?

Will America still lead the world in innovation? Will the world's leading drug and device innovators choose to innovate in America, or continue the disturbing trend of exporting great innovation and good jobs overseas in the continued face of regulatory uncertainty?

There are good provisions in this final bill, but more work remains to be done. America's patients and innovators are counting on Congress to conduct the proper oversight in the months and years ahead to ensure that these user fee agreements, authorities, and new responsibilities are implemented and fulfilled consistent with the law. They are also counting on Congress to complete the unfinished business of doing all that we can to ensure that FDA fulfills its mission on behalf of America's patients and our Nation's global leadership in medical innovation is restored. I commit to my colleagues, constituents, and the FDA that I intend to complete the unfinished business before us here today.

Mr. President, you have been patient. At this time, I will yield to my colleague Senator PAUL. When he concludes, I will continue with the 2½ additional hours I have reserved.

The PRESIDING OFFICER. The Senator from Kentucky.

FOREIGN AID

Mr. PAUL. Mr. President, I am not a big fan of foreign aid. We have a lot of problems in our country. I don't see how we can send billions of dollars overseas when we have bridges falling down in our country. Two bridges in my State were impassable. One was hit by a boat and has been impassable for 6 months. We have another bridge that is over 50 years old that was shut down for emergency repairs, and traffic stacked up for miles. Yet we send billions of dollars overseas when we don't have enough to fix our own bridges. It doesn't make any sense. We borrow $1 trillion a year from China to turn around and send it to some other country. It makes no sense.

I am not a big fan of sending our money overseas. But I am even less of a fan of sending our money to countries that don't seem to be our friends. Pakistan has worked with us on the war on terror. But recently Pakistan has chosen not to let any of our supplies—food and military supplies—traverse Pakistan. Recently, Pakistan has said we owe them $3 billion. We are giving them $2 billion a year, and they say we owe them $3 billion that is not included in that. Recently, Pakistan also said they want to charge us $5,000 per container of food that goes across their land.

For years bin Laden lived contentedly right in the middle of Pakistan underneath their noses. What is up with that? We are giving them $2 billion a year and bin Laden was twiddling his thumbs there and they are not letting our supplies go across and they are demanding a past payment of $3 billion for who knows what and we continue to pay them.

Recently, it has gotten even worse. Dr. Shakil Afridi is a doctor who helped us get bin Laden. Somehow his name was leaked. I don't know who leaked the name or if they were trying to puff themselves up and make themselves look as if they were strongly fighting terrorism, but by leaking Dr. Afridi's name, he is now in prison in Pakistan for 33 years.

Dr. Shakil Afridi is a Pakistani and they have put him in prison for 33 years. His life has been threatened. If he is released—which I hope he will be—his life has been threatened because his name is public. How did it become public? Somebody leaked his name. This is inexcusable. If this came from within our government, whoever leaked his name or this information should be held accountable. I mean put in prison in our country for leaking state secrets.

Dr. Afridi's name is now known in public, and he is being threatened, and his family is being threatened. Not only that, anybody around the world who wants to help us stop terrorism, who is willing to stand and help America, is now threatened. Do you think people are going to want to help us if they know their names will be printed in the New York Times? We have to have things that we don't divulge about people who are helping us. But Dr. Afridi is in prison for 33 years, and I am going to do what I can to free him.

We should not send Pakistan any more money. I say stop immediately. I am not saying take a small amount out next year; I say don't send them one more penny this year or next year. Don't send any of the $3 billion they want. We don't even have it to send to them. We have to borrow it from China. I would give them one chance. If they release Dr. Afridi, I would stand down.

My bill was blocked. I tried to have a vote on it last week, and the leadership said: No, you won't have that vote. But we have a process where if you get enough signatures from Senators, you can ask for a vote and get it. That is where we are now. I have enough signatures to have the vote.

I am going to be meeting with the Pakistani Ambassador, and meeting with President Obama's State Department, and what I will tell them is what I am telling you. This is not a secret. If Dr. Afridi is not successful with his appeal, which is coming up in the next 3 weeks, if he is not released and provided safe passage out of Pakistan, if he wishes, then I will have this vote. And I defy anyone in this body to stand here and vote to send U.S. taxpayer dollars to Pakistan when they are treating us this way. So we will have a vote in this body on ending all aid to Pakistan immediately if we don't get some results.

This doesn't mean I don't want to have diplomacy with Pakistan. Pakistan has been a friend over many years, and I see no reason to end that. Pakistan has many elements that are pro-Western and that want to engage in the world. I am all for that. But we shouldn't have to buy our friends. We shouldn't have to pay a ransom. We shouldn't have to lavish them with taxpayer dollars.

In fact, I think it encourages a disrespect when you give people so much money. Let's let them earn our respect. Let's work with them. Let's be friends with Pakistan. Let's have diplomatic ties to Pakistan. Let's try to help each other. Terrorism doesn't help Pakistan. They are threatened equally by it. I can list four Pakistani leaders who have been assassinated in the past 15 years. Why were they assassinated? Because of radical elements in their own country. So they should be with us in trying to stop extremism, on trying to stop this radicalism.

My words for the Senate today and for the American people are that I am watching out for your money. I realize we have needs here at home that must come first, but also that I will force a vote on this. I am not going to send any more of your money or try not to let the Senate send any more of your money to Pakistan unless they are willing to cooperate, unless they are willing to be friends with America, unless they are willing to release the man who helped us get bin Laden.

I will ask for a vote, it will come in the next few weeks, and I will keep everyone in America up to date on this.

I thank the Senate for allowing me this time, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BURR. 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. BURR. Mr. President, I thank Senator PAUL for relinquishing the microphone, and just for the purposes of Members who are planning, I think

we will be about another hour. We will know shortly, and I will put that word out, if in fact that is going to be the case, but I intend to make sure everybody is able to make a 5 o'clock briefing.

I have spent the first hour talking about the FDA user fee agreement bill, the history of it, what this bill did, and a lot about how this bill came up short. I would like to jog in a few different directions over the next period of time.

Of great interest to me, and great interest to a lot of Members, is the commitment we owe to our Nation's military heroes. Over four decades ago, at one of the two Marine Corps bases in America—Camp Lejeune in Jacksonville, NC—they experienced serious contamination of their water. That contamination is likely the worst environmental exposure incident on a domestic military installation in the history of the country, both in the magnitude of the population potentially exposed to volatile organic solvents and the duration of the contamination—estimated to be 30 years or longer, with hundreds of thousands of veterans, their families, along with civilian workers having cycled through Camp Lejeune from the busy years of World War II through the Vietnam conflict and into the mid 1980s as we rebuilt our modern military.

During these decades, unbeknownst to the base residents, the wells feeding the water supply on the base were drawing water from an aquifer contaminated with industrial chemicals that were dumped on the base, such as the degreasing solvent TCE, a known human carcinogen; and another carcinogen, benzene, from leaking underground fuel storage tanks; along with the dry cleaning solvent PCE; and a third human carcinogen, vinyl chloride. The Navy and Marine Corps began to test some of the base wells in the 1980s to comply with Federal regulations and, apparently, to also locate the source of various contaminations, yet it would take several more years and numerous warning signs before the Navy finally decided it should shut the wells down in 1985 through 1987.

