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Senate

The Senate met at 2 p.m. and was called to order by the President pro tempore (Mr. LEAHY).

PRAYER

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

Let us pray.

Our Father, be with us not only in great moments of experience but also during mundane and common tasks of life. Through the power of Your Spirit, may our Senators mount up with wings like eagles, running without weariness and walking without fainting. Lord, give them the wisdom to be patient with others, ever lenient to their faults and ever prompt to appreciate their virtues. Rule in their hearts, keeping them from sin and sustaining their loved ones in all of their tomorrows. Surround them with the shield of Your favor, as You provide them with a future and a hope.

We pray in Your sovereign Name. Amen.

PLEDGE OF ALLEGIANCE

The President pro tempore led the Pledge of Allegiance as follows:

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

RECOGNITION OF THE MAJORITY LEADER

The PRESIDENT pro tempore. The majority leader is recognized.

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 PRESIDENT pro tempore. The clerk will report the bill by title.

The legislative clerk read as follows:

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.

DRUG QUALITY AND SECURITY ACT

Pending:

Reid amendment No. 2033, to change the enactment date.

Reid amendment No. 2034 (to amendment No. 2033), of a perfecting nature.

Reid motion to commit the bill to the Committee on Health, Education, Labor and Pensions, with instructions, Reid amendment No. 2035, to change the enactment date.

Reid amendment No. 2036 (to (the instructions) amendment No. 2035), of a perfecting nature.

Reid amendment No. 2037 (to amendment No. 2036), of a perfecting nature.

Mr. REID. I now ask unanimous consent that the cloture motion with respect to H.R. 3204, the pharmaceutical drug compounding bill, be withdrawn, the pending motion and amendments be withdrawn, and the Senate vote on the passage of the bill.

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

The bill (H.R. 3204) was ordered to a third reading and was read the third time.

ANIMAL DRUG COMPOUNDING

● Mr. ISAKSON. Mr. President, I wish to thank Mr. ALEXANDER for his work on this legislation. I am happy to see that all sides have been able to reach an agreement on clarifying the oversight of large compounding facilities, while also ensuring that patients continue to have access to customized medicines at their local pharmacy. I am grateful to the chairman and ranking member for clarifying that the intent of this legislation is to maintain current law with respect to patients' and physicians' access to drugs compounded for office use. I am also very encouraged that we are finally moving forward on creating a uniform national standard for the pharmaceutical supply chain, which will allow patients to have more confidence in the safety of the drugs they receive while also ensuring that national distributors and third-party logistics providers do not face the burden of dealing with a confusing and inconsistent patchwork of State-by-State rules.

I would like to take a moment to discuss an issue that is not directly addressed in the bill before us. I have heard from my constituents that there are serious problems, similar to the ones we are seeking to address today, with the inappropriate compounding of animal drugs. As with human drugs, mass production of compounded animal drugs with inadequate safety standards has resulted in suffering and death.

While the compounding of animal drugs according to a prescription from a veterinarian for an individual patient is legal, necessary, and appropriate, it is important to draw a line between compounding and manufacturing. I am especially troubled by reports that some entities characterizing themselves as ''compounding pharmacies'' are producing large quantities of animal drugs that are essentially copies of FDA-approved products. They are then mass-marketed as cheap alternatives to approved products, without being subject to any of the safety requirements and quality controls that manufacturers must comply with.

As with human drugs, the FDA has had mixed success in taking enforcement action against questionable or abusive animal drug compounding practices. While I understand that animal drug compounding raises complicated issues that the bill before us does not address, I want to make it clear that the absence of animal drug provisions in this legislation does not constitute an endorsement of the status quo. I hope that in the months ahead, Congress can begin to investigate the issues surrounding animal drug compounding in more depth, with an eye toward spurring the FDA to make this a higher enforcement priority.

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

Mr. ALEXANDER. Mr. President, I agree that there are issues associated with animal drug compounding that should be examined. This bill does not change the current animal drug regulatory structure, and it is my hope that FDA would exercise its current enforcement authorities, as well as work with State pharmacy boards, to ensure that the law is being followed with respect to animal drug compounding, including compounding from bulk chemicals and the copying of approved drugs. In addition, Congress should utilize its oversight authorities to ensure that the agency acts accordingly. I plan to work with my colleagues in the Senate and the House to ask the Government Accountability Office to look at compounding of animal drugs.

