As for John Boehner's goal of an early extension of the Bush tax cuts, it's going to be an uphill climb. Democrats want to raise taxes, not cut them. But at least the GOP will have a coherent growth-and-jobs message. They can tell the public how important it is to avoid falling off the massive tax cliff which looms ahead. Deflationary fears can ease. And they can make it plain to voters that the GOP has a growth message in these perilous economic times, while the Obama Democrats do not.

The PRESIDING OFFICER. The Senator from Louisiana.

Ms. LANDRIEU. Mr. President, I was not here to hear all of my colleagues' remarks. I know there is a lot of concern about the end of the year and what might happen to try to balance our budget and give us a solid platform on which this economy could grow. But one of the things that is holding us up is the Republicans' refusal to put any new revenues on the table. They have been adamant and wrong and hardheaded and stubborn.

They have been very obstructionist in this way—by not being willing to put a penny of new revenue on the table. As a result, we have come to a standstill because the income coming into the Federal Treasury to support this government is at the lowest level since President Eisenhower was President. So they can come to the floor all day long and criticize the President, criticize the Democrats, but in the last 2 years Democrats have put over $2 trillion of cuts and reductions to some very important programs on the table.

Some of us have even been willing to say, yes; we know we have to reform Social Security and Medicare and Medicaid. We have also been willing to speak those words which are not easy. Yet not one single Republican leader, not one on either side, the House or the Senate, not one has come to this floor in public. Now, I have heard them say it in private. I have been in meetings when they have said it. But not one has come to this floor to say: We are willing to put revenues on the table so we can match the cuts and move this country forward.

So I am a little tired of hearing them beat up on either President Obama or the Democrats when they are more to blame for the situation we are in. The American people are getting tired of it too because they can understand it is not 100 percent President Obama's fault. In fact, when he took office, the Titanic had already hit the iceberg because they had run right smack into it with the economic philosophies and policies they had. The ship was already sinking. But all they want to do is—either MITCH MCCONNELL or JON KYL, one day the Senator from Arizona or the Senator from Kentucky—every day come to the floor and talk about how it is the President's fault there is no way forward, there is no sure path forward, when they are the ones who have put boulders in the way every day.

So I hope the people can see through it. I came to the floor to talk about something else, but I am getting a little tired of hearing it myself. So I am sure everyone else is as well.

Again, Democrats have put $2 trillion of cuts before this body, and we have implemented some of them already. But we cannot run a government on 14 percent of the GDP. The average has been about 20 to 21 percent. So until they are willing to put some more revenues on the table, we are not going to get anywhere, and we are not going to be able to extend the tax cuts that cost people money.

I hope we can do something so we can extend some tax cuts to small businesses, which I came to talk about—and you, Mr. President, know this well. Instead of giving some of the biggest tax breaks to companies that are the biggest in the world and put all of their jobs overseas, I wish the Republicans would start talking about tax relief to businesses right here at home on Main Street. That is what I want to talk about today.

(The further remarks of Ms. LANDRIEU are printed in today's RECORD under ''Morning Business.'')

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

THE INTERNET

Mr. WYDEN. Mr. President, I believe the development of the Internet, its networks, and the digital economy are one of the great achievements of our age.

The Internet links humanity together, facilitating economic growth, bringing education and health resources to remote regions, reshaping societies and advancing human rights.

While networks foster innovation, job creation, and political and social progress, networks can also be used by actors with nefarious motives. It is in our national interest to deter, detect, and destroy real and viable cyber threats, to protect Americans and preserve the benefits of the Internet. Americans must not be afraid to go online.

The Internet works not just because it is open to all but because it is founded on the principle of trust. Users trust that their browsers are visiting real Web sites, not replicated ones. Internet commerce succeeds because people trust that their transactions are private and their financial information won't be shared with others. People trust the Internet because they believe their service providers work for them, not for their advertisers, not for scammers, and not for the government.

Congress's effort to develop a comprehensive approach to cybersecurity must not erode that trust. When Americans go online to consume digital services and goods, they must believe and know with some certainty that their privacy is adequately protected. The content that Americans consume must be at least as private as their library records, their video rentals, and book purchases in the brick-and-mortar world. Our law enforcement and intelligence agencies should not be free to monitor and catalog the speech of Americans just because it is online.

But the legislation passed by the other body, known as CISPA, would erode that trust. As an attempt to protect our networks from real cyber threats, CISPA is an example of what not to do. CISPA repeals important provisions of existing electronic surveillance laws that have been on the books for years, without instituting corresponding privacy, confidentiality, and civil liberty safeguards. It creates uncertainty in place of trust, it erodes statutory and constitutional civil rights protections, and it creates a surveillance regime in place of the targeted, nimble, cybersecurity program that is needed to truly protect our Nation.

Unfortunately, S. 2105, the bill before the Senate, shares some of these defects. Currently, Internet services and service providers have agreements with their customers that allow them to police and protect their networks and users. Rather than simply allowing these Internet companies to share information on users who violate their contracts and pose a security threat, the House and Senate proposals regrettably authorize a broad-based information-sharing regime that can operate with impunity. This would allow the personal data of individual Americans to be shared across a multitude of bureaucratic, military, and law enforcement agencies. This would take place regardless of the privacy agreements individual Americans have with their Internet service providers.

In fact, both the House and Senate bills subordinate all existing privacy rules and constitutional principles to the poorly defined interests of what is called cybersecurity.

These bills would allow law enforcement agencies to mine Internet users' personal data for evidence of acts entirely unrelated to cybersecurity. More than that, they would allow law enforcement to look for evidence of future crimes, opening the door to a dystopian world where law enforcement evaluates your Internet activities for the potential that you might commit a crime.

In establishing this massive new regime, these bills fail to create the necessary incentives for operators of critical networks to keep their networks secure.

It is a fundamental principle of cybersecurity policy that any network whose failure could result in a loss of

life or significant property should be physically isolated from the Internet. Unfortunately, many of our critical network operators have violated this principle in order to save money or streamline operations. This sort of gross negligence ought to be the first target in any cybersecurity program—not the privacy of individual Americans.

Congress could target this behavior with yet one more rule book and one more bureaucracy, creating a cybersecurity contractor full employment program. I am not, however, convinced this is a problem that requires that kind of solution.

At the same time, Congress should not allow our critical network operators to ignore best practices with impunity. It is vital they understand that any liability for a preventable cyber attack is their responsibility. There is not going to be a governmental bailout after the fact in the cybersecurity area. Shareholders and boards of directors must be vigilant and understand the risks to their investments. Executives must understand that ignoring critical cyber threats in the interest of cost savings and convenience will leave them personally exposed.