As we know now, the Navy and Marine Corps had specific regulations of their own to maintain safe drinking water and test for contaminants. Had they adhered to their regulations, the many years of problems at Camp Lejeune might have been avoided. It is also important to note the source of those contaminations should never have been in question, since Lejeune's drinking water was then and is now solely derived from the wells located within the perimeters of Camp Lejeune, NC.

In 1989, the EPA designated Camp Lejeune a Superfund site, and in 1991 the CDC, via its Agency for Toxic Substances and Disease Registry—or ATSDR—began a statutorily mandated study of the contamination. Those studies continue to this day, in large part because the Navy's records of the contamination were not completely turned over to the ATSDR until 2009 and 2010. Scientists at the ATSDR and others involved in the review of the Navy's records have stated the levels of certain contaminants recorded in well samples taken by the Navy were at such high levels they have never been seen before, and in many cases they far exceed what we now consider to be safe levels for drinking water.

The Veterans Administration is awarding disability benefits to Lejeune veterans on a case-by-case basis today, but that is a slow and unpredictable process, while many are suffering without adequate health care. It is my hope in the coming weeks we will finally pass critical legislation in this Congress to require the VA to take care of these veterans and their family members. Many of them are ill from exposure-related conditions and have no other means of getting health care. They are rightly looking to the VA and to the Congress for help. If we can get this legislation passed, it will be a starting point on the road to doing the right thing for those who have sacrificed so much for our Nation.

I think it is absolutely a crime that some 40 years later we haven't even completed the studies to understand the severity of the problems we have. I might add that some of the servicemembers and some of the family members who served at Camp Lejeune during this time are no longer with us. It may be hard to reconstruct exactly why, but I can assure you, when some estimate there are 10 times the number of male breast cancer cases from people who lived on that base during that time, one might conclude it was a hotspot based upon its drinking water.

My hope is this Congress will move forward with a very small initial step, but also make a commitment to these family members and servicemembers to not quit until we do the right thing.

This week the Supreme Court is going to rule on the President's health care law. One would have to live under a rock not to realize it is going to happen Thursday morning at 10 o'clock. We have waited patiently every time the Supreme Court has rolled out their announcement for the last 3 weeks of cases they have decided as the Court comes to the end of their session this summer.

Two years ago, then-Speaker NANCY PELOSI told Americans, ''We have to pass the bill so that you can find out what's in it.'' Let me repeat that: ''We have to pass the bill so that you can find out what's in it.'' It seems fitting that we stop and take stock of what the American people have learned about the President's health care law over the past 2 years.

The American people have found they can't afford the President's health care law. The Medicare Chief Actuary, in his final estimate of the health care law, projected it will increase health care spending across the economy by $311 billion. That is a 10-year number, but understand the President promised the health care law would reduce cost. It wasn't a goal. He promised it would reduce cost. Unfortunately, it has made things worse by increasing health care costs. And I think the estimate given by Medicare's Chief Actuary is probably a very conservative estimate—an increase of $311 billion.

Growth in U.S. health care spending will almost double by 2014 due to the President's new law. This is at a time when we already are in a situation where we are on a financially unsustainable path. The predictions the President's health care law would increase insurance premiums are already being felt by the American people. Depending upon where you live, who you are an employee of, and whether you buy your own insurance depends on how hard you have been hit, but there is nobody in America who has not seen their premium go up since Congress passed this health care bill that was supposed to reduce the cost of health care.

The Congressional Budget Office estimated the new law will increase health insurance premiums by 10 to 13 percent. This means a family purchasing coverage on their own will have to pay $2,100 a year more because of the President's health care law. And by the way, 10 to 13 percent is what many Americans have felt as an increase on an annual basis.

New taxes. New taxes on lifesaving drugs, devices, and health plans. Think about that, with the hour I just finished. I talked about the fact Congress needs to be focused on the efficiencies of government, and how we bring innovative products, devices, pharmaceuticals, biologics, and generics to the marketplace. Yet embedded into ObamaCare are new taxes on drugs, devices, and health plans.

The American people haven't felt this yet. At a time we are supposed to be passing legislation to bring down health care costs, not only does the Congressional Budget Office say this is going to increase premium cost, not only does the President's Chief Actuary—CMS is under the executive side of government, not under Congress's authority—say health care spending across the economy, based upon the health care law, is going to be $311 billion, we have yet to kick in the new taxes on lifesaving drugs, devices, and health plans, which will drive up consumer cost and additionally drive up premium cost.

Just after passage of the new law in May 2010, the Director of the Congressional Budget Office said:

> Rising health costs will put tremendous pressure on the Federal budget. In CBO's judgment, the health legislation enacted earlier this year does not substantially diminish that pressure.

The question is what were we thinking? And now we have the Supreme Court that will decide whether this is constitutional. CBO's latest long-term fiscal outlook notes that spending on

health care has been growing faster than the economy for many years, posing challenges for Medicare, Medicaid, State and local government, and the private sector.

Sometimes this is missed by Members of Congress and our constituents. There is a tremendous cost that we shift to States and local governments depending upon how they share in the Medicaid State obligations for cost sharing. States are picking up a tremendous amount of additional cost because of the passage of the President's health care plan because we are doubling, through legislation, the amount of people who are on Medicaid.

So now you are going to get hit by the increase in your insurance premium; you are going to get hit by the increase in overall health care costs; you are going to get hit by the new taxes on lifesaving drugs, devices, and health care plans; and, oh, by the way, you are going to get hit in your State taxes because of the increased burden of Medicaid beneficiaries who are in part funded by the State and are going to now require States to find new ways to raise revenue, which is typically through our State taxes.

CBO was right to conclude that such rates of growth cannot continue indefinitely because total spending on health care would eventually account for all the country's economic output, which CBO concludes ''is an impossible outcome.''

We need real reform that actually lowers costs, not increases costs. We need real policy that institutes better outcomes, not rationing of care. The American people need to look at what the President promised when he created this legislation. He promised: If you like your plan, you get to keep it.

Unfortunately, the administration has estimated that up to 69 percent of all businesses could lose the ability to keep what they have as a result of the administration's grandfather health plan regulation. The former Director of CBO, Doug Holtz-Eakin, warned that the law ''provides strong incentive for employers and their employees to drop employer-sponsored health insurance for as many as 35 million Americans.''

Well, if employers drop their health care coverage, how can employees cash in on the President's promise to keep what they have?

Millions of seniors will lose access to their Medicare Advantage Plan. I am not quite there, but some of my colleagues have reached that magic number.

Do seniors not deserve choice? Is that what it is? Do we just want to give them one thing and no choice? The truth is we allowed—we didn't create it; the private sector created it, but we allowed the private sector to create Medicare choice years ago, and for many seniors they chose to take the private sector product. Why? Because it provided more coverage to them. It provided preventive care. They actually got covered physicals every year. In many cases they didn't have copayments. In many cases their prescriptions were covered long before we created Part D Medicare.

