EXECUTIVE SESSION

NOMINATION OF ROBERT LEON WILKINS TO BE UNITED STATES CIRCUIT JUDGE FOR THE DISTRICT OF COLUMBIA CIRCUIT

Mr. REID. Mr. President, I move to proceed to executive session to consider Calendar No. 381.

The PRESIDING OFFICER. The question is on agreeing to the motion to proceed.

The motion was agreed to.

The clerk will report the nomination.

The assistant legislative clerk read the nomination of Robert Leon Wilkins, of the District of Columbia, to be United States Circuit Judge for the District of Columbia Circuit.

CLOTURE MOTION

Mr. REID. Mr. President, I sent a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the nomination of Robert Leon Wilkins, of the District of Columbia, to be United States Circuit Judge for the District of Columbia Circuit.

Harry Reid, Patrick J. Leahy, Tom Udall, Mark Begich, Brian Schatz, Al Franken, Barbara Boxer, Richard J. Durbin, Christopher A. Coons, Tammy Baldwin, Debbie Stabenow, Benjamin L. Cardin, Sheldon Whitehouse, Patty Murray, Barbara A. Mikulski, Kirsten E. Gillibrand, Tom Harkin.

Mr. REID. Mr. President, I ask unanimous consent the mandatory quorum under rule XXII be waived.

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

LEGISLATIVE SESSION

Mr. REID. Mr. President, I move to proceed to legislative session.

The PRESIDING OFFICER. The question is on agreeing to the motion.

The motion was agreed to.

DRUG QUALITY AND SECURITY ACT—MOTION TO PROCEED—Continued

Mr. REID. If I understand, H.R. 3204 is now the pending matter.

The PRESIDING OFFICER. The Senator is correct.

CLOTURE MOTION

Mr. REID. Mr. President, I have a cloture motion with respect to the bill, which is at the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on H.R. 3204, an Act to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

Harry Reid, Tom Harkin, Patrick J. Leahy, Jack Reed, Angus S. King, Jr., Mark Begich, Richard Blumenthal, Benjamin L. Cardin, Tim Kaine, Christopher A. Coons, Tom Udall, Sheldon Whitehouse, Joe Manchin III, Bill Nelson, Mark R. Warner, Debbie Stabenow, Amy Klobuchar.

Mr. REID. Mr. President, I ask unanimous consent the mandatory quorum under rule XXII be waived.

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

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2014—MOTION TO PROCEED

Mr. REID. Mr. President, I move to proceed to calendar No. 91, S. 1197.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant legislative clerk read as follows:

The Senator from Nevada [Mr. REID] moves to proceed to consider Calendar No. 91, S. 1197, a bill to authorize appropriations for fiscal year 2014 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

CLOTURE MOTION

Mr. REID. Mr. President, I have a cloture motion at the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the motion to proceed to Calendar No. 91, S. 1197, a bill to authorize appropriations for fiscal year 2014 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

Harry Reid, Carl Levin, Jack Reed, Angus S. King, Jr., Mark Begich, Richard Blumenthal, Benjamin L. Cardin, Tim Kaine, Christopher A. Coons, Tom Udall, Sheldon Whitehouse, Bill Nelson, Joe Manchin III, Mark R. Warner, Debbie Stabenow, Amy Klobuchar, Richard J. Durbin.

Mr. REID. Mr. President, I ask unanimous consent that the mandatory quorum under rule XXII be waived.

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

MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent the Senate proceed to a period of morning business until 5 p.m. today with Senators permitted during that time to speak for up to 10 minutes each.

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

The PRESIDING OFFICER. The Senator from Kansas.

DRUG QUALITY AND SECURITY ACT

Mr. ROBERTS. Mr. President, I come to the floor today to speak in support of the Drug Quality and Security Act, H.R. 3204. Getting this bill to where it is today—and I thank the leader for just making that possible, along with our minority leader—has been a long and sometimes very difficult road, one on which I have been working for over a decade—yes, 10 years.