Mr. ISAKSON. I thank the chairman, and I look forward to working with him.●

ACCESS TO COMPOUNDED DRUGS

Mr. ALEXANDER. Mr. President, I have been working very hard with Senator HARKIN, members of the HELP Committee, and members of the House Energy and Commerce Committee on legislation to provide options for patients and providers who want compounded drugs made in FDA-regulated facilities. As we debate this bill today, I want to make clear that all involved on this legislation have no intent of limiting patient or provider access to quality compounded drugs that fill a clinical need.

The process in the HELP Committee began as soon as news of the outbreak broke in Tennessee, and I cannot thank enough the folks at the Tennessee Department of Health, including Dr. Kainer, for all their good work that prevented so many further cases and lives being destroyed.

We have been working very hard to reach an agreement on how compounding should be regulated—and we have come a long way. Stakeholders including pharmacists, public health groups, and the FDA, have been sitting around a table to find a consensus solution. We have made good progress, and I want to talk about this legislation.

For traditional pharmacy, currently regulated under 503A of the Food, Drug, and Cosmetic Act, we strike the provisions found unconstitutional by the Supreme Court related to marketing.

In addition, and what will help prevent another New England Compounding Center, NECC, the Drug Quality and Security Act establishes a completely separate and distinct section 503B that authorizes FDA to regulate an optional category for larger compounding facilities. Sterile compounding facilities that do not want to comply with the patchwork of State laws and requirements can choose instead to have FDA regulate their compounding. 503B establishes rigorous quality standards, registration, adverse event reporting, inspections, and fees. If there are unintended consequences to this legislation, I stand ready to work with my colleagues and provide necessary oversight.

It has been almost 10 years since the Supreme Court decision that left a great deal of uncertainty in the regulation of pharmacy compounding. We clarify that 503A applies nationwide, and create an FDA regulated source for sterile compounded drugs. Nothing in the legislation is intended to limit access to quality compounded drugs for providers and patients or alter the practice of medicine but, rather, create a whole new alternative for safe sources of sterile compounded drugs that are held to a nationwide quality standard. The legislation does not change current law on office use compounding or repackaging.

Chairman HARKIN will discuss the importance of this language, and I thank him for working with me so hard on this over the last year.

Mr. HARKIN. Mr. President, as Senator ALEXANDER has indicated, we have been working together for a long time to develop legislation that will ensure that patients have access to the compounded drug products they need and that they can have greater confidence that their compounded drugs are safe. We ultimately landed on a package that preserves current law for traditional compounders but creates a new option for entities that choose to operate outside the bounds of traditional pharmacy practice to allow them to serve as safe sources of the compounded drugs that providers and their patients need.

We have worked very hard to craft a proposal that preserves patient access to clinically necessary medications while helping to ensure that providers have access to safe sources of compounded drugs. As Senator ALEXANDER noted, section 503A of the current Federal Food, Drug, and Cosmetic Act governs traditional compounding. This bill preserves current 503A but removes the unconstitutional advertising provisions so 503A is the uniform policy nationwide.

Similarly, we do not change current law regarding repackaging or biologics. The Senate bill established a new regulatory regime for repackaging and biologics, but ultimately, after our bipartisan, bicameral discussions, we made no changes to current law on those subjects nor do we change current law on the compounding of animal drugs. The existing restrictions on animal drug compounding have not been rigorously enforced. We will be asking GAO to take a closer look at the laws regulating animal compounding because we weren't able to address it in this package.

This bill also creates an entirely new source of quality compounded drugs. It permits entities that want to serve as outsourcers for entities that need large volumes of clinically necessary compounded drugs to provide those drugs, as long as they register with FDA and pay a registration fee, adhere to high quality standards, submit to FDA inspection, and tell the agency if adverse events occur.

I recognize that many patients need drugs that are not available from pharmaceutical manufacturers, and I have no interest in cutting off patients' access to those drugs. But I do want to ensure that when patients do need a compounded drug, it is safe. By ensuring that current law—FDCA section 503A—applies nationwide and creating a new safe source of outsourced drugs, this bill should enhance patients' ability to get the drugs they need without having to worry about their safety.