So what does the President's health care plan do? It tightens the requirements on Medicare Advantage to the point that some seniors who are on it today will lose it because it is no longer an option in the markets they live in. How in the world can someone do that and make the promise: If you like it, you get to keep it?

Health plans offered by religious-affiliated organizations will be compelled to offer products that violate the tenets of their faith—a new mandate that jeopardizes an employee's existing coverage and infringes on religious liberty. That is going into ground we have never entered, and I think there is a reason we have allowed people to hold to their moral standards they believe are important.

Then-Speaker of the House PELOSI said the health care law will create 4 million jobs—400,000 jobs almost immediately. Yet the Director of the Congressional Budget Office testified that the new law will reduce employment over the next decade by 800,000 jobs.

Think about that. Then-Speaker PELOSI said 4 million jobs—400,000 almost immediately—and the CBO Director testified we are going to lose 800,000. That is a difference of 4.8 million jobs in America.

The President said he was not going to touch Medicare. We heard that over and over. He said to seniors: I am not going to touch Medicare. He had already taken Medicare Advantage away as a choice, but he wasn't going to touch Medicare. The law took more than $500 billion out of Medicare, a health care plan that today is not financially sustainable, and the President, in his health care legislation, shifted $500 billion out of Medicare—not to put Medicare on a sustainable path but to fund new government programs the American people cannot afford.

Arbitrary cuts to providers that jeopardize access to care will not put Medicare on a sustainable path for current and future retirees. What does that mean? Doctor cuts. We cut the reimbursements to doctors, we cut the reimbursements to hospitals. We now have doctors who will not see Medicare beneficiaries. If you are 65 and you move to Raleigh, NC, the likelihood is you are not going to find a primary care doctor that is going to take you if you are on Medicare. To that person, to that senior, that is rationing. I don't care how you say it. And the reality is this bill caused that.

The President promised no family making less than $250,000 a year will see any form of tax increase. I just covered a second ago that the new health care law is riddled with new taxes and penalties that directly fall on the middle class and will harm small businesses. New taxes on lifesaving drugs, devices, and health plans are all going to be passed on to consumers. It is disingenuous to say everybody in the system is not going to feel the effects of taxes. They might not be directly on us, but they are on the products that constitute our health care system. We should be advancing policies that help small business to thrive in America, not policies that increase health care costs. We should not be advancing policies that encourage innovators to export innovation and good-paying jobs overseas. We should be advancing policies that focus on helping to get our economy back on track.

Unfortunately, the President's health care law does just the opposite. According to the U.S. Chamber of Commerce Survey on Small Business, 74 percent of small businesses said the health care spending law makes it harder for their firms to hire new workers. Thirty percent said they are not hiring due to the law.

There is only one issue in America: How do we get the American people back to work right now? How do we turn this economy around right now? We can have all the cuts we want to have from the standpoint of spending. But unless we are willing to put Americans back to work and get them productive and participating in the revenue collection of this country, we are not going to get on a pathway to financial sustainability.

This country wasn't created because people came here and said: Let's create a place called America where everything is free. It was created as an area of unlimited opportunity. That is why millions a year come here, for unlimited opportunity, not for unlimited handouts.

When de Tocqueville left the United States, he talked about ''the greatest country in the world,'' and he defined it this way: the capacity of the American people to give of their time and their resources for people who are in need. He never mentioned State or Federal Government.

He talked about a responsibility of the American people to help somebody that was down on their luck, hungry, homeless. Do you know what. For those of us who are adults, it is our responsibility to set the example for the next generation to come and assume the same individual responsibility. But now it seems as though all we talk about is legislation that inserts the Federal Government or the State government or the local government in the place of what historically made this country great, which was our willingness to assume the responsibility ourselves.

Let me assure you, we shouldn't be surprised by the results of the assessment that the government running health care means job loss and increased costs. We have to make sure we provide more choice, not less choice. We have to get the American people engaged in negotiating their health care costs, not letting the Federal Government negotiate their health care costs.

I came here for the first time 18½ years ago. I worked for a company of 50 employees. I came to the U.S. House of Representatives and chose the same plan I had with that small employer in Winston-Salem, NC. The only difference was that when I got here, the Federal Government paid 75 percent where my employer had paid 75 percent. I paid 25 percent here; I paid 25 percent there. I got exactly the same plan and the same coverage. Everything was identical.

When I left Winston-Salem to become a Member of the U.S. House of Representatives, my cost of that health care plan was $105. When the Federal Government got through negotiating my same health care plan, it went up to $160. I knew on day one I did not want the Federal Government negotiating my health care because it meant higher prices and no change in coverage.

I think many Americans have realized that about ObamaCare. My hope and my plea and my prayers are that Thursday the Supreme Court nullifies this bill and this Congress is challenged with going back and step by step or in a comprehensive fashion write a health care bill that includes the participation of the American people and puts responsibility on everybody. Everybody in America should have the responsibility to pay something when they go in to access it. It doesn't matter whether it is private insurance, it doesn't matter whether it is Medicare, it doesn't matter whether it is Medicaid.

If we want to solve the financial hole we are in in this country, then we have to income-test everything that comes out of the Federal Government. It means people who have more pay more. It means people who have less pay something. But we have to be a country of unlimited opportunity and not of unlimited handouts.

A February 2012 Gallup survey found that 48 percent of small businesses are not hiring because of the potential cost of health care. Studies indicate that the law's innovative tax killing on medical devices could cost an additional 43,000 jobs in America. The President's health care bill is the wrong prescription for America.

Regardless of the Supreme Court's decision this week, it is clear: We must advance commonsense sustainable reforms that actually fulfill the promise to lower health care costs. Without that America should be outraged and, I believe, will be outraged.

Also in the news in the last several weeks is an issue that is somewhat personal to me as a member of the Senate Intelligence Committee, as a former member of the House Intelligence Committee, as one who has dealt with the work of the Intelligence Committee since the year 2000, and as one who lived up close and personal with everything that has happened since 9/11. We have seen an incredible spree of security leaks—leaks of classified and sensitive information.

When I go home on the weekends and there is a news report on something, my wife will look at me and say: Why is this reported? There is no reason for the American people or for anybody in the world to know about that.

I can tell you it was not that long ago that even if the press found out, they would never print it. Today, routinely there are leaks of classified and sensitive information. Recently there has been a series of articles published that have described, in some cases in extreme detail, highly classified unilateral and joint intelligence operations.

I am not talking about suggesting that it might be there without detail, I am talking about specifics of what happened. To describe these leaks as troubling and frustrating is an understatement. They are inexcusable by whomever. Our intelligence professionals, our allies, and, most importantly, the American people, deserve better than what they have seen over the last several weeks. I am personally sick and tired of reading articles about sensitive operations based on ''current and former U.S. officials—individuals who were briefed on the discussions—officials speaking on condition of anonymity to discuss the clandestine programs—a senior American officer who received classified intelligence reports—according to participants in the program—according to officials in the room—and individuals none of whom would allow their names to be used because the evidence remains highly classified and parts of it continue today.''

