Some of them, in fact, have been pending on the calendar longer than the Pillard nomination. But rather than work with us to schedule votes on those nominations in an orderly manner, as we have been doing all year long, the majority prefers to concoct a crisis on the DC Circuit so it can try to distract the American people from the failings of ObamaCare.

Unfortunately, our friends appear to be more concerned with playing politics than actually solving real problems. So I will be voting no on this afternoon's political exercise. I hope the Senate in the future will focus on what the American people care about rather than spend its time trying to distract them.

CONGRATULATING ARCHBISHOP JOSEPH KURTZ

Finally, I congratulate Archbishop Joseph Kurtz, the Catholic archbishop of Louisville, on his election as president of the U.S. Conference of Catholic Bishops. Archbishop Kurtz is not a native Kentuckian—he is originally from Pennsylvania—but we have adopted him as one of our own since he was appointed head of the Louisville Archdiocese in June 2007. I wish him all the best as he seeks to promote the church's mission in the United States.

Congratulations.

Madam President, I yield the floor.

RESERVATION OF LEADER TIME

The PRESIDING OFFICER. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The PRESIDING OFFICER. Under the previous order, the Senate will be in a period of morning business until 4:30 p.m., with Senators permitted to speak therein for up to 10 minutes each.

The Senator from Iowa.

PILLARD NOMINATION

Mr. GRASSLEY. Madam President, I come to the floor to speak in opposition to the motion to invoke cloture on the nomination for the DC Circuit nominee Cornelia Pillard. Although her record makes clear that her views are well outside the mainstream on a host of issues, I am not going to focus any attention on those concerns today. I am going to focus instead on the standard the Democrats established in 2006. Based on that standard, the court's caseload makes it clear that the workload simply doesn't justify additional judges, particularly when those additional judges cost approximately $1 million per year per judge.

I have walked through these statistics several times now, and I am not going to go in depth again. The bottom line is the data overwhelmingly supports the conclusion that the DC Circuit is underworked. Everyone knows this is true. That circuit does not need any more judges. Take, for instance, the appeals filed and appeals terminated. In both categories the DC Circuit ranks last, and in both categories the DC Circuit is less than half the national average. To provide some perspective on this point, compare the DC Circuit to the Eleventh. After another judge took senior status about a week ago, both the DC Circuit and the Eleventh Circuit have eight active judges. If we don't confirm any more judges to either court, the numbers remain the same as last year. The Eleventh Circuit will have 875 appeals per active judge compared to the 149 appeals filed per active judge in DC, which also has 8 active judges. Again, that is 875 cases for the Eleventh compared to 149 for DC.

Some might argue that we shouldn't look only at active judges because those averages will change if and when we confirm more judges to the Eleventh Circuit. Suppose we fill each judgeship on the Eleventh Circuit and each judgeship on the DC Circuit, as the Democrats want to do. If we fill them all, there would be 583 appeals filed per judge for the Eleventh Circuit and only 108 for the DC Circuit. The Eleventh Circuit, then, would have over five times the caseload. This is why everyone who has looked at this objectively understands that the caseload for the DC Circuit is stunningly low. That is why current judges on the court have written to me and said things such as this—and I will quote from one of the letters: ''If any more judges were added now, there wouldn't be enough work to go around.''

Some of my friends on the other side recognize that the DC Circuit's caseload is low, and they claim then that the caseload numbers don't take into account the ''complexity'' of the court's docket. They argue that the DC Circuit hears more administrative appeals than other circuits do, and they claim these administrative appeals are more complex. This argument is nonsense, and I will tell my colleagues why it is nonsense.

I have heard my colleagues argue repeatedly that the DC Circuit's docket is complex because 43 percent of the docket is made up of administrative appeals. But, of course, that is a high percentage of a very small number. When we look at the actual number of those so-called complex cases per judge, the Second Circuit has almost twice as many as the DC Circuit. In 2012 there were 512 administrative appeals filed in DC. In the Second Circuit, there were 1,493 compared to that 512.

We can look at this differently as well. In DC there were only 64 administrative appeals per active judge. The Second Circuit has nearly twice as many per judge with 115. Again, that is 64 administrative appeals per active judge in the DC Circuit as opposed to the Second Circuit, which has almost twice as many with 115.

So this entire argument about complexity is what I already called it—nonsense—and the other side knows it, and if they don't know it, they ought to know it.

Let me raise another question regarding caseload. If these cases were really that hard, if these cases were really so complex, then why in the world would the DC Circuit take the entire summer off? I am not talking about just a couple of weeks in August; they don't hear any cases for the entire summer. The DC Circuit has so few cases on their docket that they don't hear any cases from the middle of May until the second week of September. This past term, the last case they heard before taking the summer off was May 16. The court didn't hear another case until September 9—4 months later.