This is an issue that hit far too close to home in Kansas. Several years ago, a pharmacist in Kansas City, Robert Courtney, was found to be diluting cancer drugs for his patients. Unfortunately, over 4,000 patients were affected before authorities could stop him. Senator Kit Bond at that time and myself worked together to hold the first Health, Education, Labor and Pensions Committee hearing on pharmacy compounding.

Since that time I have continued my interest in the compounding-related issues. Unfortunately, last September, over a year ago, the tragic meningitis outbreak began. This outbreak was the result of contaminated compounded medications produced by the New England Compounding Center.

Of the 751 people who became ill, 64 people lost their lives. Many of those who became ill are still suffering and have experienced painful relapses in their condition. Unfortunately, that is not the only occurrence in the last 10 years. Without proper safeguards and clear authority, I fear that these tragedies would only continue.

We acknowledged then that we had to buckle down and really get something done. Since that time, I have been working with my colleagues to draft the pending legislation before this body, the Drug Quality and Security Act, with the desire to protect patients and improve regulation of the pharmacy compounding industry.

I think that we have finally achieved what we all intended from the beginning, which is a bipartisan, bicameral product that is supported by a majority of the stakeholder groups and a variety of those groups. This legislation has the support of the pharmacists led by the National Community Pharmacists Association and the American Pharmacists Association. It has the support of the patient advocacy groups such as the Cancer Leadership Council and of industry groups such as the Pharmaceutical Distribution Security Alliance. In fact, this is quite a long list. I will not take the Senate's time to go over that list. But I would ask unanimous consent that this list be printed in the RECORD at this point in its entirety.

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

SUPPORTERS OF H.R. 3204—DRUG QUALITY AND SECURITY ACT

Abbvie (PDSA), Academy of Nutrition and Dietetics, Actavis (PDSA), Allergy and Asthma Network Mothers of Asthmatics, American Medical Student Association, American Pharmacists Association, American Public Health Association, American Society for Radiation Oncology (CLC), American Society for Reproductive Medicine, American Society of Clinical Oncology (CLC), American Society of Health System Pharmacists, American Women's Medical Association, AmerisourceBergen (PDSA), Annie Appleseed Foundation.

Association of State and Territorial Health Officials, AstraZeneca (PDSA), Bayer (PDSA), Biotechnology Industry Organization (PDSA), Bladder Cancer Advocacy Network (CLC), Blue Ribbon Advocacy Alliance, Boehringer Ingelheim (PDSA), Cancer Action Network (CLC), Cancer Leadership Council (CLC), Cancer Support Community (CLC), CancerCare (CLC), CAPS—Central Admixture Pharmacy Services, Cardinal Health, Caregiver Action Network.

Center for Medical Consumers, Center for Science and Democracy, Union of Concerned Scientists, Chamber of Commerce of the United States of America, The Children's Cause for Cancer Advocacy (CLC), Community Catalyst, Connecticut Center for Patient Safety, Covectra, CreakyJoints.org, DSC/HC (PDSA), EMD Serono, Federation of American Hospitals, Fight Colorectal Cancer (CLC), Friends of Cancer Research, Generic Pharmaceutical Manufacturers Association (PDSA).

Genentech (PDSA), Global Healthy Living Foundation, Grifols (PDSA), Healthcare Distribution Management Association (Big Drug Wholesalers) (PDSA), HIDA (PDSA), Institute for Nurse Practitioner Excellence, International Myeloma Foundation (CLC), International Warehouse Logistics Association (PDSA), Johnson and Johnson (PDSA), Kidney Cancer Association (CLC), Eli Lilly (PDSA), The Leukemia & Lymphoma Society (CLC), LIVESTRONG Foundation (CLC).