Internet providers and backbone operators clearly have a role in this fight. When they detect abnormal network activity or have a user violating their contract in a way that constitutes a cyber threat, they can and should inform our cyber defense officials. If it is necessary to grant them immunity to share this kind of information, the Congress could grant it—narrowly and with careful consideration.

Mr. President, there would be bipartisan support for the proposition that the Federal Government also has a significant role that does not necessarily require billing taxpayers for legions of private cybersecurity contractors. The Department of Defense, the Department of National Intelligence, Homeland Security, and the Justice Department—four major parts of our government—all have cybersecurity specialists. The Congress ought to be promoting the cyber capabilities of these agencies and providing the resources that are needed to protect these networks. These Federal agencies should do a better job of consulting the private Internet companies to better understand the attacks that are occurring every day across the net.

Some of these steps may require legislation, but many can be carried out by responsible actors in the public and private sector without waiting for the Congress to act. However, the legislation before the Senate and the cybersecurity legislation that passed the other body leads our country away from the kind of commonsense approach to cybersecurity I have outlined this afternoon.

As they stand, these bills are an overreaction to a legitimate and understandable fear. The American people are going to respond by limiting their online activities. That would be a recipe to stifle speech, innovation, job creation, and social progress. I believe these bills will encourage the development of an industry that profits from fear and whose currency is Americans' private data. These bills create a cyber industrial complex that has an interest in preserving the problem to which it is the solution.

In terms of the process, the Senate ought to proceed in a way that is as open and collaborative as the Internet the Congress seeks to promote and protect. On substance, any cybersecurity bill must contain specific and clear descriptions of what types of data and when such data can be captured, with whom it can be shared, and under what circumstances. Anything not specifically covered ought to remain private. Privacy in the cybersecurity arena should be the default not the exception. Legal immunity to corporations that share information should be the exception not the rule and void if privacy protections or contracts are disregarded.

The Congress and the public must have the ability to know how any cybersecurity program that is established is to be implemented. That means routine public and unclassified reports and hearings to examine whether there were any unintended privacy or civil liberty impacts caused by the program. No secret law, Mr. President.

Bad Internet policy is increasingly premised on false choices. Earlier this year, during the consideration of the Protect IP Act and the Stop Online Piracy Act, the Congress was told again it had a false choice. The Congress was told it either could protect intellectual property or it could protect the integrity of the Internet. This was a false choice. I and others said so at the time because achieving one should not and does not require sacrificing the other.

Now the Congress is being asked once again to make a false choice—a choice between cybersecurity and privacy—and I don't think these two are mutually exclusive. I think we can have both. Our job is to write a cybersecurity bill that protects America's security and the fundamental right to privacy of our people. There is no sound policy reason to sacrifice the privacy rights of law-abiding American citizens in the name of cybersecurity. It is my intent to fight any legislation that would force Members of the Senate to make that choice.

Mr. President, with that I yield the floor.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. COATS. Mr. President, I rise today to talk about the Food and Drug Administration Safety and Innovation Act. I believe we are going to have a cloture vote on this bill tonight, and I am pleased that all early indications are it will pass tonight and we will move forward on this bill.

There has been considerable time spent drafting this legislation. It gained bipartisan support both in House and Senate committees, and it is moving through what I would call a regular process. We haven't seen too much of that in the last year and a half or so. This is the regular process. For those who say Congress can't get anything done, hopefully, with passage of this bill we will take a very significant step forward in terms of being able to provide and bring to patients, doctors, administrators, and others across the Nation new drugs, new treatments, and new medical devices that can ensure better health, prevent potential terminal situations, and provide better drug availability and device availability. So I think it is very important that this legislation goes forward.

I am pleased we have gotten to this point on a bipartisan basis. I think Senators HARKIN and ENZI deserve commendation for their work in the Senate, and those in the House as well for bringing the bill along on a parallel track.

The whole idea of this legislation is to continue to provide the safest, most effective and most efficient drugs and devices for American citizens and people around the world. These are two very important industries in which the United States has had the leading edge as providers and we don't want to lose that. It has meant a lot for our economy, and it has meant a lot of jobs for Americans. I think the passage of this bill will continue what has been a remarkable nearly three decades' worth of innovation that has taken place both in the biopharmaceutical industry as well as the medical device industry.

Part of this bill deals with drug shortages. I have talked to a number of doctors—my staff has been traveling the State talking to medical providers—and there is an alarming number of drug shortages in critical drugs, particularly those designed to deal with more rare instances of health problems and yet, obviously, important to those people who are suffering from those incidences of disease or health threats.

It was reported to me that last year FDA received a record number of drug shortage reports—more than 250—including critical drugs used in surgery, emergency care, and oncology. The problem continues today, but the this bill addresses that and, hopefully, will move us forward significantly in terms of dealing with this current problem.

In Fort Wayne—my hometown in Indiana—Parkview Health's pharmacy director said nearly 80 percent of hospitals consistently face shortages in drugs needed for emergencies, including cardiac and diabetic prescriptions. This bill incorporates significant reporting requirements to the FDA that I hope will help mitigate this critical problem. I think we are going to need to figure out ways to further address this, but this can be an important first step.

The whole concept has been somewhat unique in the Federal Government; that is, the makers of the products essentially pay a fee to a regulatory agency for the regulatory agency to conduct the work necessary to gain approval to sell their drugs on the market. We have had a situation which is sort of a cornucopia of new innovations in drugs and medical devices. Yet they have been delayed by the bureaucracy or the inability of the FDA to move in an efficient, effective way to run this through the process.

The biopharmaceutical industry has basically said: Look, we are willing to put up between $3.5 billion and $4 billion in new user fees—I believe it is over a 5-year period of time—which will account for nearly 60 percent of the funding designated by the Center for Drug Evaluation and Research. In exchange for putting up those fees, the FDA has agreed to new performance goals and process improvements that will reduce the time it takes drugs to reach the market.

So the key is to provide the funds necessary to hire the right people and put the right procedures in place to expedite the study and approval of safe, effective, efficient drugs that have been sent to the FDA for approval so we can get them into the market. Of course, the ultimate goal is to get them not only into the market but use them to provide health and safety benefits for the American people.

The Medical Device User Fee Act is also part of this. In Indiana, we have not only a very large biopharmaceutical company and a number of affiliated companies, we also have a vibrant and dynamic medical device industry. That industry employs over 20,000 Hoosiers directly and many more indirectly with good-paying jobs. Many of these companies are right on the leading edge of new innovation and new developments. So included in the legislation that we will be voting on is a 5-year agreement known as the Medical Device User Fee Act that improves the regulatory pathway for medical devices.

This is the medical device equivalent of the pharmaceutical user fee. Device companies have worked with the FDA, again in an agreement where each side contributes. The medical device manufacturers will contribute user fees to go to the FDA that can be used to streamline—without compromising safety in any way—the regulatory process so the approvals can be made.