The bottom line is everyone knows this court doesn't have enough cases as it is, let alone if we were to add more judges. That is why, when we ask the current judges for their candid assessment, they write: ''If any more judges were confirmed now, there wouldn't be enough work to go around.''

While I am discussing the caseload issue, I will remind my colleagues of a little bit of history that is very pertinent to this debate. In 2006 the Democrats on the Judiciary Committee blocked Peter Keisler's nomination to the DC Circuit. They blocked Mr. Keisler's nomination based upon—my colleagues can guess it—the court's caseload. Since that time, by the standard set by the other side, the court's caseload has declined sharply.

We did not set this standard. The Democrats set that standard. I recognize that the other side wants to rewrite history. They try to compare John Roberts' second nomination to the circuit, which passed fairly easily, with the current nomination. What they conveniently forget in a misleading way is that they blocked Keisler's nomination after Roberts' nomination.

I recognize the other side hopes we on this side will forget they established these rules and these precedents. I recognize the other side finds those rules very inconvenient today. But these are not reasons to ignore rules and precedents they established. There is simply no legitimate reason the other side should not embrace those very same rules, those very same standards they established in the year 2006.

So under that standard established by the Democrats in 2006, then, very simply, these nominations are not needed. According to the current judges themselves, these judges are not needed. According to the chief judge of the DC Circuit, who happens to be a Clinton appointee, the senior judges are contributing the equivalent of an additional 3.25 judges. So, as a result, the court already has the equivalent of 11.25 judges, and that is beyond even the authorized number.

It seems pretty clear the other side has run out of legitimate arguments in support of these nominations. Perhaps that is why, then, they are resorting to such cheap tactics.

Over the last couple days, I have heard my colleagues on the other side

come to the floor and actually argue that Republicans are opposing the nominee because of her gender. That argument is offensive. But, you know, it tends to be very predictable. We have seen this before. When the other side runs out of legitimate arguments, their last line of defense is to accuse Republicans of opposing nominees based upon gender or race. It is an old and it is a well-worn card, and they play it every time.

The fact is—and this is why it is offensive to me—I voted for 75 women nominated to the bench by President Obama, as well as a host of other nominees of diverse backgrounds. Those are the facts. But the other side is not concerned with facts. They are more interested in coarse rhetoric as well as demagoguery, and it is very unfortunate. Those types of personal attacks on Members of the Senate are beneath this institution.

Given there is no legitimate reason to fill these seats, why is the other side pushing these nominations so aggressively? And this is really the bottom line. But you can also ask, why waste $3 million a year of taxpayers' money for reasons that are not legitimate, particularly in violation of the constitutional checks and balances?

As to these other reasons, we do not have to guess. We know the reason. We have all heard the President pledge repeatedly: If Congress will not act, I will. What he means, of course, is that he will rule by executive fiat. He will not go to Congress. He will not negotiate. He will go around this constitutionally elected body whose constitutional powers are to make law. That is not his power. He does not need legislators, then, to enact legislation. He will just issue executive orders or issue new agency rules. Why bother with us pesky Senators and Members of the House when you can make laws with a stroke of the pen? In effect, the President is saying: If the Senate will not confirm who I want when I want them, then I will recess-appoint them when the Senate is even in session. If Congress will not pass cap-and-trade fee increases, then I will go around them. And I will do the same thing through administrative action at the Environmental Protection Agency. If Congress will not pass gun control legislation, then I will issue executive orders.

That is what the President means when he says: If Congress will not act, I will. But remember, we have a system of checks and balances. Under our system, when the President issues orders by executive fiat, it is the courts that provide a check on his power. It is the courts that decide whether the President is acting unconstitutionally.

So the only way the President's plan works is if he stacks the deck in his favor. The only way the President can successfully bypass Congress is if he stacks the court with ideological allies who will rubberstamp those executive orders.

There is no big secret here. The other side has not been shy about this strategy. Here is how the Washington Post described this strategy:

> Giving liberals a greater say on the D.C. Circuit is important for Obama as he looks for ways to circumvent the Republican-led House and a polarized Senate on a number of policy fronts through executive order and other administrative procedures.

Here is how another high-profile administration ally put it:

> There are few things more vital on the president's second-term agenda. With legislative priorities gridlocked in Congress, the president's best hope for advancing his agenda is through executive action, and that runs through the D.C. Circuit.

So the President is willing to waste $3 million of taxpayers' money a year—and every year—in order to bypass Congress and make sure his executive orders do not lose in court. Every Member of this body should find that very troubling.

Finally, I want to mention a couple points on the so-called Gang of 14 agreement, which argument comes up quite frequently here on the floor, even though it is going back to the 109th Congress.

First, by the very terms of that agreement, it applied only to those 14 Senators for that specific Congress, the 109th.