PRACTICE OF MEDICINE

Mr. COBURN. Mr. President, I wish to express support moving forward with the Drug Quality and Security Act but want to express my concern that this legislation should not be used by the FDA to interfere with a doctor's ability to practice medicine and choose the best therapy for his or her patients. Patients have allergies, conditions, and diseases on an individual basis. So often drugs in the form made by manufacturers are not the best option for an individual patient's needs, especially in some specialties such as ophthalmology. A varying strength or dose may need to be made by the pharmacy and many States have laws permitting physician compounding as well.

I understand and have received assurances from my colleague Senator ALEXANDER that limiting access to necessary treatments by providers and patients was not the intent of this legislation and look forward to working with him should any unintended consequences arise.

Mr. ALEXANDER. Mr. President, I thank my friend Dr. COBURN for his remarks, concern, and assistance with this legislation. I agree with him, and want to clarify that nothing in this legislation will constrain a doctor's options to practice medicine. The legislation tries to ensure that if a doctor or patient needs access to compounded drugs, that there is an FDA-regulated source for those drugs where the quality standards are uniform nationwide. Doctors know their patients best and should have access to accurate information on the safety and quality of the drugs they use.

If there are unintended consequences to this legislation, I stand ready to work with my colleagues and provide necessary oversight.

Mr. ALEXANDER. Mr. President, I rise today to speak about the Drug Quality and Security Act and also to thank the members and staff who have worked with us to reach an agreement and pass this bill. The legislation addresses the current ambiguity around the regulation of compounding pharmacies, one of which is tied to more than 60 deaths. It also establishes a workable system to get to unit level tracing of the nearly 4 billion prescriptions filled a year in the U.S. within a decade. In addition to bipartisan support in Congress, the bill enjoys broad support from the biomedical industry,

patient groups, consumer groups, and other stakeholders.

Over a year ago, staff began to work on identifying the cause and possible solutions to help prevent another meningitis outbreak. A group of staff from Republican and Democratic offices on the Health, Education, Labor, and Pensions Committee began a series of standing meetings and proceeded to meet every week for several months. They met with stakeholders and discussed policy solutions that each member thought would solve the problem. After much discussion of the benefits, costs, and possible unintended consequences, members agreed to a list of policy concepts. That bill, S. 959, is a strong bill, and was voted out of committee unanimously. While I believe our Senate bill was a stronger solution, it would not have gotten through the Chamber on the other side of the Capitol.

We held bipartisan and bicameral meetings throughout August to try to find a consensus that could pass both Chambers, and that legislation is what you see before you. Is it perfect? No, but I believe it is a good first step and a market-driven solution to this terrible tragedy.

I would like to thank Senator HARKIN for his tireless work on this bill, along with Chairman UPTON and Ranking Member WAXMAN of the Energy and Commerce Committee. Senator HARKIN's staff has also worked tirelessly on this bipartisan bill. They worked many late evenings, long weekends, and through countless discussions to get the bill to where it is today.

Specifically, I want to recognize and thank Jenelle Krishnamoorthy, Elizabeth Jungman, and Nathan Brown. I also want to thank Pam Smith, Senator HARKIN's staff director, for her leadership in getting this bill to the finish line.

I also would like to thank Jennifer Boyer with Senator ROBERTS and Hannah Katch with Senator FRANKEN for all their help as well.

Senators BENNET and BURR were instrumental in the drug tracing title on which they have been working for almost 2 years. Rohini Kosoglu with Senator BENNET and Anna Abram and Margaret Coulter with Senator BURR worked very hard to craft this section, and I would like to thank them, too. I would also like to thank our Senate legislative counsels Stacy Kern Scherer and Kim Tamber, and from the Congressional Budget Office Julia Christensen, Jean Hearne and Ellen Werble.

Finally, I would like to thank my staff—Grace Stuntz, and my Health Policy Director, Mary-Sumpter Lapiniski. I also want to thank my staff director, David Cleary, for his work on this bill. My staff has been working around the clock for many days and weeks, and I sincerely appreciate their dedication to getting this bill passed.

I know Members are pulled in many different directions and there is always a lot of work to complete. We have a bipartisan bill that we believe will pass the Senate later today and passed the House on Saturday, September 28th, that takes a big step in addressing the regulation of compounded drugs and preventing counterfeit, stolen, and substandard drugs from reaching consumers. I urge my colleagues to support this compromise.