Why is this important? Well, it is important not only to getting these products into the marketplace so they can be used to safely improve the health of American citizens, but this is a dynamic export industry where America has been the leading exporter of medical devices. I have heard from so many medical device manufacturers throughout Indiana that they are faced with the dilemma of having to potentially think about moving overseas simply because of the delays and the time lapse that exists for approval. They can manufacture these products overseas and get approval overseas and sell them on a worldwide basis much more quickly, but they do not want to do that. The United States is their home and they want to produce here, but they have to compete with their competitors across the waters that are subjected to fewer delays in implementing approvals.

To counter that, we simply want to use this medical device user fee in a way that will help the FDA's review process and eliminate these unnecessary delays, unpredictability, and inconsistency of past practices.

I do want to thank the FDA for paying significant attention to our device users by coming to Indiana and listening to them—a forum that I convened. There has been interaction back and forth, whether it is FDA traveling to Indiana or device manufacturers traveling here to Washington. I am pleased that this bill contains some items that are the result of all those negotiations and all those exchanges between the two.

Let me mention one last thing before closing, and that is the medical device tax, which is not part of this bill. To pay for the so-called affordable health care law, the administration included a 2.3-percent tax on medical devices, which will begin in 2013. That tax essentially was imposed on an industry that is paying its full share of taxes, contributing to the user fee, and yet it was slapped on as a way to pay for the costly health care bill. That has an enormous impact over a period of time on these device manufacturers and jeopardizes manufacturers' ability to remain based here in the United States rather than looking overseas.

There are a number of States in addition to Indiana—and my colleague from Minnesota is waiting to speak, and her State is also a major manufacturer and innovator of medical devices. California, Florida, Illinois, Massachusetts, New Jersey, New York, Ohio, Pennsylvania, Texas, and Wisconsin will all suffer potential job losses if this medical device tax is imposed.

We are not taking it up in this bill so as not to try to derail the bill. I understand an agreement has been made that it would be set aside. I know Senator HATCH, on our side, is looking for an opportunity to bring that up in another vehicle, and I want to support that. I encourage my colleagues to take a look at the impact of that fee on our ability as a nation to be the leader in innovation and export of medical devices.

I thank Senators HARKIN and ENZI for shepherding the Food and Drug Administration Safety and Innovation Act through the committee. I believe this legislation will help improve patients' access to new medical technology, and it will protect American jobs and improve the FDA so that America can remain a global leader in biomedical innovation. I encourage my colleagues in the Senate to support this important legislation.

I yield the floor.

The PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, I thank the Senator from Indiana for his words.

We both are from States that have a lot of jobs involved in medical devices, and, in fact, this bill is something we worked on very hard. I am the cochair of the medical device caucus in the Senate. This has been our top priority, to try to move those FDA rules along, and this bill does that. It is an agreement—a rare agreement—between government and industry, which is something both parties want. We would like to move those approvals along for the patients, long-suffering patients who should have access to medical devices, and then also for the industry, where we have seen way too much venture capital money go to places such as Europe simply because that process moves faster. So this is a very good bill, and I am so pleased we have bipartisan support.

I see that the Senator from Wyoming, Mr. ENZI, has come into the Chamber, and both he and Senator HARKIN deserve a lot of praise.

I wish to focus today on one piece of this bill, something I have worked very hard on, and it really came out of things I heard in my State, things I heard from pharmacists literally 2 years ago, things I have heard from patients. I got together with our staff. I see that our legislative director, Rose Baumann, and Andrew Hu, who did a lot of work on this bill, are here today. We went and talked to all kinds of people involved. We talked to pharmaceutical companies to try to figure out what was going wrong with drug shortages; we talked to the people who were suffering the most—the patients; we talked to the pharmacists, and we said: What would work here? And the FDA told us that, in fact, when they did get early notification from pharmaceutical companies that there was going to be some kind of shortage, it helped. They were able to avert that shortage. They have done it successfully over 100 times, and they have done it many times with some key drugs. And the earlier notice they have, the better it is for everyone because they can, in fact, then avert the drug shortage, and that is what this is about.

I will tell you that, for me, this whole bill and this whole provision really comes down to a little boy named Axel Zirbes, a young boy with bright eyes and a big smile. Because of leukemia, this little boy, when I saw him, had no hair on his head. He and his family were thrown into a panic about 1 year ago when they learned that an essential drug—cytarabine—was in short supply and might not be available for their son, who they had just found out was diagnosed with leukemia and was supposed to start treatment, and the doctor says: You know

what, we don't know if you should start it—you should start it immediately, but we don't have this critical cancer drug, this critical leukemia drug.

They decided they would take Axel to Canada, where the drug was readily available, and just when they were making those plans to go there, they found out that some of the drug had been located and that Axel could come in for his treatments. Well, that should never have happened, not in the United States of America, not to a family of a little 4-year-old boy, both parents working hard to make sure their child could have health care and then this happens. It makes no sense.

There is the story of Mary McHugh Morrison, who joined me at a forum I held on this topic in Edina, MN. Mary is a woman whose cancer had, unfortunately, returned after a shortage of Doxil. That is a chemotherapy drug that had kept her ovarian cancer at bay. In fact, this shortage interrupted her chemotherapy regimen. Mary struggled to find remaining vials of Doxil and then struggled with the ethical dilemmas of using the drug she found when others would not be able to use it. She literally talked at the forum about how she had personally called people, used connections, tried to find those vials, and she realized that when she got those drugs, other people wouldn't have them.

Again, this shouldn't be happening in the United States of America. She shared her experience with us. And because of a few delays in treatment, Mary's doctor told her that her tumor had, unfortunately, returned and that she was then no longer responding to that drug. This past February, CT scans, unfortunately, showed that Mary's tumor size had doubled. She was immediately accepted into a clinical trial at the Mayo Clinic and began treatment. Fortunately, she is so far responding well and her health is improving.

These shortages are happening all over this country. Every single Senator in this Chamber has heard about one of them. You heard Senator COATS from Indiana talking about what he had heard. So the fact that we heard this first in Minnesota I don't think is any surprise. We have an active State. We have people who believe you can still make a difference. We have pharmacists who are on the front line every day, and they came to us to get this bill introduced. We heard from emergency medical responders, who have told me that shortages have made it difficult to stock lifesaving drugs in their ambulances. I have listened to stories from parents whose children rely on drugs to help maintain their focus at school. I have seen firsthand how doctors and pharmacists have had to struggle to keep their patients alive as they look for these drugs.

These shortages have had significant impact on these patients' quality of life, oftentimes forcing them to pay hundreds more for expensive alternatives or risking their professional careers to adjust for their diseases and spending hours and days just trying to find a way to fill a prescription.