That is the basis on which these front-page stories run. I am not confirming or denying that anything in it is accurate or inaccurate because as a member of the committee I sign an obligation that says no covert action will I even comment on. Any person who holds a secret compartmentalized clearance has an obligation to never acknowledge the existence of a program.

I asked, not long ago, was the drone program still a classified program? The answer I got is yes. But the White House Press Secretary for the last 3 weeks stood at the podium and talked about drone attacks—on a program that I technically cannot go out and acknowledge either exists or does not.

Our freedom, with understanding that politics trumps security, has reached a new level. It has to stop and it has to stop now. The unauthorized disclosure of classified intelligence at best violates trust and potentially damages vital liaison relationships and at worst it gets people killed. Clandestine operations are often, as I wrote with Senators COATS and RUBIO in the Washington Post, ''highly perishable and they depend on hundreds of hours of painstaking work and the ability to get foreigners to trust our Government. I strongly believe that these leakers are also violating the trust of the most important constituency of all—the American people.''

Even more troubling is that there appears to be a pattern to these stories and leaks, that they may be designed to make the administration look good on national security. It used to be that the good stuff was buried by the media and the worst was run. Not anymore. Truth be told, rarely have I seen a story that paints this administration in a bad light. Then, when we are about to, the administration invokes executive privilege. They can do that. That is OK. But there is a big difference between invoking executive privilege on not producing documents for Fast and Furious, and releasing classified information that puts at risk individuals who are embedded in terrorist organizations, who are doing their job to keep America safe.

This has crossed the line. I wish this administration was as concerned about preventing leaks of classified information as it is about keeping a lid on the information Congress is asking for. As a member of the Senate Intelligence Committee I understand firsthand the grave importance of keeping information secure. The unauthorized and reckless disclosure of classified information undermines the hard work of our intelligence officers and puts lives at risk, and it jeopardizes our relationship with overseas partners. Congress's intelligence oversight committees will not tolerate it, nor should the American people.

Simply, I come to the floor today to deliver a message to those individuals who were briefed on the discussions, who were part of the program, who were in the room, who are speaking on condition of anonymity: Stop talking. Whatever agenda you have, I can assure you it is not worth the damage you are causing and the lives you are putting at risk. We cannot continue to tolerate leaks at any level or branch of government.

My colleagues and I are considering every available legislative option to ensure the security of the intelligence community operations and the people who support them. If you have access to classified information and are tempted to leak that information for whatever reason, I ask you to remind yourself what you may be hurting and what trust you are violating and, more importantly, keep your mouth shut.

The Intelligence Committees on both sides of the Hill I think will take action in their authorization bill to try to address a structure that brings a new level of oversight and hopefully prosecution to those who choose to leak secrets. In the interim, I am still considering the fact that for any person who openly talks about a program that is secret or compartmentalized, the day they say one word about that program they lose their top secret clearance. I would love to see them lose their pension but I understand how problematic that is. But at least we can stop the bleeding by taking away their access to the conversations or the meetings they happen to be a participant in or the information they happen

to be entrusted with in a fashion that allows them to go out and publicly talk about that and jeopardize the lives of Americans, the lives of our partners and, more importantly, the security of the American people.

On August 5, 2011, Standard & Poor's downgraded the credit rating of the United States for the first time in our history and they cited out-of-control debt and lack of a serious plan to address it as its main reason. Nearly a year later the administration has done nothing to remedy this problem. As a matter of fact, sometime at the end of this year we are going to run out of our ability to borrow money. It is called the debt ceiling. I cannot tell you today, because we are not told, whether that is going to happen in October, November, December, January—but it doesn't go much past the end of the first of the year. I sort of pity the next President, whoever that is. They are probably going to get inaugurated one day and the next day they are going to have to come to Congress and ask for a $3 trillion increase in the national debt.

As difficult as it is for me to say, we are going to have to do it. The country has to have the capacity, the capabilities to borrow money to function. But you would think with this all known we would take the opportunity now to begin to change the grotesque spending habits, to begin to prioritize the investments we make, that we would attempt to reform the programs that cost us the most and lead to an unsustainable financial future for the United States—a country that will soon be $17.8 trillion in debt, a debt I will not be here to pay back but my children and my grandchildren will.

You have to ask yourself as a parent: Is that fair? The answer is it is not. Instead of doing anything, last year the debt ceiling needed to be increased by $2.1 trillion. We are about to blow through it. Why? Because we spend $1 trillion more on an annual basis than what we collect. There is no business, no family, no institution in the world that could spend $1 trillion more than they collect and be in business—nor can this country. The time is running out.

By the way, it is hard to put a calculation on $1 trillion. What is $1 trillion? It is 100 percent of the Federal investment in K–12 education, 100 percent of the Federal investment in higher education, it is 30 percent of the VA budget, it is 100 percent of the National Institutes of Health; it is 100 percent of the cost of the National Science Foundation, it is 100 percent of the Federal partnership with States and localities for infrastructure—bridges, roads, sidewalks. It is 100 percent of our national defense, it is all branches of the military, active and reserve, all bases of the military, domestic and foreign. It comes up to about $942 billion. If you want to balance this year's budget you have to cut everything I just talked about and find $60 billion more, just to balance this year's budget.

The take-away from this is we are not going to delete our national security. We are not going to decrease our investment in the National Institutes of Health, National Science Foundation. We are going to be a partner in K–12 and higher education. There are a lot of places we can cut and should prioritize and we can do it, but the take-away is we can't get there unless we are willing to reform entitlements, unless we are willing to look at where the majority of the money is spent. We cannot get there.

We have to do something. I tell you it starts with addressing the imbalance we have in spending and collection right now—not next year.

Consistent with this is the Senate still has not passed a budget. In fact, the President's own budget did not receive a single vote in Congress when we voted on it. I should not laugh. We are on track for another year with a $1 trillion deficit. How could anyone run their company on an annual basis without a budget, without a financial roadmap as to what they do? But now, for over 1,000 days the U.S. Senate has not passed a budget. And the law says we have to do it. That is incredible. It is absolutely incredible. Over the last 3½ years we have added $5 trillion to the national debt, more than in the previous 8 years combined, and current estimates by the CBO put Federal debt at 70 percent of our gross domestic product by the end of this year.

We are reaching irreversible levels of debt, as it relates to the size of our economy. It is unsustainable and it is dangerous for the fiscal health of our country. The status quo needs to change. Congress needs to address the impending fiscal cliff or risk another downgrade in the coming months.

We can accomplish this by passing a budget that moves us toward balance. We can accomplish this by reforming entitlements and not putting Band-Aids on issues for another time. Our debt will begin to decrease when we put the American people back to work and we get policies in place that encourage the investment of capital.