Second, even though that agreement, by its own terms, expired at the end of the 109th Congress, just last week one of the Members who was actually in the Senate back in 2005 determined that these nominations, in his judgment, constituted ''extraordinary circumstances,'' which those two words implied that a filibuster would be justified.

And third, in 2006, after the so-called Gang of 14 agreement, Senate Democrats created a standard that we call the Keisler standard. They blocked Peter Keisler based on caseload, after the so-called Gang of 14 agreement. Peter Keisler waited in committee for over 900 days for a vote, a vote that never came.

These are the rules established by the other side. And now, when they are on the receiving end of those same rules, they want those rules changed. We do not intend to play by two sets of rules around here.

And that brings me to the constant threat from the majority about changing the rules on the filibuster. I have been in the minority for a number of years. I have also had the privilege of serving in the majority for a number of years. Many of those on the other side who are clamoring for rules changes—and almost falling over themselves to do it—have never served a single day in the minority. All I can say is this: Be careful what you wish for.

I have come to the conclusion that if the rules are changed, at least we Republicans will get to use those new rules when we are back in the majority. Republicans had the chance 7 or 8 years ago to change the rules, and we decided, out of respect for the integrity of this institution, not to change them. I am glad we did not. And I would imagine we would not be the first to change them in the future.

Remember, it was the Democrats who first used the filibuster to defeat circuit judges. It was the Democrats who first used the caseload argument to defeat circuit judges such as Peter Keisler. So if the Democrats are bent on changing the rules, then I say go ahead. There are a lot more Scalias and Thomases out there whom we would love to put on the bench. The nominees we would nominate and confirm with 51 votes will interpret the Constitution as it was written. They are not the type who would invent constitutional law right out of thin air.

I urge my colleagues to oppose cloture on the Pillard nomination.

I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Madam President, I have high hopes that the Senate will soon vote to enact the Drug Quality and Security Act, the so-called compounding and trace and track bill. This legislation helps ensure the safety of compounded drug products. It also secures the pharmaceutical supply chain.

I am pleased to report that it is the product of excellent bipartisan collaboration on the HELP Committee, where I worked very closely with our ranking member, my good friend Senator LAMAR ALEXANDER. It also reflects productive conversations with our colleagues in the House, including Chairman UPTON and ranking member WAXMAN of the House Energy and Commerce Committee.

The House passed this bill on September 28. Now it is our turn to do our part. Title I of the bill addresses drug compounding. This is basically what happened here just over a year ago, when we were shocked to learn one of the worst public health crises that we have experienced in recent years was a meningitis outbreak that claimed the lives of 64 Americans and sickened 651 people in 20 States.

You can see the hardest hit were the home State of Senator ALEXANDER, 153; Indiana, 93; Michigan, 264; Virginia 54, New Jersey, 51; Florida 25. Twenty States. A lot of people got really sick. I will be talking in a moment about those that still linger today.

What this outbreak did is it brought attention to the legal and regulatory gaps that allowed owners and managers at the New England Compounding Center to disregard basic procedures to ensure that the products they were manufacturing were sterile and safe.

This gross negligence had heartbreaking consequences for families nationwide, patients that were sick—patients such as Karina Baxter, whose

three adult children—Anita, Andrew, and Brian—lost their mother, and whose community lost a dedicated math teacher and tutor when she died of this meningitis outbreak at age 56.

Dawn Elliot, from Indiana, who used to scuba dive in her free time is now in unrelenting pain and has had to give up her job and deplete her savings.

Evelyn Bates, from Michigan, who was diagnosed last November, continues to struggle with tremendous pain every day, and her daughter had to quit her job to take care of her.

Dennis Blatt lives on the West Virginia-Ohio border with his wife and three young children. They have had to watch their father go from being an involved parent with a steady income to a man whose daily life feels, in his own words, like a ''slow, tortuous death.''

These meningitis outbreaks linger on. It also has a personal sensitivity to me. My older brother some years ago went deaf at a very young age because of meningitis. So it has lingering effects for a lifetime. That is what happened a little over a year ago. Although we know that it was not just an isolated incident, we know it was the biggest.

This chart is somewhat hard to read. It shows—going clear back to 2001—that we have had 4, 11, 64, 18. In other words, every year we have had some results we have noted from compounding that made people sick or cause deaths. So this has been ongoing for a long time.

It is just that what happened a little over a year ago in Tennessee and in these other States was that the dam broke. It is beyond all comprehension how many people got sick and died. So again, in response to these facts, beginning last year Senator ALEXANDER and I convened the members of the HELP Committee, with assistance from Senator FRANKEN and Senator ROBERTS, in an effort to identify the gaps in current policy, to solicit stakeholder views, to craft bipartisan legislation to better ensure the quality of compounded drug products.