When we are dealing with so many costs and resource issues with health care, the last we want is for doctors and nurses and pharmacists to be wasting away hours trying to find drugs and then ultimately, in most cases, finding them, but this is no way to run a railroad. Across the country, hospitals, physicians, and pharmacists are confronting unprecedented shortages of these drugs.

So those are the stories, but here are the numbers.

The number of drug shortages has more than tripled over the last 6 years, jumping from 61 drug products—remember, there are thousands of shortages, but this is 61 different drug products in 2005 to more than 200 drug product shortages in 2011.

A survey by the American Hospital Association found that virtually every hospital in the United States has experienced shortages of critical drugs in the past 6 months. More than 80 percent reported delays in patient treatment due to shortages.

For some of these drugs, no substitutes are available or, if they are, they are less effective and may involve greater risk of adverse side effects. The chance of medical errors also rises as providers are forced to use second- or third-tier drugs that they are less familiar with using.

A survey conducted by the American Hospital Association showed that nearly 100 percent of their hospitals experienced a shortage—100 percent. Another survey conducted by Premier Health System showed that 89 percent of its hospitals and pharmacists experienced shortages that may have caused a medication safety issue or an error in patient care.

It is clear that there are a large number of overlapping factors that have resulted in these unprecedented shortages. Experts cite a number of factors: market consolidation, poor business incentives, manufacturing problems, production delays, unexpected increases in demand for a drug, inability to procure raw materials, and even the influence of the gray market. Literally, people are trying to make money off of this now. They hear there is a shortage, and they buy up the supply and then sell it at a higher price. Financial decisions in the pharmaceutical industry are also a major factor. Many of these medications are in short supply because the companies have simply stopped production. They decided it didn't work for their profits to keep producing them. Mergers in the drug industry have narrowed the focus of product lines. As a result, some products are discontinued or production is moved to different sites, leading to delays. When drugs are made by only a few companies, a decision by any one drug company can have a large impact. That would make sense.

To help correct a poor market environment or to prevent gray market drugs from contaminating our medication supply chain, we must address the drug shortage problem at its root. Last year I introduced the Preserving Access to Life-Saving Medications Act with Senator BOB CASEY. We also have the support of Senator COLLINS and others. This is a bipartisan bill that would require drug manufacturers to provide early notification to the FDA whenever there is a factor that may lead to a shortage. We also had support from the Presiding Officer, as well as Senator BLUMENTHAL of Connecticut and many other people from across the Senate.

This bill will help the FDA take the lead in working with pharmacy groups, drug manufacturers, and health care providers to better prepare for impending shortages, more effectively manage shortages when they occur, and minimize their impact on patient care. And that is why I am pleased that the early notification provision from my bill is included in the Food and Drug Administration Safety and Innovation Act, the one that Senator COATS and I were just discussing and that we are debating today.

I thank Senator HARKIN and Senator ENZI for their leadership on the HELP Committee in bringing this legislation forward and including my provision. In a bipartisan manner, the HELP Committee brought together several working groups to address a wide range of issues, from medical device innovation to drug shortages. In the drug shortage working group, we spoke with experts from patient groups, providers, drug manufacturers, and the FDA to try to find an appropriate solution.

Ultimately, the legislation now includes many policies that I believe will help address shortages. In addition to the early-notification requirement, again, the FDA is going to be able to look in our own country, and if they can't find something in our own country they can look at safe locations overseas. You simply can't keep these patients waiting for their treatment.

In addition, the bill directs the FDA to improve communications inside and outside its walls, requires more robust record-keeping and reporting, and asks for studies on how pricing factors impact drug shortages.

I believe this bill represents a step forward in our ability to prevent these shortages—a strong step forward. With manufacturers providing early notification, the FDA's drug shortage team can then appropriately use their tools to prevent shortages from happening. As I mentioned, in the last 2 years, the FDA, with more information, has successfully prevented nearly 200 drug shortages. Imagine the hundreds of thousands and millions of patients that has helped. So we need to extend it. That is what this bill does.

One such example is the recent shortage of methotrexate. This is a very common drug used in chemotherapy to

treat cancers such as leukemia. For me, the most devastating part about the shortage is that I heard about it from the Zirbes family—the family of this little 4-year-old boy who had to suffer through the shortage of cytarabine earlier. Only this time, the FDA took quick action once it learned of this potential shortage and worked with other manufacturers to boost production and helped stop the bleeding before this became a major crisis. That is an example of what can happen with early notification. They are allowed to then go to other manufacturers and find the people who can make the drug to get it to the hospitals, to get it to the patients. And today, with strong cooperation between the FDA and pharmaceutical manufacturers, methotrexate is available for patients who rely on it just like that little 4-year-old boy Axel Zirbes.

Together with Senator CASEY, we were able to work with the HELP Committee and in a bipartisan manner come up with a solution that would give the FDA more tools to prevent drug shortages and ensure patients such as Axel or Mary have the drugs they need when they need them. Recent announcements by the FDA have proven that early notification and cooperation with manufacturers have helped reduce the number of drug shortages by over half. There have been 42 newly scarce drugs so far this year, compared to 90 in the same period last year. That is progress.

While I applaud the FDA in their efforts to address this crisis, 42 drugs in shortage is still 42 too many for me. That is why it is so important to pass this provision and give the FDA the tools it needs to get the number down to zero.

I understand that early notification requirements may be a short-term solution to a long-term problem. That is why I will continue to work with my Senate colleagues to come up with a broad permanent solution, one that includes methods to address the root causes of drug shortages.

It has been a long road to get to this point. Nearly 2 years ago I began hearing about this drug shortage issue, and when I first talked about it some of the doctors said: Really? I haven't heard about it. Now, 2 years later, they have all heard about it. That is why we introduced the Preserving Access to Lifesaving Medication Act. That is why we came together to get an agreement in this legislation. That is why the President issued an Executive order that pushed for more voluntary notifications from manufacturers, and the FDA released an interim final rule that broadened the scope of the current notification requirement. That is why it is so important that we pass this legislation.

Patients such as Axel or Mary should not have to be burdened with the added stress and worry about whether they are going to have enough medication to get through their next treatment. They have enough on their minds. Let's get this done. It is a great example of people working across the aisle. When they heard something from their constituents, they were willing to listen and to put this bill together. Me, I would like to have gotten it done 2 years ago, but later is better than never. We can get it done this week.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant bill clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, after many months of bipartisan negotiation, the Senate will proceed this evening to vote on the motion to proceed to consideration of the Food and Drug Administration Safety and Innovation Act of 2012. I hope it will receive an overwhelming vote so we can move ahead with it and dispense with the bill on the floor this week. This bill is the product of excellent bipartisan collaboration on the Health, Education, Labor, and Pensions Committee which I chair. All Senators on the committee have been involved. Going back almost a year, we set up working groups. Different Senators had different interests in different parts of the bill. They and their staffs on both sides were invited, Republican and Democrat, to be involved in those working groups to put this bill together.