How about something novel? Why don't we reform our Tax Code? Give me the ability to go to a small business in North Carolina and tell them they are going to pay exactly the same thing GE pays. It is hard for me to explain how they pay 36 percent and GE paid nothing. I am not faulting GE, don't get me wrong. That is exactly what the Tax Code currently says. That doesn't make it right. It doesn't mean we have an obligation to leave it like that in the future. I look at it as an opportunity for us to bring equity. But as we bring equity, why don't we bring everybody's obligation—their rates—down. It is time for us to reform individual corporate taxes in America, to do away with loopholes and deductions, to flatten the rates for everybody, to broaden the participation by more Americans. Guess what. If we do that, we will be like a magnet for global capital. What does it take to create jobs in the United States? It takes an investment. Reform the Tax Code, flatten the rates, broaden the base, and we will attract capital that will flee to America and create jobs like we have never seen. At a time where the world continues to try to figure out how to get out of a hole, we have an option to do it.

I yield to the Senator from Iowa.

Mr. HARKIN. Madam President, I ask unanimous consent that Senator BURR have the time until 4:40 p.m.; that I be recognized for up to 5 minutes, following the remarks of Senator BURR; further, that after my remarks, all remaining time be yielded back, the motion to concur with an amendment be withdrawn, and the Senate proceed to vote on adoption of the motion to concur in the House amendment to 3187.

The PRESIDING OFFICER (Mrs. SHAHEEN). Is there objection? Without objection, it is so ordered.

Mr. HARKIN. I thank the Senator from North Carolina.

Mr. BURR. I thank the Senator from Iowa. So I just gave us a recipe for solving our economic crisis in America. Some might say it will not work. I don't know. I think it will. I can say this. What we are doing is not working. We are not putting anybody back to work. We are still losing. My State of North Carolina has 9.4 percent unemployment. How long does it have to continue before we look at it and say this might be a systemic problem? Can we recover from this?

How many law school graduates can we look at this year where 60 percent of the class of graduates from the first of May to the end of June doesn't have a job? As a parent, I always thought the toughest job was to make sure my kids got in school and that they graduated in 4 years. Now the greatest burden on a parent is to make sure when they get out, they get a job that has a paycheck and maybe that check puts them in a situation where they are self-sustainable. That is not the promise we made to our kids and that ought to be the driving force behind every adult in this country demanding a change.

Most of our kids did exactly what we asked them to do—stay in school, make good grades, go to college, get a major. If they do that, they will be guaranteed a job and an unlimited future. Now the seniors who graduate from college who are not finding a job, their experience is being questioned by their little brother or sister at home who is struggling to get through high school and wondering why they want to do 6 more years of education if their older sibling can't find a job.

It doesn't have to be like this. All we have to do is muster up the backbone we need to pass legislation that creates the atmosphere for capital to be invested in job creation.

I am not rich, but I am getting tired of us dividing America in as many

pieces as we can divide it. We already divide it based on political boundaries. Now we are trying to divide it on everything we can find. Yet for every politician when they give that big speech on TV, they boil it down to this is about America. But when we look at the campaign rhetoric out there, they slice it and dice it and try to divide it in many ways. Let me assure everyone, we are not going to solve this if America doesn't solve it. It is not going to be solved in the Halls of Congress unless the American people demand it. It is not just one segment of America; it is all segments of America.

I talked about de Tocqueville's definition of the greatness of America earlier. He didn't point out some Americans who did it good or did it right. He looked at America as one.

As a matter of fact, when we look historically at this country—and I realize I only have a couple minutes left; I will be brief. When the Capitol dome was torn off and the new construction started, it was because of the wing we are currently in, the Senate, and the identical wing that was built on the House side. When those wings were added, architecturally, the dome that was on top of the Capitol was out of proportion, and that dome was called a Bulfinch dome. In about 1851 or 1852, they started building the dome we see today, made of 9 million pounds of cast iron. As that dome was about one-third of the way finished, Abraham Lincoln was President, and they could actually watch the Civil War battles across the Potomac on the other side of the river.

Then came the end of the war and Lincoln was President and had every right to be punitive to the South because they lost. I challenge everybody to go back and read Lincoln's speeches after the Civil War. Remember, the first action was to let every southerner go and keep their gun because he knew they needed to eat. In every speech President Lincoln gave after the end of that conflict where he could have in his remarks been punitive to the South, President Lincoln talked about one Nation, one people. As the leader of the United States, he understood his single job was to bring this country back together. Even though he probably had the greatest reason to draw division in America, he refrained from that temptation and spent all his time redefining what makes America great; that is, a united country of people.

In the temptation to win elections and the temptation to show the highlights or successes of one party over the other, I will conclude with this: As leaders in the country, we have a real opportunity to set by example how we go forward. Let's quit the political divisions. Let's start it with the two Presidential candidates. Don't slice and dice America to where it is that group against this group and that group. Let's realize if we want to change the direction of this country, somebody has to stand and bring America together. My belief is we need to do it now or there may not be another opportunity.

I can look at my good friend Senator HARKIN and myself and we are at an age where we are not going to drastically change the future. We made the bed we are going to sleep in. But for our children and our grandchildren, the impact of what we do can drastically change the opportunities they have for a lifetime.

I would love to leave this institution believing we have had an impact that extends prosperity and opportunity for generations to come. But for a majority of the 2½-plus hours I have taken today, if we don't have the backbone to take it on, it is not going to happen. If we don't do it, nobody else will. Let's demand that the leadership we put in place is willing to show the leadership needed to bring this country back together for a common purpose. That purpose is to be a country of unlimited opportunities, where everybody is being treated fairly.

I thank the Presiding Officer for her attention.

I yield the floor.

NEW ANTIBIOTICS

Mr. MENENDEZ. Madam President, I ask to be recognized to engage in a colloquy with my good friend from Iowa, the Chairman of the HELP Committee, Senator HARKIN.

I want to thank the Chairman for his leadership on this bill, the Food and Drug Administration Safety and Innovation Act. This is a critically important piece of legislation and I am proud to support it. I wanted to ask the Senator to clarify something for me regarding language in the bill dealing with the development of new antibiotics. This bill contains language to incentivize the development of antibiotics, both for newly-discovered infections where antibiotics do not yet exist as well as for those resistant infections where currently available antibiotic treatments may no longer work. These incentives are available for qualified infectious disease products, that is, products intended to treat serious or life-threatening infections, including those caused by resistant gram positive pathogens and multi-drug resistant gram negative bacteria. It is my understanding that products intended to treat serious or life-threatening infections caused by gram negative anaerobic bacteria are also considered qualified infectious disease products, and therefore eligible for the incentives contained in this provision. Is that the case?

Mr. HARKIN. I thank my friend from New Jersey for the opportunity to clarify this point. The Senator is correct that this provision aims to provide incentives in the form of extended market exclusivity for certain antibacterial and antifungal drugs that treat serious or life-threatening infections. He is also correct that the list of qualified pathogens in the legislation is illustrative, and not exhaustive. Products intended to treat serious or life threatening infections caused by gram negative anaerobic bacteria would be qualified infectious disease products and would therefore be eligible for the 5 years of extended market exclusivity.

Mr. MENENDEZ. I appreciate the Senator clarifying that point. As he knows, infections caused by gram negative anaerobic bacteria such as Bacteroides and Garnerella have a disproportionate impact on women of color and cause an increased risk of HIV infection and complications of preterm labor. I am pleased that this bill takes the steps necessary to ensure treatments for these infections can come to market and help those in need. Again, I thank the Senator for his leadership on this bill and for clarifying this point today.