We formally solicited three rounds of public comment. We held two public hearings before marking up the bill last May. Then over the summer we worked with our colleagues in the House to craft a package with strong bipartisan and bicameral support.

Now, the compounding provisions in this bill are an unqualified step forward from current law and practice. Basically, what this bill does in the compounding in title I—I will get to title II in a second—it distinguishes compounders engaged in traditional pharmacy practice from those making large volumes of compounded drugs without individual prescriptions.

So those who wish to remain in traditional compounding, that we might know where they are making small amounts for a certain type of illness or for a certain hospital—that sort of thing—they stay under the State boards of pharmacy as they are in current law.

An entity that neither stays within those limits of traditional pharmacy compounding nor registers as an outsourcing facility, if they do not do one of those two, then they are illegally selling unapproved drugs.

So that is what it does. It distinguishes. It defines the Food and Drug Administration's role in the oversight of these outsourcing facilities. They will be subject to FDA oversight in much the same way as traditional drug manufacturers are today.

FDA will know who these outsourcers are and what they are making, receive adverse event reports about compounded drugs, and have authority and resources to conduct risk-based inspections. In other words, the lines of responsibility are more clearly defined.

I give much credit to my friend from Tennessee for continuing to work on who is raising the flag, who has the flag, and who is responsible, because we found out there was a confusing mess for everybody about who was responsible and who was not. Thanks to Senator ALEXANDER, we have cleared that up in this bill.

The bill offers providers and patients better information about compounded drugs, and it directs FDA to make a list of FDA-regulated outsourcer facilities that will be available on their Web site. It requires detailed labeling of compounded drugs and prohibits false and misleading advertising. Finally, it clarifies current Federal law regarding pharmacy compounding. It strikes the unconstitutional provisions that were in current law which led to a lot of this mess. We had different courts in different parts of the country interpreting it differently. So anyway, we resolve that patchwork and apply a uniform standard nationwide.

Now, that is title I. Title II of the bill is the track and trace provisions. Basically, this committee, again working in a bipartisan fashion a little over a year ago—as you may remember—brought an FDA user bill to the floor, passed and signed by the President. That cleared up the upstream part of where drugs come from; in other words, from the initial—from the plant derivation to the distilling of a product to everything—all the way up to the manufacturing. So now we have a much better regulation, a clearer picture of drugs that come from China and Indonesia and the U.S.—no matter where they come from, up to the manufacturing standpoint.

What we did not have at that time was a real understanding of or an agreement on how to control it from the manufacturer down to the consumer. So our committee got involved. Again, Senator ALEXANDER was helping to lead the way with Senator BENNET and Senator BURR—almost 2 years working on this issue. So now we have this system. I think this chart shows it. As I said, everything up to the manufacturer we took care of in the FDA user bill.

Now this bill takes care of everything from the manufacturer down to the dispenser; that is, down to the consumer. So no matter where the drug goes, whether it goes directly from a manufacturer to a wholesaler to a dispenser, or whether it goes from here to a secondary wholesaler, another secondary wholesaler, and another secondary wholesaler, we found that in this country there is a patchwork, all kinds of different ways for a drug to get from a manufacturer down to a consumer.

So Senator BURR, Senator BENNET, Senator ALEXANDER, and our staffs worked together to get this picture put together and to have a track and trace so that we can track the drug. No matter how it goes, we can track it and we can trace it. That will come into being over 10 years with electronic interoperable product tracing.

You might say that 10 years is a long time. I would point out that the House had 27 years. They agreed with us and made it 10 years. But that is for electronic interoperability. Beginning in January 2015, they will have to start paper tracing. So there will be paperwork, but it will take 10 years to get it all at a unit-level and all electronic and interoperable. You can understand, it takes a long time; different manufacturers and different suppliers have different systems. So these will be worked in over that period of time.

But we will have tracing after January, 2015. It establishes nationwide drug serial numbers and requires a pathway to unit-level tracing, as I said. It strengthens licensure requirements for wholesale distributors and third-party logistic providers. Again, there was a lot of hodgepodge of different kinds of licensures for wholesalers. We strengthened that. Then, as I said, we have a nationwide serial number established for that. That will come 4 years after the date of enactment. That will serialize drugs in a consistent way across the country.

Again, this is a bill that many might say is long overdue. Better late than never. I am sorry it took a terrible calamity such as the outbreak of meningitis to get us to really focus on this and move it. But it did. I think this is a good example of where the Congress can work in a bipartisan, bicameral fashion. I met Chairman UPTON on the House side earlier this year to talk about a pathway of getting this done. In fact, what we are working on here is the House bill. The House passed it by unanimous consent. If you have been reading much about the House, you know they do not do a lot by unanimous consent. That just shows you how much work went into the bill and how it was done in a true bipartisan, bicameral fashion. So the House passed it by unanimous consent. Now we have it. I daresay, but for a Senator, one person, we probably would have passed it by unanimous consent here.