The bill passed overwhelmingly out of our committee—actually by voice vote, with only two reserving their ''no'' votes. So it had overwhelming support on both sides in our committee.

This bill, of course, reauthorizes important FDA user fee agreements. It modernizes the FDA's medical product authority to help boost American innovation and ensure patients have access to the therapies they need. The backbone of this legislation is the user fee agreements that FDA has negotiated with industry. We must remember that a sizable part of FDA's budget comes from user fees that the industry agrees to pay, that allows the FDA to hire the personnel and get the equipment they need to more quickly review product applications. We need to reauthorize this bill to implement those agreements if we want to keep the FDA running at full steam, which is critical to preserving jobs at both the agency and in industry, and to ensuring that FDA has the resources to get safe medical products to patients quickly. Again, these agreements affect all of us by helping to maintain and create jobs in our home States. For example, in my own State of Iowa, these agreements will support our bioscience sector which is growing and is increasing employment in our State. Implementation of these agreements will continue to foster biomedical innovation and job growth throughout our country.

The bill before us reauthorizes the prescription drug user fee agreement, which is known in the nomenclature as PDUFA. The medical device user fee agreement is known as MDUFA. These will continue and improve the agency's ability to speed market access to both drugs and medical devices while ensuring patient safety.

We have a new part of the bill called the generic drug user fee agreement, which is expected to slash review times to a third of current levels—from 30 months to 10 months—and will improve the speed with which generic products are made available to patients. This will generate significant savings in our health care system. In the last decade, from 2001 to 2010, it saved the U.S. health care system more than $931 billion.

This agreement will ensure we continue to see those savings and that patients will have access to cheaper drugs when they need them. It also obviously means taxpayers will be saving money because many of these drugs come through both Medicaid and Medicare. By having generic drugs available more rapidly than they have been in the past, it will mean taxpayers will save a significant amount of money in the future.

This bill also authorizes another new section, the biosimilars user fee agreement, which will further spur innovation by shepherding the biologic industry as it matures.

These agreements are vital to FDA's ability to do its job, to the medical products industry's ability to survive some very challenging economic times, but, most importantly, to the patients who are the primary beneficiaries of this longstanding and valuable collaboration between FDA and industry. As I said, after months of negotiations with our staffs, with FDA, with the industry, and with consumer groups, I think they have crafted win-win agreements that they stand behind. So industry is behind this bill, the FDA is behind this bill, and hundreds of groups throughout this country have been supporting it. They have done their job and now it is time for us to do ours.

It is absolutely imperative that we authorize these user fee agreements before they expire. If we don't, the FDA will lose about 60 percent of its drug center budget and 20 percent of its device center budget. It will have to lay off nearly 2,000 employees, which would grind the drug and device approval processes to an unacceptably slow pace, with devastating consequences for patients, jobs, for the industry, and further innovations both in drugs and devices. We cannot let that happen, and that is why for more than a year we have worked very closely in our committee.

I see the ranking member, Senator ENZI, is here. We and our staffs have worked together. As I said, we set up

these working groups in our committee. They were not divided along any kind of partisan lines. They were set up along interest groups so we had both Democratic and Republican Senators and their staffs working together for years.

I am sure I can speak for Senator ENZI when I say all along our aim has been to ensure that in addition to the user fee agreements and all the other things, this is the product of a consensus, bipartisan, policymaking process that we have had for the last year. It was an open and transparent process. We had input not only from our members but other Senators were also involved as they had interest in this bill. Throughout negotiations on this bill the stakeholder community-at-large was involved.

Again, I can assure everyone that this legislation benefited greatly from all of the diverse input from Senators on both sides, industry stakeholders, consumer groups, and patient groups. It is a result of concerted efforts to define our common interests, and I believe these efforts will directly benefit patients and the U.S. biomedical industry.

Very briefly, I want to say as a broad stroke that this bill authorizes key user fee agreements for both drugs and medical devices. It streamlines the device approval process while again enhancing patient protections.

We do one other thing. We modernize the FDA's global drug supply chain authority so we have a better handle on and better information and knowledge of where our products are coming from. Of the drugs manufactured in this country, 80 percent of the ingredients come from abroad. In the past we have not had a tight handle on where they were coming from and what kind of manufacturing processes were involved. This bill closes that up. It gives the FDA much better authority over that and much better input from where the drugs come from to make sure they follow good manufacturing practices. It spurs innovation and incentivizes drug development for life-threatening conditions.

We reauthorized the pediatric trial program and improved it so we have specific trial programs for pediatric drugs. Children are not just small adults. What may work for an adult in terms of a drug, we don't just cut the drug in half and give it to a child. Sometimes it takes specialized, specific kinds of drugs for children that are not something an adult gets. So this reauthorizes and improves those trials for children.

Senator ENZI and I and others in our committee wanted to do something about preventing and mitigating drug shortages, so we have provisions in this bill that will do that and help prevent and mitigate these drug shortages by making sure the FDA gets timely information from manufacturers if there is going to be any interruption at all in the supply chain. Also I believe this bill increases FDA's accountability and transparency.

That is sort of a broad-brush stroke of what is in this bill. I will be over in the next day perhaps getting into some more of the specifics. It is imperative that we keep pace with and adapt to technological and scientific advances. Things move very rapidly in this area and we want to make sure we get the drugs and devices approved as quickly as possible, but always with keeping patient safety foremost. That is the single most important aspect, to make sure that patient protections will remain key. Keeping pace with the biomedical landscape that changes so rapidly is the aim of this bill, to ensure the drugs coming from abroad are safe, and to take appropriate measures to protect our patients.

I believe we have a good compromise. Neither Democrats nor Republicans got everything they wanted in this bill. As I have said before, I didn't get all of what I wanted in this bill. I am sure others didn't either, but that is the process of a consensus. And where we could not achieve consensus, we didn't allow those differences to distract us from the important goal of producing a bill that everyone could support.

Again, it is a true bipartisan bill that is broadly supported by the patient groups and industry. I have letters from over 100 groups outlining their support. To name a few: the Pew Charitable Trust, Consumers Union, the Pharmaceutical Manufacturers Association, the Generic Pharmaceutical Industry, the Biotech Industry Organization, BIO, the American Academy of Pediatrics, Advanced Medical Technology Association, American Foundation for the Blind, and many more. Those are just a sampling of over 100 groups.

Mr. President, I ask unanimous consent that the list of those groups be printed in the RECORD at the conclusion of my remarks.