Lymphoma Research Foundation (CLC), McKesson Corporation, MD Support, Medline (PDSA), Men's Health Network, Merck (PDSA), Mylan (PDSA), National Association of Chain Drug Stores (PDSA), National Association of County and City Health Officials, National Coalition for Cancer Survivorship (CLC), National Community Pharmacists Association (PDSA), National Lung Cancer Partnership (CLC).

National Patient Advocate Foundation (CLC), North American Menopause Society, Novartis (PDSA), Ovarian Cancer National Alliance (CLC), Pancreatic Cancer Action Network (CLC), Perrigo (PDSA), Pfizer (PDSA), Pharmaceutical Distribution Security Alliance, Pharmedium, PhRMA (PDSA), Premier Healthcare Alliance, Prevent Cancer Foundation (CLC), Prostate Cancer Education and Support Network (CLC), Richie's Specialty Pharmacy, Sarcoma Foundation of America (CLC), Society for Women's Health Research, StopAfib.org, Susan G. Komen Advocacy Alliance (CLC), Takeda (PDSA), Tennessee Pharmacists Association, Terri Lewis, Meningitis Outbreak FB Community Manager, The Pew Charitable Trusts, Trust for America's Health, UPS (PDSA), Us TOO International (CLC), Walgreens (PDSA).

Mr. ROBERTS. Title I of the Drug Quality and Security Act addresses the oversight of compounding pharmacies, and Title II provides a mechanism for securing our pharmaceutical drug supply chain. Together, we are making patients safer and ensuring that they can better trust the drugs that they take.

This took a significant amount of time and effort. I especially thank Chairman HARKIN, Ranking Member ALEXANDER, Senators BURR, BENNETT, and FRANKEN for sticking with it. This is a true bipartisan effort. Personally, I thank my staffer Jennifer Boyer for her determined dedication and the many hours of work to get this job done.

In September, with the leadership of Mr. UPTON and Mr. WAXMAN in the other body, this legislation was passed by the House by a voice vote. I am hoping we can see a similar outcome in the Senate. I urge my colleagues to support this legislation and encourage its swift passage and the signature by the President of the United States.

I yield the floor.

Ms. MIKULSKI. Mr. President, I am here today to talk about the Drug Quality and Security Act. This legislation does two things. First, it improves the regulation of compounding pharmacies, and second, it strengthens the security of our drug supply chain. This legislation has been in the works for quite a while and I am so pleased that the HELP Committee came together on a bipartisan basis and put together legislation that will truly save lives—across the country and in my home State of Maryland.

This bill has been through regular order. We had multiple hearings in the HELP committee, we had working groups, of which I was a member, and we held a bipartisan markup. Our counterparts in the House did the same. And here we are today. This bill has passed the House and it is my hope that it will pass the Senate and be signed into law by the President.

Let me first talk about the Compounding Quality Title of the bill and why it is so important. Last year, our Nation was devastated by a meningitis outbreak that sickened 751 people and killed 64 people. In Maryland, 26 people fell ill and 3 people died. As the HELP Committee looked into this outbreak, we quickly learned two things. First, these illnesses and deaths were caused by contaminated compounded drugs from the New England Compounding Center, NECC, located in Massachusetts. And second, these illnesses and deaths were entirely preventable.

Hospitals, doctors, and patients are increasingly relying upon compounded drugs, which are supposed to be made on an individual basis to respond to a patient's unique health needs. For instance, if a patient is allergic to a certain ingredient in a drug, a compounding pharmacy can make the drug without that ingredient. Or if a child needs a smaller dosage strength, a compounding pharmacy can do that. Today, 1 to 3 percent of the U.S. prescription drug market is made up of compounded drugs.

But the problem we have is twofold. The first problem is that where there is need, there is greed. Compounded drugs are supposed to be made on an individual basis for an individual patient and provided only with a prescription from a doctor. What the HELP Committee learned was that certain compounding facilities were blatantly and flagrantly violating these rules. Not only was NECC mass producing drugs and dispensing them across State lines without prescriptions, NECC also knowingly disregarded sterility tests and prepared drugs in unsanitary conditions. And why? To make a profit.