I have not found anyone who is opposed to this bill and who does not recognize that this is well supported. We

have a plethora of people and industry and consumer support: American Pharmacists Association, American Public Health Association, Biotechnology Industry Organization, plus a lot of the big pharmaceutical manufacturers and some of the small pharmaceutical manufacturers. Everyone recognizes that we need a better system to clearly outline who the traditional compounders are and who the outsourcers are, to give the FDA clear-cut authority over one segment, give the States the clear-cut authority over the other segment. As I said, if you do not fall into one of those two, you are outside the law. So it really does clear it up. This will ensure the quality and safety of the drugs on which patients rely.

We have a cloture vote later today. I am hopeful we will have a good strong vote on cloture on this bill. As I said, I honestly can say standing here I have not heard one Senator from either side of the aisle tell me or inform my staff that they were opposed to the bill as such.

I hope we have a strong vote. I am going to yield the floor and again pay my compliments and my highest respect to Senator ALEXANDER for his leadership. His State was hit very hard. I know he is very sensitive to that. I know from my talks with him that it pained him a great deal to see so much suffering and death in his own State. Senator ALEXANDER got on top of this and pulled us all together and basically said: We have to get it done.

So I thank Senator ALEXANDER very much.

The PRESIDING OFFICER (Mr. MANCHIN). The Senator from Tennessee.

Mr. ALEXANDER. On behalf of the people of Tennessee, whom I represent, and the American people, as well, I wish to thank the Senator from Iowa for his leadership on these two bills, but particularly on the compounding pharmacy bill.

Our differences of opinion in the Senate are well advertised on ObamaCare, on debt, on Syria, and on a whole variety of matters. In fact, one would say the reason we exist is to debate the big issues that haven't been resolved somewhere else.

There is another aspect of the Senate that is rarely well advertised, and that is when we get a result. Sometimes the results take a long time, involve a lot of people, and are very difficult to reach, and that is the case with this bill. Had not Senator HARKIN been patient, as well as aggressive at the same time, in working with Republicans and Democrats and with Members of the House, we would not have reached this point today.

It is important to call the attention of the American people to this result, these two pieces of legislation. One makes it clear who is in charge, as Senator HARKIN said, who is on the flagpole when it comes to making sure the sterile drugs that are injected into your back—because a person has back pain—are safe so that they don't end up with a horrible death from fungal meningitis. Who is responsible for preventing that?

The second bill is how are we going to make sure the 4 billion prescriptions we have every year in this country are safe, that they are not stolen, and that they do what they are supposed to do. How are we to make sure we can track them all the way from the manufacturer to the pharmacy who dispenses them?

We have been working on these bills for 2 years. Lest anyone think that because it was a voice vote in the House and because we are close to unanimous consent in the Senate that it was easy to do, it is not that easy to do. In fact, it is worth going through how this happened before I say just a word to add to what the Senator said about the importance of bills.

The FDA became involved in the fungal meningitis issue in September of 2012, 1 year ago, after reports from Tennessee that fungal meningitis was tied to a sterile compounded drug. This hits home to many Americans because a great many Americans have been injected in their necks, their backs, or their feet with a drug that is supposed to be sterile. If it is not, it could have terrible consequences.

Immediately, Senator HARKIN called a hearing. November 15, 1 year ago, we had our first hearing. Within 6 months we released draft legislation to address the compounding pharmacy issue. We then had a hearing on that legislation. Then we passed the legislation after a lot of comment, all in the open. Everyone had a chance to weigh in. We passed it unanimously.

This committee on which we serve, Health, Education, Labor and Pensions, probably reflects the widest span of ideological differences we have in the Senate. The Republicans can be very conservative and the Democrats can be very progressive or very liberal, so one would think it would be hard to get a unanimous agreement, but we did.

The House went to work and came up with their own version of the bill, taking our work into account. We then worked with them through the summer to reach an agreement on how to reconcile the two. The House passed it by a voice vote and sent it to us. Today we have a piece of legislation that has been hot-lined. That means that both sides have sent it around to every single office. All but one Senator have agreed we can pass it by unanimous consent. The Senator has that right, as I have that right, the Senator from West Virginia, and the Senator from Iowa has that right, and sometimes we exercise that right. Later this afternoon we will be having a cloture vote, a vote to move to this bill. That cloture vote is going to succeed. There will be a sufficient number of Republican votes and a sufficient number of Democratic votes to say we are ready to deal with this.

Why are we ready to deal with this? Because Commissioner Hamburg of the Food and Drug Administration told us at our hearing what would happen if we don't. She said:

> We have a collective opportunity and responsibility to help prevent further tragedies. If we fail to act, this type of incident will happen again. It is a matter of when, not if, I'm afraid. If we fail to act now, it will only be a matter of time until we're all back in this room asking why more people have died and what could have been done to prevent it.