Mr. HARKIN. We are expecting that there will probably be some amendments to this bill, and that is fine. That is the way the Senate should operate. We expect all amendments to this bill will be relevant to the bill. I hope Senators on both sides of the aisle who want to see this bill passed expeditiously would keep that in mind. If there is a relevant amendment and Senators feel they want to bring that up, that is fine. That is the way the Senate should operate.

I hope nonrelevant amendments which have nothing to do with the bill will not be promoted on the Senate floor. That would only slow the bill down and put us into some untenable position on the Senate floor in terms of getting this bill expeditiously done.

We cannot allow unrelated, partisan disagreements or Presidential-election year politics to interfere with this bill and keep us from completing our job. So amendments that are offered must be relevant to the bill, and we must pass it now.

The clock is ticking. Everything ends by the end of this summer. We are out of here in August. We have the 4th of July break and Memorial Day break coming up. In order for us to go to conference with the House and work out whatever differences we may have and get this back here so we can finish it by late June or early July—I hope we could even finish this by late June so there would not be any disruptions at all in the FDA and their planning for the future or in the industry itself.

I urge my colleagues to join in the bipartisan spirit of cooperation that we have witnessed in the HELP Committee over the last year. Let us come together to pass this legislation that is of critical importance to the American people.

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

SUPPORT FOR PROVISIONS IN THE FDA SAFETY AND INNOVATION ACT

A. Philip Randolph Institute; Ablitech, Inc.; Academy of General Dentistry; Academy of Managed Care Pharmacy; Action Aids; Action CF; Advanced Medical Technology Association; AFL–CIO, Maryland and DC Chapter; AIDS Alliance for Children, Youth, and Families; AIDS Delaware; AIDS Foundation of Chicago; Alder Health; Alexion Pharmaceuticals; Allegheny Conference of Community Development; Alliance of AIDS Services—Carolina; Alzheimer's Association—Capital of Texas Chapter; Alzheimer's Association—Indiana Chapter; Alzheimer's Association; American Academy of Child and Adolescent Psychiatry; American Academy of Dermatology Association.

American Academy of Emergency Medicine; American Academy of Emergency Medicine Residential and Students Association; American Academy of Pediatric Dentistry; American Academy of Pediatrics; American Academy of Periodontology; American Association of Nurse Anesthetists; American Association of Oral and Maxillofacial Surgeons; American Association of Women Dentists; American Cancer Society Cancer Action Network, Colorado Chapter; American Cancer Society, Delaware Chapter; American Cancer Society, South-Atlantic Division; American College of Clinical Pharmacy; American College of Emergency Physicians; American College of Gastroenterology; American Council of the Blind; American Dental Association; American Foundation for the Blind; American Hospital Association; American Liver Foundation—Allegheny Division; American Medical Association.

American Pediatric Society; American Pharmacists Association; American Printing House for the Blind; American Psychiatric Association; American Public Health Association, Delaware Chapter; American Society for Gastrointestinal Endoscopy; American Society for Parenteral and Enteral Nutrition; American Society of Anesthesiologists; American Society of Clinical Oncology; American Society of Dentist Anesthesiologists; American Society of Health-System Pharmacists; American Society of Hematology; American Society of Pediatric Nephrology; American Thoracic Society; Amgen; Analtech; ARCA Biopharma; Arthritis Foundation; Association of Community Cancer Centers; Association of Medical School Pediatric Department Chairs; AstraZeneca Pharmaceuticals LP; Augmenta Biologicals.

Bayer Healthcare; BHGR Law; BIO; BioCrossroads; Biogen Idec; BioHouston; BioNJ;

BioOhio; BioRelix, Inc.; Biotech Vendor Services; Black Mental Health Alliance of Massachusetts; Bleeding Disorders Alliance Illinois; Blood Bank of Delmarva; Bloomington Chamber of Commerce; Boehringer Ingelheim Chemicals, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Vetmedica, Inc.; Boehringer Ingelheim, Inc.; Bristol-Myers Squibb; Burlington Chamber of Commerce.

Cambridge Chamber of Commerce; CARA Therapeutics; Celgene Corporation; Central Connecticut Chambers of Commerce; Cerebral Palsy Association of Eastern Massachusetts; Chamber of Commerce of Eastern Connecticut; Child Neurology Society; Children's Defense Fund; Children's Hospital Association; Citizens Opposed to Additional Spending and Taxes (COAST); Cleveland Clinic; Coaches Against Multiple Myeloma; Coalition of Texans with Disabilities; Colorado Association of Commerce and Industry; Colorado Bioscience Association; Colorado Gerontological Society; Commerce and Industry Association of NJ; Community Health Charities of Iowa; Connecticut AIDS Resource Coalition; Connecticut Business & Industry Association (CBIA).

Connecticut Retail Merchants Association; Connecticut State Building and Construction Trades Council; Connecticut United for Research Excellence (CURE, CT's BIO); Consumers Union; Council of Pediatric Subspecialties; CT BEACON; Cubist; D'Souza and Associates; Delaware Academy of Medicine; Delaware AFL–CIO; Delaware Ecumenical Council on Children and Families; Delaware HIV Consortium; Delaware Technology Park; DelawareBIO; Denver Metro Chamber of Commerce; Des Moines Area Community College; Detroit Regional Chamber of Commerce; Develop Indy; Dun & Bradstreet.

East End Group, LLC; Easter Seals of Massachusetts; Economic Alliance Snohomish County; Eli Lilly and Company; Elizabeth Glaser Pediatric AIDS Foundation; Endocyte; Engineered BioPharmaceuticals; Epilepsy Foundation of Greater Chicago; Exemplar Genetics; Farmington Chamber of Commerce; Feed Energy Company; Fort Wayne Chamber of Commerce; Generic Pharmaceutical Association; GlaxoSmithKline; GlycoMimetrics; Grand Rapids Area Chamber of Commerce; Greater Boston Chamber of Commerce; Greater Des Moines Partnership; Greater New Haven Chamber of Commerce.

HealthHIV; HeathCare Institute of New Jersey (HINJ); Hematology/Oncology Pharmacy Association; Hep C Connection; Hon. Edd Houck, Former Virginia State Senator; Hospira; Hudson County Cancer Coalition; IBI Scientific; Illinois BIO; Illinois Biotechnology Industry Organization (iBIO); Illinois Chamber of Commerce Healthcare Council; Illinois Manufacturers' Association; Illinois Science and Technology Coalition; Incyte; Indiana Association of Cities and Towns; Indiana Health Industry Forum; Indiana Manufacturers Association; Indiana Medical Device Manufacturer's Council; Indiana State Chamber of Commerce; Infectious Diseases Society of America.