The second problem is that our existing regulatory framework is insufficient. NECC made drugs in unsanitary conditions, mass produced drugs, and provided medicines without prescriptions. And our regulatory framework was ill-designed to catch problems and prevent the outbreak.

We cannot undo the tragedy caused by NECC's actions, but we can and must find a way to prevent this from happening again, and that is where this legislation comes into play. The bill before us makes two major changes, which will help prevent another NECC-like tragedy. First, it gives the FDA the authority to regulate large-scale compounding pharmacies. Compounders who wish to make large volumes of these drugs will be regulated by FDA, will be required to register with FDA, will be required to report adverse events to FDA, and will be subject to risk-based inspections by FDA. Smaller traditional compounding pharmacies will continue to be regulated by State boards of pharmacy.

Second, this legislation will ensure that patients and providers have better information about compounded drugs. The FDA will post online a list of compounding facilities they regulate, detailed labeling will be required on compounded drugs, and false and misleading advertising will be prohibited.

Let me now talk about the Drug Supply Chain Security Title of the bill. This deals with all drugs, not just compounded drugs. Today, we have a patchwork of 50 different State laws that govern drug distribution in our 50 different States. What this means is that if we become aware of a contaminated drug in our supply chain, there is no uniform way to track that drug back to its source and get it off the market quickly.

This bill will improve patient safety by replacing today's patchwork of product tracing laws with a strong, uniform standard that will ultimately lead to an electronic, interoperable product tracing system for the entire country. This is commonsense legislation that has been long in the making.

These issues are particularly important to me, not only because ensuring the safety of our Nation's drug supply is of the utmost importance but also because I have the distinct honor of representing Maryland, which is home to the FDA.

The FDA is our Federal agency tasked with ensuring the safety of our

Nation's drugs, through the more than 14,000 dedicated, talented, hardworking employees who work there. Fifty-five percent of FDA's employees were furloughed during the recent government shutdown. I would like to take this opportunity to remind my colleagues why the work that the FDA does is so important. If we want our drugs to be safe, if we want our food to be safe, if we want our medical devices to be safe, we cannot furlough our FDA staff and we cannot pursue cuts to FDA in coming years.

This bill was done the right way. We had hearings, markups, and working groups in both the House and Senate and we had input from both Republicans and Democrats. I want to thank Chairman HARKIN and Ranking Member ALEXANDER for all of their work to get us here. I urge my colleagues to support this bill, which will improve drug safety and save lives.

Mr. COBURN. Mr. President, it has now been about 1 year since the fungal meningitis outbreak last fall associated with the tainted sterile compounded drugs from the New England Compounding Center. This week on the floor of the Senate, we have a bill that is, in many senses, Congress's response to the lack of policy clarity that many have suggested failed to prevent that tragedy.

As I have watched the Senators and their staff who have been working on this bill over the past several months, I applaud the bipartisan manner they have used in creating legislation that could help prevent similar tragedies in the future.

I am planning on voting for this legislation because I do think Congress needs to legislate. The courts have not been clear. However, I want to note that, despite the strong bipartisan collaboration, this legislation leaves some regulatory oversight concerns outstanding that I want to comment on and make clear today.

There has been a lot of concern that by reaffirming section 503(a) of the Food, Drug and Cosmetic Act, office use of compounded drugs is not recognized as permissible compounding activity. Therefore, I want to make clear that this legislation does not change current State law or authority over the dispensing or distribution of medications by pharmacists, compounded or manufactured, for a prescriber's administration to or treatment of a patient within their practice.

Currently, the compounding and dispensing of prescription drugs for in-office administration by a prescriber to their patient is governed by State boards of pharmacy, and States have determined what is best for their State regarding office use. In fact, more than 40 States have passed laws over the last 15 years related to current practices of using compounded drugs in the office context.