Ms. MIKULSKI. Madam President, I come to the floor to talk about antibiotic resistance, a public health threat to Americans across the country. I have heard first hand from hospitals, health care providers, public health officials, scientists, and life sciences companies in Maryland that we need new antibiotics in our arsenal. Bacteria, like viruses, are crafty and constantly evolving to thwart existing treatments. Everyday, Americans are infected by multi-drug resistant microbes.

In most instances, antibiotics, much like vaccines, are not meant to be used everyday to treat a condition for months, years, or a lifetime. You use antibiotics sparingly, so you do not build up resistance. Yet, drug development for these infectious pathogens can take just as long as developing any other drug whether it is for HIV, heart disease, or cancer. Because antibiotics are used for a short period of time, they are not really profitable to the companies investing the time and money to develop the product. There are not many small start-up companies or big pharma companies that want to take the risk. Research and development costs hundreds of millions of dollars, so these companies are reluctant to invest in a safe and effective drug that doctors are told to use sparingly. Bottom line, developing a next generation Viagra pill is far more profitable for shareholders.

So, House and Senate Republicans and Democrats came together and worked on a bipartisan bicameral solution to incent development of drugs to treat serious or life-threatening bacterial infections. We need to get more antibiotics in the drug development pipeline. We are running out of antibiotics to treat MRSA, tuberculosis, acute pelvic infections, complicated urinary tract infections, or complicated intra-abdominal infections. There are many anaerobic gram negative and anaerobic gram positive bacteria that are fatal, cause lifelong injuries, increase the transmission of HIV and other sexually transmitted diseases, or affect the reproductive and gastrointestinal tracts.

Title VIII of our bill, provides incentives for the development of antibiotics to treat serious or life-threatening infections, including infections where tolerance and resistance to existing antibiotics make them ineffective. We need to clear up infections that can cause poor outcomes for patients or negatively impact the public's health.

This bill will increase exclusivity for manufacturers that invest the time as well as the research and development dollars to bring new antibiotics to the market that knock out infections that cause pre-term labor or target bacterial infections in patients with unmet needs.

Mr. LEAHY. Madam President, I am pleased that Congress will finally send to the President the bipartisan Food and Drug Administration Safety and Innovation Act, FDASIA. This legislation previously received overwhelming support in the Senate and was passed by the House of Representatives by a voice vote just last week. This final action by the Senate will reauthorize the prescription drug user fee program and medical device user fee which are set to expire on October 1, 2012. It will also authorize two new provisions to allow the FDA to review and approve generic drugs and biosimilar drugs in a timely manner. Importantly, this bill includes several provisions that I have supported to prevent access to dangerous drugs.

Passage of the FDASIA will help stop drug shortages that affect thousands of Americans. I have heard from a number of Vermonters concerned about the uncertainty of availability of lifesaving drugs and devices. While the FDASIA will not stop all drug shortages, I hope it will give Vermonters who depend on these medications relief knowing more steps are being taken to ensure these shortages don't happen.

This legislation also includes an important provision I have been proud to author to address the problem of counterfeit drugs. In March, the Senate passed by unanimous consent bipartisan legislation that I introduced with Senator GRASSLEY to deter the sale of counterfeit drugs. The Counterfeit Drug Penalty Enhancement Act, S. 1886, has the support of groups such as the Alliance for Safe Online Pharmacies, the Easter Seals, and the U.S. Chamber of Commerce. The legislation is consistent with recommendations from the Intellectual Property Enforcement Coordinator and the administration's Counterfeit Pharmaceutical Interagency Working Group. I am pleased that a compromise version of this legislation will become law as part of S. 3187.

I am also glad that the final bill includes important provisions addressing the issue of synthetic drugs. These provisions correspond to three bills that the Senate Judiciary Committee passed last year—the Combating Dangerous Synthetic Stimulants Act, S. 409; the Combating Designer Drugs Act, S. 839; and the Dangerous Synthetic Drug Control Act, S. 605. I was glad to move these bills through the committee last year and to work to try to pass them in the full Senate. They address substances commonly known as ''bath salts'' and other synthetic drugs that have no legitimate use and can too easily be obtained under current law. Bath salts have resulted in a number of reports of individuals acting violently in the United States, including in Vermont, and have led to injuries to those using them and to others.

I thank Senators KLOBUCHAR, GRASSLEY, PORTMAN, and SCHUMER for their leadership on this issue. I was glad to be able to work with them and with Senator HARKIN to support including these important provisions in the FDA bill and keeping them there in negotiations with the House. It is good that we are able to make real progress in this area.

I am also glad that we are moving forward on this issue in a responsible way after appropriate consideration. Adding chemicals to schedule I of the Controlled Substances Act has serious consequences and is not a step that we should undertake without careful consideration. We will continue to study this issue and consult with the DEA, FDA, and others going forward.

I note also that Senator PAUL has expressed serious concerns about the mandatory minimum sentences contained in the Controlled Substances Act, mandatory sentences that are expanded every time we schedule new substances. I appreciate those concerns. As more and more of our criminal justice budget goes to housing more and more people in prison for ever longer periods of time, rather than supporting prevention programs and law enforcement which can more efficiently and effectively reduce crime, we have to rethink our reliance on mandatory minimum sentences, particularly for nonviolent drug offenses. In the future, I intend to work with Senator PAUL and others on this vital issue.

Finally, I am pleased that the final FDASIA includes language to protect the public's ability to access information under the Freedom of Information Act, FOIA. This bill will allow the Food and Drug Administration, FDA, to obtain important information about drug inspections and drug investigations undertaken by foreign governments, while at the same time ensuring that the American public has access to information about potential health and safety dangers. This provision carefully balances the need for the government to keep some information confidential, with the need to ensure free flow of information in our democratic society. A number of Senators, including Senator HARKIN and Senator ENZI, and a number of open government and consumer groups, including OpenTheGovernment.org and Public Citizen, worked with me to protect the public's access to FDA information in this bill.

Sending this legislation to the President's desk will save lives. The Senate's action will also mitigate the uncertainty facing the FDA should these user fees expire. I am pleased to support this legislation and urge other Senators to do so as well.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Madam President, we are about to move to a vote on the FDA reauthorization bill, a bill which I have said earlier we spent more than 1 year working on in committee. It has had a lot of input from Senators on all sides, including industry stakeholders and consumer groups. This is the result of a wide collaboration on all these issues.

I wish to respond to a couple things my friend from North Carolina—and he is my friend—said earlier about the amendment he was concerned about on the track-and-trace amendment. The Senator from North Carolina talked about speed. He said we were rushing this through. The vote in the Senate was 96 to 1. The House vote was unanimous. That doesn't happen if a bill is being rushed through. Anybody who tries to rush a bill is not going to get 96 votes in the Senate or a unanimous vote in the House.