Innovation NJ; Institute for Safe Medication Practices; Institute For Systems Biology; Integrated Laboratory Services—Biotech; Iowa Academy of Family Physicians; Iowa Biotech Association; Iowa Nurses Association; Johns Hopkins Medicine; Johnson & Johnson; Joy's House; Junior Achievement of Central Maryland; Junior Achievement of Delaware; Junior Blind of America; Juvenile Diabetes Awareness Coalition; Juvenile Diabetes Research Foundation; Kalamazoo Chamber of Commerce; Kidney Cancer Association; Kolltan Pharmaceuticals, Inc.

Lancaster General Health; Legacy Community Health Services; Leukemia & Lymphoma Society Iowa and Nebraska; Life Science Greenhouse of Central Pennsylvania; LifeScience Alley; Lighthouse International; Lupus Alliance of America—Michigan Indiana Affiliate; Lupus Foundation of America—Illinois Chapter; Lupus Foundation of America DC/MD/VA Chapter; Lupus Foundation of America, Connecticut Chapter, Inc.; Lupus Foundation of America, DC/MD/VA Chapter; Lupus Foundation of New England; Lupus Foundation of Pennsylvania; Maetrics; March of Dimes; Maryland Chamber of Commerce; Maryland State Medical Society; Massachusetts Association of Mental Health; Massachusetts Biotechnology Council; Massachusetts Chamber of Commerce.

Mayors Committee on Life Sciences; MedCara Pharmaceuticals; Medical Device Manufacturers Association; Medical Imaging & Technology Alliance; Medical Society of Virginia; Mental Health America of Colorado; Mental Health America of Greater Tarrant County; Mental Health America of Illinois; Mental Health America of Indiana; Mental Health Association of Connecticut; Merck; Metro Denver Economic Development Corporation; MichBio; Michigan Chamber of Commerce; Michigan Council of the Blind and Visually Impaired; Michigan Manufacturers Association; Middlesex County Chamber of Commerce; Midwest Business Group on Health; Millennium, The Takeda Oncology Company; Morris County Chamber of Commerce; Mylan.

NAACP Columbus Chapter; NAMI Colorado; NAMI Indiana; NAMI NC; NAMI-IL; National Alliance for Mental Illness—Gulf Coast; National Alliance for Mental Illness—Metropolitan Houston; National Alliance for Mental Illness—Texas; National Alliance on Mental Illness; National Alliance on Mental Illness, Michigan; National Association of Chain Drug Stores; National Association of Manufacturers; National Association of Pediatric Nurse Practitioners; National Dental Association; National Federation of the Blind; National Kidney Foundation of Indiana; National Organization for Rare Disorders; National Parkinson Foundation, Central and Southeast Ohio Chapter; National Processing Solutions; National Research Center for Women & Families.

NC Autism Society; NC Bio NC Chamber; NC Psychological Association; Neurofibromatosis Mid-Atlantic; Neurofibromatosis of the Mid-Atlantic; Neurofibromatosis of the Mid-Atlantic; New Jersey Business and Industry Association (NJBIA); New Jersey Community Research Initiative; New Jersey Laborers' Union; New Jersey Life Science Vendors Alliance (NJLSVA); New Jersey State League of Municipalities; Newark Senior Center; NJ Healthcare Advocate Volunteer Effort (NJ Have); North Carolina Association for Biomedical Research; North Carolina Biotechnology; North Dakota Association of the Blind; North Hudson Community Action Corporation; North Texas Commission; Northwest Connecticut Chamber of Commerce.

Novo Nordisk Inc.; Nuclea Biotechnologies; NYU Langone Medical Center; Ohio Chamber of Commerce; Ohio Coalition of Concerned Black Citizens; Ohio Laborers' District Council; Ohio State Building and Construction Trades Council; One Southern Indiana; Ovarian Cancer National Alliance; PACT, Greater Philadelphia Alliance for Capital and Technologies; Parent Project Muscular Dystrophy (PPMD); Parkersburg Economic Development; Patient Advocates for Advanced Cancer Treatments; Pediatric Infectious Diseases Society; Pediatric Pharmacy Advocacy Group; Pennsylvania Bio; Pennsylvania Chamber of Business and Industry; Peoples Settlement Senior Center; Pew Charitable Trusts; Pfizer, Inc.; PhRMA; Pittsburgh Life Science Greenhouse.

Pittsburgh Technology Council; Pittsburgh Venture Capital Association; Plymouth/Terryville Chamber of Commerce; Premier healthcare alliance; Prevent Blindness America; Prevent Blindness Mid-Atlantic; Prevent Blindness Ohio; ProteoTech Inc; Psychiatric Society of Virginia; Respiratory Health Association of Metro Chicago; Rib-X Pharmaceuticals; Rio Grande Valley Diabetes Association; Rocky Mountain Stroke Center; Rush To Live Organization; Rx Partnership; San Antonio AIDS Foundation; Sanofi; Seattle BioMed; Sequella, Inc.; Sheet Metal Workers Local 40.

Society for Adolescent Health and Medicine; Society for Pediatric Research; Somerset County Business Partnership; South Jersey Geriatric Care, P.C.; South Jersey Senior Marketing Group; South Shore Chamber of Commerce; Southwest Michigan Pharmacists Association; Spanish American Merchants Association (SAMA); Stanford Hospital & Clinics; Supercritical Fluid Technologies; Susan G. Komen, Denver Metro Affiliate; Susan G. Komen for the Cure Advocacy Alliance; Takeda Pharmaceuticals U.S.A., Inc.; Targepeutics; Tech Council of Maryland; TECHQuest Pennsylvania; Teva Pharmaceuticals; Texas BioAlliance; Texas Health Care & Bioscience Institute.

The Arc of Connecticut; The Association for Corporate Health Risk Management; The Center for Health Care Services; Trinity Health—Novi, Michigan; Trust for America's Health; Union of Concerned Scientists; United Mitochondrial Disease Foundation; University City Science Center; University of Utah Health Care; University of Washington; Virginia Biotechnology Association; Virginia Chamber of Commerce; VisionServe Alliance; Visiting Angels; Washington Biotechnology & Biomedical Association.

Washington Global Health Alliance; Washington State Department of Commerce; Washington State University; Waterbury Regional Chamber of Commerce; We Work For Health; We Work for Health New Jersey; WellDoc, Inc.; Western Economic Council; Western Michigan University; Westside Health; Wolcott Chamber of Commerce; Worcester Chamber of Commerce; Wright Runstad & Company.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the chairman for his remarks and wish to be associated with them. It has been a very bipartisan process that has resulted in this bill coming to the floor, and I am hoping there will only be relevant amendments and that there will be few of those. Every amendment has the potential for disrupting the entire bill. This has been a very inclusive process that has led to this legislation.