No one is saying this legislation is going to guarantee that there will never ever be a tragedy again, but it will help prevent future tragedies. It will take up the responsibility she challenged us to do. We have spent 1 year on it, so many people have been involved, and it is time we move to do it. My hope is that after the cloture vote tonight, very soon thereafter, after everyone has had a chance to speak and say what they have to say, that we can pass this by unanimous consent, send it to the President, and say to the American people that our differences are well advertised, but our results can be equally important. We can pass a piece of legislation which, when taken with the track-and-trace legislation which accompanies it, affects the health and safety of every single American, period. I know the people of Tennessee would welcome a prompt solution to this, and this is what I hope we have.

Senator HARKIN, as he often does, spoke in very personal terms about this legislation. I want to tell one story from Tennessee so we know what we are talking about.

Diana Reed, 56, of Tennessee, had tried massage and acupuncture, but neither eased her neck pain. One of the potential causes for her pain was an injury sustained while helping her husband, who has Lou Gehrig's disease, in and out of the wheelchair. Diana Reed was healthy, either ran or swam every day, in addition to becoming Wayne's arms, legs, and voice, according to her brother, Bob.

She decided to try a series of epidural steroid injections for her neck problems before her health insurance ran out after losing her job at a nonprofit group. This decision ended her life on October 3 of last year. She began receiving injections August 21, with a total of three scheduled, one every 2 weeks. She felt pain and nausea for a full day after the first two injections. After the third she began having headaches.

September 23, she finally agreed to go to a doctor and was quickly diagnosed with meningitis. While she remained stable for a few days and was mostly concerned about her husband's well-being—remember, he has Lou Gehrig's disease—and getting home to him as soon as possible, she took a turn for the worse. Her speech began to slur, she had trouble seeing, and eventually she had a stroke. One day later she was in a coma.

One thousand people packed Otter Creek Church for her funeral, among them the alumni of a childcare learning center for inner-city preschoolers that she and her husband had founded. The autopsy found fungal meningitis at the injection site and in Mrs. Reed's brain.

Mr. Reed has a rare form of ALS that worsens more slowly, and his mind has not been affected. Diana Reed would help him get in and out of bed, the shower, and his wheelchair. She became more instrumental in his accounting business as his speech worsened. After her death, members of their church brought meals, did laundry, and the church accepted donations to hire help to assist Mr. Reed with his personal care.

This is only one story of the tragedy that the Commissioner of the FDA says will happen again if we don't act. We believe this bill will help to prevent such a tragedy. Steroid injections last year were meant to ease the pain of hundreds of Americans, and for many Tennesseans, instead, it became their worst nightmare. These vials of compounded medicine were contaminated. Sixty-four Americans, including sixteen from my State, died from the outbreak. It is a horrible way to die.

When the HELP Committee held its first hearings on this tragic outbreak in November of last year, we looked at how could this possibly happen. It became clear that these contaminated vials were produced in a facility that was nothing like a traditional pharmacy, a corner drugstore, if you will. It operated more like a manufacturer, but it was unclear which regulator was in charge. Was the State in charge or was the FDA in charge? I made it clear at the beginning of the hearing that my priority was to find a way to clarify who is accountable for large-scale drug compounding facilities, who is on the flagpole for overseeing the safety of drugs made in these facilities.

I used the example of Hyman Rickover and the nuclear Navy in the 1950s. Admiral Rickover was doing something new. He was doing something dangerous, potentially dangerous. He was putting reactors on submarines and ships, and no one knew quite how that was going to work.

What did he do about it? Admiral Rickover hired the captain. He interviewed the captain and said: First, you are responsible for your ship; and, second, you are responsible for the reactor. If there is ever a problem with the reactor, your career is over.

The U.S. Navy has never had a death on a nuclear ship as a result of a reactor problem because everyone knew, after Admiral Rickover made those decisions, who was on the flagpole.

There should be no confusion, after this bill is passed and signed by the President, who is on the flagpole for a particular facility that makes sterile drugs. We should be able to walk into any one of our 60,000 drugstores, pharmacies, our doctors' offices, or pain clinics, and not have to worry about whether the medicines we get there are safe. The bill we are voting on represents that year of work we talked about to find a solution.

Today we have drug manufacturers on the one hand and traditional pharmacies, the corner drugstore, on the other. This legislation creates a new, voluntary third category which we call an outsourcing facility. If a drugstore chooses to be in this category, they follow one nationwide quality standard, and the FDA is responsible for all the drugs made in that facility. FDA is on the flagpole.

What is the advantage of this? First, it eliminates the confusion, it eliminates the finger pointing. If, Heaven forbid, this should happen again, it will be clear whose fault it was, who didn't do their job of regulating.