Again, my friend questioned how hard we tried to get the track-and-trace provision included in the conference report. I might turn the question around and question how hard the Senator from North Carolina and the Senator from Colorado worked to get this included. We have been working on this bill for over 1 year. My friend, a good member of the committee, and his staff has been very much involved in many aspects of this bill. So I wonder why the amendment was dropped on our staff 1 day before filing the bill at the midnight hour. I might also point out that on September 14, 2011, our committee had a hearing on the supply chain issue. The record will show that I, the chairman, was the only one to raise the issue of track and trace at that hearing.

Two weeks before markup, Senator BURR and Senator COBURN introduced an FDA bill. Senator ENZI's staff and my staff worked for 2 weeks to incorporate elements of this bill into the reauthorization. These are elements of the bill that were introduced 2 weeks before by the Senator from North Carolina, Mr. BURR, and Senator COBURN. So our staff spent 2 weeks trying to incorporate elements into the bill, and they did. We did incorporate a lot of elements. I would point out there was nothing that mentioned track or trace that was in that bill that was introduced 2 weeks before.

Again, I just say, if this was so important, why wasn't it in their bill? If it was so important, why did they wait until Sunday evening at 6:20 p.m., the day before filing, to get the language? Again, who is trying to rush what? We did not try to rush anything, but when we get something dropped in our lap at

6:20 p.m. the night before the filing, it is hard to build a consensus, and that is what this bill is. We did go to conference on this, but this issue involves a lot of different players, and we could not get that consensus.

So I say to my friend from North Carolina, we are still working on this. We will work on it in good faith, but we have the State of California, we have the pharmaceutical manufacturers, we have drugstores, we have consumers, we have a lot of people out there who have something to say about this, and we have to build that coalition in order to get a good track-and-trace bill through.

We are now about to vote on the critical FDA bill reauthorizing user fees, modernizing FDA's authority in several meaningful and targeted ways, addressing the drug shortage problem, streamlining the device approval process, enhancing our global drug supply chain authority and all the while maintaining and improving patient safety. Because this bill will directly benefit patients and the U.S. biomedical industry, it is critically important to the agency, industry, and most important to patients that we get this done.

I urge my colleagues to vote for final passage and pass this bill. It is the same bill the House passed unanimously. Once it is done here, we can send it to the President and get it signed and move ahead with a good reauthorization of the Federal Food and Drug Administration.

The PRESIDING OFFICER. Under the previous order, the motion to concur with amendment No. 2461 is withdrawn.

The question is on agreeing to the motion to concur in the House amendment to S. 3187.

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Colorado (Mr. UDALL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Utah (Mr. HATCH), the Senator from Illinois (Mr. KIRK), and the Senator from Arizona (Mr. MCCAIN).

Further, if present and voting, the Senator from Utah (Mr. HATCH) would have voted ''yea.''

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

The result was announced—yeas 92, nays 4, as follows:

[Rollcall Vote No. 168 Leg.]

YEAS—92

Akaka	Bennet	Brown (MA)
Alexander	Bingaman	Brown (OH)
Ayotte	Blumenthal	Cantwell
Barrasso	Blunt	Cardin
Baucus	Boozman	Carper
Begich	Boxer	Casey
Chambliss	Johanns	Portman
Coats	Johnson (SD)	Pryor
Cochran	Johnson (WI)	Reed
Collins	Kerry	Reid
Conrad	Klobuchar	Risch
Coons	Kohl	Roberts
Corker	Kyl	Rockefeller
Cornyn	Landrieu	Rubio
Crapo	Lautenberg	Schumer
DeMint	Leahy	Sessions
Durbin	Lee	Shaheen
Enzi	Levin	Shelby
Feinstein	Lieberman	Snowe
Franken	Lugar	Stabenow
Gillibrand	Manchin	Tester
Graham	McCaskill	Thune
Grassley	McConnell	Toomey
Hagan	Menendez	Udall (NM)
Harkin	Merkley	Vitter
Heller	Mikulski	Warner
Hoeven	Moran	Webb
Hutchison	Murkowski	Whitehouse
Inhofe	Murray	Wicker
Inouye	Nelson (NE)	Wyden
Isakson	Nelson (FL)	

NAYS—4

Burr	Paul
Coburn	Sanders

NOT VOTING—4

Hatch	McCain
Kirk	Udall (CO)

The motion was agreed to.

Mr. HARKIN. Mr. President, today, with final passage of the FDA Safety and Innovation Act and the reauthorization of the FDA user fee agreements, we have helped both the FDA and the biomedical industry ensure that they can get needed medical products to patients quickly. This legislation, now headed to the President for his signature, will ensure that the FDA can swiftly approve drugs and medical devices, save biomedical industry jobs, protect patient access to new therapies, and preserve America's global leadership in biomedical innovation. It will keep patients safer by modernizing the FDA's inspection process for foreign manufacturing facilities, while also improving access to new and innovative medicines and devices. It will reduce drug costs for consumers by speeding the approval of lower cost generic drugs and help prevent and mitigate drug shortages.

Finally, by improving the way FDA does business, increasing accountability and transparency, U.S. companies will be better able to innovate and compete in the global marketplace.

With the FDA Safety and Innovation Act ready to be signed into law, we have taken an important step to improve American families' access to lifesaving drugs and medical devices.

As I have said throughout this debate, the bipartisan process that produced this excellent bill has been a shining example of what can be achieved when we all work together in good faith. I worked very closely with my colleagues on both sides of the aisle, as well as industry stakeholders, patient groups, and consumer groups, to solicit ideas and improvements on the critical provisions in this bill. We have a better product thanks to everyone's input.

My colleague, Ranking Member ENZI, deserves special recognition, and I extend my sincerest gratitude to him. Without his strong leadership and cooperation in this open bipartisan process, we would not have the exceptional consensus measure we have today. So I thank Senator ENZI for his partnership and collaboration throughout the past almost year and a half.

I wish to specifically thank the staff of Ranking Member ENZI, as they have devoted countless hours to working with my staff and others throughout this process to build consensus for this legislation.

I thank Frank Macchiarola, Chuck Clapton, Keith Flanagan, Melissa Pfaff, Grace Stuntz, Katy Spangler, and Roley Swinehart. I sincerely thank them for their tireless efforts and loyal commitment to this cause.

I also thank all of the HELP Committee members as well as other Senate Members and their staffs who were thoroughly engaged with this process from the beginning as part of the bipartisan working groups. Each of you has contributed significantly to this legislation, and I am sincerely grateful for your contribution.

I also recognize Chairman UPTON and Representative WAXMAN, as well as their staffs, who worked tirelessly to reconcile the differences between the Senate and House legislation.

Of course, I thank my own staff on the HELP Committee, who have spent many a night and weekend with Senator ENZI's staff, other Members' offices, and our colleagues in the House working to come to consensus on the critical policy issues in this legislation.

First of all, I thank our staff director Pam Smith, and I especially want to note the tremendous work done by Jenelle Krishnamoorthy through this last almost 15 months or more, for pulling people together and working on weekends. I don't know how she does it, and she still has time for the twins. It is remarkable, but she does it, and it is done remarkably well, and I thank Jenelle especially for her great leadership.