Over a year ago staff began to meet with stakeholders on the policy issues that are addressed in S. 3187. Starting in the spring of 2011, staff from Republican and Democratic offices on the Health, Education, Labor and Pensions Committee began a series of standing meetings. The groups 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 to a list of policy concepts. If it was not a consensus on a particular policy, then it

was not included. The chairman mentioned the importance of consensus, and that is what we worked on.

As this process progressed, my staff met with the Republican staff on the HELP Committee for at least 2 hours every week to keep them informed of everything that was happening. I personally met with the members of the committee before the markup to make sure I understood their priorities. No one office got the entirety of what they wanted. However, we did find the 80 percent of each solution we could all agree could help solve whatever policy the group was working on.

What we see before us now is the outcome of the hard work of these groups. The bill passed the committee by a voice vote. The 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, and many members of the committee worked with us to find consensus measures that addressed their priorities as well.

This legislation is a model for how the process can and should work no matter what the political environment. This went to committee, it was worked in committee, it is now at the Senate floor, and I hope my colleagues will join me in supporting this truly bipartisan provision that reduces the debt and ensures that the United States will maintain its leadership in the innovation of safe and effective biomedical product.

I yield the floor.

EXECUTIVE SESSION

NOMINATION OF PAUL J. WATFORD, OF CALIFORNIA, TO BE UNITED STATES CIRCUIT JUDGE FOR THE NINTH CIRCUIT

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider the following nomination which the clerk will report.

The legislative clerk read the nomination of Paul J. Watford, of California, to be United States Circuit Judge for the Ninth Circuit.

The PRESIDING OFFICER. Under the previous order, there will be 1 hour of debate equally divided and controlled in the usual form.

The Senator from Vermont.

Mr. LEAHY. I am glad we are finally able to debate and vote on the nomination of Paul Watford of California to fill a judicial emergency vacancy on the Ninth Circuit. As the distinguished Presiding Officer knows, it was 3½ months ago that we voted Mr. Watford out of committee. We had not been able to get an agreement to debate or vote on this nomination since it was approved. So for the 27th time, the majority leader was forced to file cloture to get an up-or-down vote on one of President Obama's judicial nominations.

Thankfully enough, Senate Republicans came forward to say they are not going to delay a vote or to continue a filibuster. We ought to just have an up-or-down vote, which we always used to do. Hopefully, we will not vote to promote a filibuster, but vote up or down, and I thank those Republicans who came forward and said enough of the cloture votes, let's vote.

This nominee, Paul Watford, is highly qualified. In fact, he has the highest qualifications for the Ninth Circuit. He shouldn't be filibustered. He should not require a cloture vote. He is a nominee with impeccable credentials and qualifications. He served as a Federal prosecutor and is now a highly regarded appellate litigator in private practice. He served as a law clerk at the United States Supreme Court and at the United States Court of Appeals for the Ninth Circuit. The ABA Standing Committee on the Federal Judiciary gave Paul Watford the highest possible rating they could give and they gave it to him unanimously. He also has the strong support of his home State Senators, Senator FEINSTEIN and Senator BOXER. He has widespread support across the spectrum, including known conservatives such as two former Presidents of the Los Angeles chapter of the Federalist Society, as well as Judge Alex Kozinski, a conservative Reagan appointee who is now Chief Judge of the Ninth Circuit. By any traditional measure, Paul Watford is the kind of judicial nominee who should be confirmed easily by an overwhelming vote—a vote of both Republicans and Democrats.

I had hoped after the agreement between the Democratic and Republican Senate leadership to begin finally considering the backlog of judicial nominations from last year that the Senate was at last returning to regular order. The refusal of Senate Republicans to consent to a debate and vote on this nomination for more than 3½ months, however, again required the Majority Leader to file cloture to end another Republican filibuster.

Senate Republicans continue to apply what they have admitted is a ''new standard'' to President Obama's judicial nominees. From the beginning of the Obama administration, Senate Republicans abandoned the standards and arguments they used to say should apply to judicial nominations. During the administration of the last President, a Republican, they insisted that filibusters of judicial nominees were unconstitutional. They threatened the ''nuclear option'' in 2005 to guarantee up-or-down votes for each of President Bush's judicial nominations. Many Republican Senators declared that they would never support the filibuster of a judicial nomination.

Senate Republicans reversed course and filibustered President Obama's very first judicial nomination, that of Judge David Hamilton of Indiana. They tried to prevent an up-or-down vote on that nomination even though he was nominated by President Obama after consultation with the most senior and longest-serving Republican in the Senate, Senator DICK LUGAR of Indiana, who strongly supported the nomination. Fortunately, the Senate rejected that unjustified filibuster and Judge Hamilton was confirmed with Senator LUGAR's support.

Senate Republicans previously engaged in misguided filibusters last year of Goodwin Liu's nomination to the Ninth Circuit and Caitlin Halligan's nomination to the D.C. Circuit. Each of those nominees is the kind of brilliant lawyer we should encourage to join the Federal bench. There were certainly no ''extraordinary circumstances'' for filibustering their nominations. Senate Republicans filibustered them anyway, setting a new and unfortunate standard for the Senate. Those filibusters demonstrated that any nominee can be filibustered based on concocted controversies and baseless claims. That was unfortunate and unwise. Senate Republicans have already succeeded in preventing confirmation votes on five of President Obama's judicial nominees who were blocked from a Senate vote after being voted out of the Senate Judiciary Committee.

Paul Watford is the kind of person we want in our Federal judiciary. This is the kind of person when we talk about the Federal courts, we can say here is a judge we can look up to and who can inspire others who seek to be judges. He is not a nominee against whom a partisan filibuster would be justifiable, and I thank some of those Republican Senators who called me this weekend who said they would oppose a Republican filibuster. I thank them for that, because what they are doing is what is best for the Senate. By allowing a vote, they are doing the best for the Ninth Circuit but, even more importantly, they are doing what is best for the independence of our Federal judiciary. Because if one is going to vote to try to block somebody as qualified as Paul Watford, one is basically saying they don't care who the nominee is, they are going to block it, and that is not the message we should send if we are going to have an independent Federal judiciary in this country.

He has a mainstream record. He demonstrates legal excellence and experience at the top of his profession. He clerked at the United States Supreme Court for Justice Ruth Bader Ginsburg and on the Ninth Circuit for now-Chief Judge Alex Kozinski, a conservative appointee of President Ronald Reagan. Over his 17-year legal career, Paul Watford has worked on briefs in nearly 20 cases before the United States Supreme Court, and has argued numerous cases before the Ninth Circuit Court of Appeals as well as the California appellate courts. As a Federal prosecutor in the 1990s, Mr. Watford handled prosecutions involving immigration and drug offenses, firearms trafficking, and major frauds.