The issue of office use, indeed all of pharmacy practice regulation, is best left to the States. So the omission of office use from 503(a) should not signal to the FDA that it has the authority to encroach upon State authority to regulate office use.

In addition, there have been concerns whether the provisions within the legislation that grant authority to the FDA to set up systems of procedure for the direct communication between State boards of pharmacy and the FDA will give FDA more authority over compounded prescriptions shipped across State lines. I want to also take this opportunity to make clear that these provisions within the legislation require ''appropriate investigation'' on complaints and other issues that arise by the FDA and in no way provide some new expansive authority to the FDA to restrict interstate commerce or regulate intrastate commerce.

Finally, the legislation does not change the ability of ophthalmologists to administer drugs in their office to individual patients for the purposes of reducing macular degeneration. Under this legislation, physicians retain the ability to use compounding drugs in their office for their patients. This is a practice-of-medicine issue, so the art and science of medicine should not be impeded by the FDA.

I will continue to monitor the implementation of section 503(A) in consultation with physicians, medical professionals, and pharmacy professionals. I also strongly encourage the FDA to ensure that these provisions are not used to restrict office use and restrict interstate sales of compounded pharmaceuticals within all applicable laws and regulations.

I suggest the absence of a quorum.

The PRESIDING OFFICER (Ms. BALDWIN.) The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

RECESS

Mr. REID. Madam President, it is my understanding there is an order in effect that we would recess starting at 1 p.m.

The PRESIDING OFFICER. That is correct.

Mr. REID. Madam President, I ask unanimous consent that time be advanced and we begin recess now.

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

Thereupon, the Senate, at 12:40 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Ms. HEITKAMP).

The PRESIDING OFFICER. The Senator from Louisiana is recognized.

UNANIMOUS CONSENT REQUESTS

Mr. VITTER. Madam President, I come to the floor again to try to achieve what I think is a very simple and straightforward but important objective: to get a clear up-or-down vote on a pure disclosure proposal I have. This proposal would say that the elections all of us make as Members of the Senate and all of the House Members make with regard to how our offices go to the ObamaCare exchange as mandated by statute do not go through this end runaround of the OPM rule. That is simply public information. How each office handles the situation is public information.

Whatever we believe about the Washington exemption from ObamaCare, whatever we believe about that debate and that exemption and that subsidy, it should be a no-brainer, not partisan debate, how each of us and how each of our offices handle whether this election is public information. Right now it is not. A lot of Members, including me, have explained what they are doing, but certainly not all have, and that is not public information. This amendment which I am proposing would simply produce full disclosure and have that be public information.

I am open to any way to get a clear vote on that this calendar year, so I am completely flexible on how that happens—on this bill before us—and I would certainly like to expedite consideration and passage of this bill; or an amendment on the Defense bill next week—that would be another possibility; or a quick debate on my freestanding bill—that would be a third possibility. None of those would take significant time in the Senate. In fact, all of those would expedite Senate business, including leading to the passage of the bill now on the Senate floor right now, today. So it would actually expedite the process and expedite consideration.

With that, Madam President, I ask unanimous consent that my amendment No. 2024 be called up, that a Democratic side-by-side amendment be in order to be called up, and that those be the only amendments in order other than those currently pending; that both those amendments be subject to a 60-vote affirmative threshold for adoption; I further ask that there be a total of 2 hours of debate equally divided on both amendments and that upon the use or yielding back of that time, the Senate proceed to a vote on the Democratic amendment, followed by a vote on my amendment; that following the disposition of the amendments, the bill be read a third time and passed and the motion to reconsider be considered made and laid upon the table with no intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Mr. REID. Reserving the right to object, I have made statements over the past many weeks about why I object to this. I object.

The PRESIDING OFFICER. Objection is heard.

Mr. VITTER. Madam President, reclaiming the floor, again I am open to any reasonable way to get a simple