I also thank Elizabeth Jungman, Bill McConagha, Kathleen Laird, Dan Goldberg, Justine Sessions, Kate Frischmann, Elizabeth Donovan, Frank Zhang, and Evan Griffis.

I also thank our former staff director Dan Smith, who left the committee as staff director a couple of months ago, but he was very much involved in this until the time of his departure.

I also thank the Congressional Budget Office for their knowledgeable and capable team that was willing to work around the clock sometimes to estimate the budgetary effect of the legislation.

We also owe our gratitude to the staff members in the Legislative Counsel's Office—specifically Stacy Kern-Scheerer and Kim Tambor. This bill is a result of tremendous effort by their team to draft and redraft provisions in this measure, as well as address technical issues well into the nights and over weekends. I thank them profusely for their dedication.

This bill's final passage is a victory for millions of Americans who need medicines or medical devices, a victory that would not have been possible without the dedicated work of our Senate family.

The PRESIDING OFFICER. The majority leader is recognized.

SMALL BUSINESS JOBS AND TAX RELIEF ACT—MOTION TO PROCEED

Mr. REID. Mr. President, I now move to proceed to Calendar No. 341, S. 2237.

The PRESIDING OFFICER. The clerk will report the motion.

The legislative clerk read as follows:

Motion to proceed to Calendar No. 341, S. 2237, a bill to provide a temporary income tax credit for increased payroll and extend bonus depreciation for an additional year, and for other purposes.

Mr. REID. Mr. President, I made a commitment to proceed to a 5-year flood insurance bill following the farm bill. We have done that. It is the right thing to do. It is an extremely important piece of legislation. So I have lived up to that commitment. I had hoped the broad support we have for this extremely important bill would allow us to reach an agreement and finish the bill in a relatively short period of time.

As everyone knows, the senior Senator from Arkansas has had some issues with the bill. I have suggested that he have a vote. From talking to my Republican friends, they do not have a problem with that, giving him a vote. Unfortunately, as happens around here more often than I would like, we have not been able to reach agreement because a small group of Republicans is stopping us from doing this.

So my options are really very limited at this stage. I can file cloture and put at risk our ability to complete action on student loans and the Transportation bill. That is what it would do because if I file cloture, we will have to have a cloture vote on this on Thursday. And I would have to file cloture twice because there is the bill and there is the substitute, which everybody agreed was the right thing to do to move forward on the substitute. That is two votes, so at least 60 hours. The flood bill is a very important piece of legislation. It is not something we have to complete the day after tomorrow, but it is something we have to complete a month from now. So do I file cloture and put at risk these important pieces of legislation, meaning the Transportation bill, the student loans—put everything at risk—or I can give supporters of this bill time to try to come to an agreement on limiting the number of amendments.

I really believe the right thing to do is to give the people who want this bill passed, Democrats and Republicans, people who support this extremely important piece of legislation, a day or two to figure out if they can get something done. I hope they can. I honestly do. So I am not filing cloture on this bill as I had really actually contemplated. I hope my Republican friends will work with us to get this bill done.

This is a bill that deals with flood insurance. I have spoken to a number of Republican Senators, including Senator VITTER, who is the person who has spoken out on this more than anyone else, and he acknowledges that there may be a few relevant amendments that we should have on this bill. I do not care. That is fine with me. Let's set up a list of amendments and finish this bill. So I hope we can get that done. I really do. We should not get in a legislative morass on a bill that is extremely important for the country no matter what part of the country you live in. The dry deserts of Nevada, this is an important piece of legislation; the wetlands of Florida and Louisiana, very important piece of legislation. So I hope we can get this done.

Let me just say another word or two. I am very pleased to say that we are close to an agreement to prevent student loan rates from doubling for 7 million young men and women. That would happen at the end of the week. So I appreciate the leadership of President Obama. He has pushed forward on this for a long time. He has given many public statements in this regard. He has been talking to students around the country. He was in New Hampshire yesterday talking to students. They waited in the rain to hear him talk. He has been working with leaders in Congress to ensure that students will not pay the extra $1,000 to get a degree.

I would remind my colleagues, the Republicans, including the Speaker, my friend, were willing to give up on this issue a few weeks ago. We are not willing to give up on this issue. I am glad my Republican colleagues have agreed we should not give up on this issue. We do not want to let the rates double. Leader CANTOR even said Republicans were done legislating. Remember that? But with the President's leadership and our persistence and the help of my valiant Republican friends, we are going to be able, with a little bit of good luck, to protect 7 million students. I hope that is, in fact, the case.

I appreciate the diligent work of the chairman of our committee, Senator HARKIN. Senator JACK REED has worked very hard on this, as have other Senators. I am leaving a few out, but I am certainly not doing that intentionally.

I hope everyone understands the legislative issues we have to work to toward the end of this week. I hope we can get it done. I hope we do not get trapped in one of these Senate procedural bogs where we are going to have to be here Friday, Saturday. You know, I hope we do not have to do that. There is no reason to. We can get all of our work done, but we do need a little bit of cooperation.

The PRESIDING OFFICER. The Senator from Tennessee.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

Mr. ALEXANDER. Mr. President, I congratulate Senators HARKIN and ENZI, their staffs, and all who worked for 15 months on this important piece of legislation. I have watched the Senate for a long time—first as a staff member and then as a Senator—and it has always been a little messy and complicated. There are always disagreements. That is the purpose of the Senate, to work out arguments. But over the last few months, this Senate has done a much better job of operating in the way the American people expect us to operate. We are all here to try to get results after we state our positions. This bill especially affects the health and safety of millions of Americans. Almost every American family buys the prescription drugs and medical devices we are talking about in this legislation. I am glad to see this happen for two reasons—one, because of the result, and two, because of the way the Senate has worked. It is a fine example of what I hope to see happen more often.

I also thank the majority leader, Senator REID, and the minority leader, Senator MCCONNELL, for creating an environment in which we could have a large number of amendments, debate, and discussion. I think we all appreciate that very much and want to create an environment in which they can provide that kind of leadership.

I ask unanimous consent to speak as in morning business.

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

LAND GRANT UNIVERSITIES

Mr. ALEXANDER. Mr. President, on Monday, at the Library of Congress, was the 150th anniversary celebration of the creation of land-grant universities and the National Academy of Sciences. The assemblage also took a moment to throw a bouquet to Andrew Carnegie for founding so many free public libraries.

I am on the floor to ask this question: What was in the water in Washington, DC, 150 years ago, in 1862 and 1863? During the 2 years after the telegraph dispatched the Pony Express in 1861, Congress and President Lincoln enacted the Morrill Act creating land-grant colleges, authorized the Transcontinental Railroad—reducing the time for getting from New York to San Francisco from 6 months to 6 days—as well as the National Academy of Sciences, and enacted the Homestead Act. They also agreed on a conscription law with teeth, a National Banking Act, establishing a national currency, a new internal revenue law, and created the Department of Agriculture. To top it off, on December 2, 1863 the last section of the Statute of Freedom was put in place on top of the Capitol dome, with a great celebration.

Mr. President, if I were the Republican national chairman, I might suggest that this transforming burst of governing was simply a matter of turning the government completely over to