Second, it provides an option available to doctors and hospitals who, if they wish, can choose to buy all their sterile drugs from a facility regulated by the FDA.

Outsourcing facilities are subject to regular FDA inspections. The New England compounding center that caused these problems was not inspected by the State or the FDA from 2006 to 2011. Outsourcing facilities must report the products made at the facility to the FDA. The New England center that caused the problems was making copies of commercially available drugs, which is illegal. Outsourcing facilities must report to FDA when things go wrong with a product. Currently, large-scale compounders don't have any required reporting to FDA if they know about a problem with a product.

Finally, outsourcing facilities, this new category, must clearly label their products so patients know it is compounded rather than FDA approved. Traditional pharmacy compounders will continue to be primarily regulated by the States, but for outsourcing facilities, the FDA is in charge.

During our discussions we heard a lot about drug shortages. The Senator from Iowa and I worked especially to deal with that. We tried to address it where appropriate in this legislation. We know that compounded products aren't the answer to drug shortages. We don't want compounded products to be the backup solution to drug shortages; we want a better answer than that. We recognized the problem and tried to address it.

Because of heroic reactions of State officials with the Tennessee Department of Health, more people didn't become sick from the outbreak last fall. I don't intend to sit through another hearing where FDA can point the finger at someone else instead of taking responsibility or claim it doesn't have enough authority, and if we pass this legislation, FDA won't be able to.

This legislation also establishes clear rules for outsourcing facilities and puts FDA on the flagpole for drugs made in those facilities.

I hope my colleagues will vote this afternoon to move to the bill, and then shortly after that we will be able to move to approve it, as the House did.

Just one other comment, Mr. President. The chairman, the Senator from Iowa, and Senator BURR, Senator BENNETt, and others have been working for at least 2 years on this form of legislation we call track and trace. It has been through vetting. I think everybody has had a chance to read it and to make a suggestion about it. There have been many changes and adjustments to make sure it works.

Here is the problem. In the United States today, we have about 4 billion prescriptions written every year. We don't have a uniform system to track and trace these drugs once they leave the manufacturer, which makes it easier for counterfeits and substandard products to enter the market and puts patients at risk. The laws governing the tracking of drugs haven't been updated since 1988. In the last 2 years alone there have been three cases of counterfeit Avastin—a cancer drug being distributed in the United States to physicians and patients—where the counterfeit did not contain any of the active ingredient.

We have seen an increase in drug theft. We have no way of knowing if and when these drugs are resold in the U.S. supply chain. In 2009 insulin stolen from a truck much earlier was sold by pharmacies, and the insulin was ineffective due to improper storage. Stealing drugs has turned into a big business, and without assurance that drugs are stored under certain conditions and handled correctly throughout the supply chain, the drugs may not work.

This legislation would set up a system over time—10 years—where products that are stolen could be flagged as such, preventing distribution to patients. It represents a consensus on establishing a national system for all prescription drugs to have a specific serial number on the bottles. That means wholesalers, repackagers, and pharmacies will be able to check the serial number on the bottle with the manufacturer to see whether that number was assigned by the manufacturer. The serial number will not only help prove it is not counterfeit, but the information can also be used to determine whether anything else has been reported about that bottle, including whether the product was stolen.

This won't happen overnight. Creating a system that traces 4 billion prescriptions, made by over 80 manufacturers on over 3,600 manufacturing lines, that are dispensed to patients through a variety of ways will take some time. But the path laid out for us over a number of years will ensure that the U.S. drug supply chain is secure and that consumers receive drugs that work.

I want to thank the Senator from Iowa, as I have already, for his leadership on these two extraordinary pieces of legislation; Senator BURR and Senator BENNET on the track-and-trace legislation; and Senator ROBERTS and

Senator FRANKEN worked hard on compounding legislation.

Let me end where I began. The FDA Commissioner challenged us. She said that if we don't act, this tragedy will happen again. We have an opportunity to act tonight. I hope we do. The families who were devastated by this tragedy because of contaminated sterile injections that caused fungal meningitis in many of our States, especially in Tennessee, expect us to act. If we do, it will not be as well advertised as the differences of opinion we can have in the Senate, but it will demonstrate how, when we work together over a period of a couple of years, we can take a very big piece of complex legislation—in fact, two—that affects the health and safety of every American and come to a consensus that takes a large step forward.