Mr. BOOZMAN. Mr. President, more than a year ago we witnessed the fatal New England Compounding Center meningitis outbreak. The Food and Drug Administration failed to pursue enforcement action against NECC, despite clear warning signs. Moreover, the Massachusetts Board of Pharmacy did not do its job. It failed to provide basic oversight. This inaction allowed a criminal compounder to operate with impunity—ending the lives of many Americans.

In contrast, the Arkansas Board of Pharmacy is competent and thorough. It does a great job. Arkansas regularly inspects all pharmacies. We are a small State, but we run a tight ship.

However, Arkansas has no way of knowing whether other State pharmacy boards are doing their job.

We need to take steps to protect patients from precarious, poorly inspected, out-of-State drugs. However, I want to make clear of something before we move on this legislation.

The practice of pharmacy, including pharmacy compounding, is a State issue. Nothing in this law changes that. Compounded drugs for office-use is a State issue. Nothing in this law changes that. Commonplace drug repackaging for drugs—like Avastin—is a State issue. I relied on compounders regularly when I practiced in a surgery center. Office-use compounding and repackaging is acceptable under Arkansas law. Nothing in this law changes that.

The omission of office-use from section 503(a) of the Food, Drug, and Cosmetic Act should not signal to the FDA that it has the authority to encroach upon State authority to regulate office-use. This is not the intent of the law, and I will closely monitor FDA implementation as this process moves forward.

If the State of Minnesota wants to prohibit drug repackaging and compounding—that is its decision. But again, this law is by no means a green light for the FDA to usurp the rights of States. I want to make that crystal clear.

Lastly, contrary to much of what has been said, compounders have really stepped up to assist providers in need. Today, America faces a serious drug shortage problem. Sterile injectable generic drugs constitute 80 percent of the drugs in short supply.

Not surprisingly, government pricing caps have caused these shortages. Thankfully, compound pharmacists in Arkansas and across the country have been meeting critical market needs that manufacturers have been unable to satisfy. Compounders have helped address supply chain gaps and sudden spikes in demand—particularly in rural and neglected areas. They have plugged holes in the system, and they have tended to overlooked markets.

Without compounders, doctors would not perform surgeries. Without compounders, oncologists would be forced to administer alternative chemotherapy drugs. Without compounders, patients would suffer from limited access. These are real issues and real problems, and we must take these realities into consideration. I look forward to working with all stakeholders to ensure commonsense compounding, repackaging, and office-use administration of compounded drugs.

Mr. LEVIN. Mr. President, the Senate is poised to pass legislation aimed at strengthening the safety of compounded pharmaceuticals and the security of the drug supply chain. It has been more than 1 year since the public became aware of what quickly became a far reaching fungal meningitis outbreak affecting citizens in 20 States, including my home State of Michigan. Following an investigation by the Centers for Disease Control and Prevention and the Food and Drug Administration, along with local health departments, it became clear the outbreak was caused by contaminated steroid injections produced by the now defunct New England Compounding Center, NECC, a compounding pharmacy in Framingham, MA. This tragedy brought a spotlight to bear on the opaque regulation of mass compounding pharmacies.

According to the CDC, over 750 people from across the United States were affected by tainted pain steroid injections produced by NECC. Victims numbering 264, more than one third of the hundreds made severely ill from contaminated injections, reside in Michigan. Sixty-four of the victims lost their life as a result of illness, including 19 Michiganians. While it is certainly important that we clarify Federal regulatory responsibilities to help ensure similar tragedies are not repeated in the future, we could have begun debate on a solution far earlier. A legislative response is surely long overdue.

Colleagues on both sides of the aisle and the Capitol have worked through this issue to produce a bill that will both strengthen Federal authority to regulate mass-compounding facilities and will lay the groundwork for a nationwide system to track prescription drugs. While not as far reaching as some may have initially intended, the bill we are considering does represent an important and necessary step forward and was unanimously passed by the House of Representatives in September.

It is important to draw a distinction, as this bill does, between so-called traditional compounding—where a pharmacist tailors a particular drug to meet the unique needs of a patient, such as removing a certain dye or altering the dosage level of an adult

medication to be suitable for a child—and the mass compounding of drugs for wholesale distribution. Compounding pharmacists have long been regulated by State boards of pharmacy. However, as was made clear in the investigation that followed the meningitis outbreak, NECC, a mass compounding pharmacy, was operating in a regulatory gray area where neither the State nor Federal Government took full responsibility for ensuring their facility and compounding practices were safe and sterile.