I thank the Chair, and I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

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

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

NOMINATIONS

Mr. CORNYN. Mr. President, back in 2005, before some of the current membership of the Senate was even here, we had a very important development when it came to judicial nominations and the advice-and-consent function of the Senate. Never, before the Presidency of George W. Bush, had nominees to the Federal court been filibustered; that is, a 60-vote threshold been imposed as opposed to a 51-vote threshold, which is, of course, what the Constitution says—requiring a majority of the Senate. But there was an impasse. A number of judges at the circuit court level and district court level were locked down in this impasse. But, as so often happens around the Senate, a gang broke out. A gang was created. Seven Republicans and seven Democrats got together and helped us work through this impasse, and they did so by adopting a new Senate precedent which says, in essence, there will be no filibusters of Federal judges absent ''extraordinary circumstances.'' Yes, you may say that is a broad standard, and it is somewhat subjective, admittedly so, but the point was that the default position would be that Federal judges would get up-or-down votes and there would not be the resort to the 60-vote threshold absent extraordinary circumstances. But the point is that has now become the precedent, basically the rule by which the Senate operates when it comes to Federal judicial nominations, and it is a precedent that has been upheld and respected by both sides of the aisle ever since President Obama took office.

This afternoon we will be voting on a second nominee to the DC Circuit Court of Appeals, a court some have called the second most important court in the Nation because, situated as it is in the District of Columbia, here in Washington, most of the judicial review of administrative decisions goes through this court at the appellate level, and because the Supreme Court only considers roughly 80 cases a year, for all practical purposes the DC Circuit Court becomes the last word on judicial review on many important decisions, particularly those involving agencies such as the Environmental Protection Agency or matters of national security or reviewing the regulations associated with the financial services industry, such as Dodd-Frank and the like—a pretty important court.

Well, unfortunately, the majority leader and the President have determined that they are going to try to jam through three new judges on the DC Circuit Court of Appeals even though these judges are clearly not needed and there is demand elsewhere around the country where the workload is far heavier. But because of the special significance of the DC Circuit Court of Appeals, there is a conscious effort being made to pack that court with three additional judges it does not need in order to change the current division—four to four—in a court where Republican Presidents appointed four, Democratic Presidents appointed four. So it is an evenly balanced court.

As I said, the DC Circuit Court of Appeals does not need any more judges. So why in the world, in a time when we are looking to make sure every penny goes as far as it can and we are not spending money we do not have, would you want to appoint three new judges to a court that does not need any new judges?

Well, here is the number: Since 2005 the total number of written decisions per active judge actually has gone down. As of September 2012 both the total number of appeals filed in the DC Circuit and the total number of appeals ended in the DC Circuit per active judge were 61 percent below the national average.

So you might ask yourself, if it carries a 61-percent reduced caseload compared to the rest of the country, why don't we put the judges where President Obama can nominate them and the Senate can confirm them in places where they are actually needed rather than this court?

Well, because of the reduced caseload and the lack of work for the judges to do on the DC Circuit, one DC Circuit judge recently told Senator GRASSLEY, the ranking member on the Senate Judiciary Committee, ''If any more judges were added now, there wouldn't be enough work to go around.'' Again, why in the world would President Obama insist and Majority Leader REID insist on us confirming judges who are not needed when there is not enough work to go around if they were?

Well, my friends across the aisle continue to say that all they care about is filling judicial vacancies, but the majority leader has made it clear that his real objective is to switch the majority when the court sits en banc. For example, ordinarily, circuit courts sit on a three-judge panel, but in important decisions you may have the entire court sit en banc or all together. And the objective is clear that the majority leader wants to stack it in favor of President Obama's nominees, to transform it into a rubberstamp for the President's big-government, overregulatory agenda.

Indeed, despite all the victories the administration has won before this court, it is apparently not good enough. This administration has won several high-profile victories—in environmental cases, for example—but they are still upset with the court because it actually ruled against President Obama on cases related to corporate governance, emissions controls, recess appointments, and nuclear waste. So our colleagues are not content to have a court that is balanced and decides cases on a case-by-case basis they want to stack the court in a way that is a rubberstamp for the President's agenda.

But here are some examples of the cases the court has decided recently. In 2011 the DC Circuit told the Securities and Exchange Commission to follow the law—believe that or not—to follow the law and conduct a proper cost-benefit analysis before adopting its regulations. That is what the law required. The Securities and Exchange Commission ignored the law, and the DC Circuit said ''follow the law'' and reversed the Securities and Exchange Commission.

In 2012 the court rejected an Environmental Protection Agency rule that went far beyond the limits of the Clean Air Act. These regulatory agencies have a lot of power and a lot of authority, but it all springs from a legislative enactment by Congress. That is the source of their power and their authority, and in this case it was the Clean Air Act. The court said the Environmental Protection Agency exceeded the limits of its authority based on the law that Congress wrote and the President signed into law.

Then, in 2013, President Obama violated the Constitution, the court said, by making recess appointments when the Senate was not actually in recess. This is a very important power that goes back to President Washington that makes sure that when Congress is in recess there is still a way for the President to fill vacancies. But that was in the old days when Congress would basically leave town for months at a time. In this case, President Obama essentially decided he did not want to wait around for the advice-