The Drug Quality and Security Act aims to address this regulatory gray area by clarifying the responsibilities of the FDA with regard to the oversight of mass compounded pharmaceuticals. Specifically, it further defines the distinction between traditional compounding and compounding manufacturers that make large volumes of drugs without individual prescriptions.

Under this bill, mass compounding pharmacies can choose to register as outsourcing facilities that would be subject to new FDA regulatory oversight similar to that of other pharmaceutical manufactures. And, in an effort to provide patients with better information about compounded drugs, this legislation calls for detailed labeling of compounded drugs and directs the FDA to make available on their website a list of FDA-regulated facilities. Importantly, this legislation also will implement a new system for tracking drugs from the manufacturer to the pharmacy in an effort to ensure accountability at every step along the way. This new system will replace the current State tracing laws with a uniform standard and also will establish nationwide drug serial numbers to allow for efficient tracing.

While this legislation will not compensate those who have been harmed or bring back those who we have lost, I am hopeful it will help to ensure Americans are not faced with a similarly tragic, avoidable situation in the future. I urge my colleagues to join me in supporting final passage of this important legislation.

Mr. WARNER. Mr. President, hundreds of people in Virginia were sickened and 2 died from an outbreak of fungal meningitis last year that was traced to a single compounding pharmacy in Massachusetts. Hundreds more in several States became sick, and dozens perished. This public health crisis highlighted the critical need for better oversight of pharmacies that are producing compounded drugs.

The Compounding Quality Act and Drug Supply Chain Security Act, which the Senate will consider for final passage today, includes important provisions that ensures that patients and providers have access to safe compounded drugs.

This legislation also includes important provisions that deal with how to better monitor and track the drug distribution supply chain. It improves on patient safety by developing a workable pathway that will ultimately result in tracing for the entire country. Additionally, it strengthens licensure requirements for wholesale distributions and third-party logistics providers, and establishes nationwide drug serial numbers. Finally, this legislation works to address the growing problem of pharmaceutical theft, counterfeiting and diversion. The Compounding Quality Act and Drug Supply Chain Security Act is the most significant piece of legislation on drug distribution supply chain in 25 years.

I am appreciative of Senators HARKIN, ALEXANDER, and all members of the Health, Education, Labor and Pension committees for their tireless work on putting together these smart, bipartisan provisions which will help improve the lives of countless Virginians and Americans.

I offer my strong support to the Compounding Quality Act and Drug Supply Chain Security Act, and encourage its swift passage.

Mrs. FEINSTEIN. Mr. President, I am proud today to support the Drug Quality and Security Act because it marks an important step forward in protecting the safety and integrity of our Nation's drug supply. California has been a leader in addressing this issue and played a key role in creating a solution.

Patients deserve peace of mind when it comes to purchasing drugs. When a parent walks into a pharmacy to pick up a prescription for a sick child, she should be confident that the drugs she is picking up are safe and have not been tampered with. What is perhaps not known to many people, however, is that in today's drug supply system, there is no standard process for oversight to trace drugs through the supply chain system and make sure they were in the right hands and properly stored the whole time.

We hear occasionally about infected or counterfeit drugs. These are shocking stories. Last year, New England Compounding Center, or NECC, a compounding manufacturer from Framingham, MA, produced contaminated medicine that sickened over 750 people all across the country. I'm very sad to say that 64 people have died, needlessly, because of these contaminated drugs.

A report by the Senate Health, Education, Labor, and Pensions, HELP, Committee from earlier this year found that NECC was known to produce drugs that were mislabeled, did not contain the correct dosage of active ingredients and were made using equipment that was not properly sterilized.

You might think that a story like this is rare. What we have learned is that it is not. The report by the HELP Committee found that in the 8 months immediately after the outbreak caused by NECC-manufactured drugs, 48 other compounding companies were found to be producing drugs that were either unsafe or were made in unsafe environments.

The problems do not stop with the manufacturers. People often do not realize that drugs do not usually travel directly from a manufacturer to a pharmacist. In fact, they may make many stops along the way. Manufacturers, resellers, wholesalers, distributors—these are some of the entities that can receive, resell and ship drugs before they get to the pharmacist or patient. At any time in the delivery process, there is opportunity for counterfeit drugs to enter the supply chain or real drugs to be diverted for illegitimate uses.

In 2009, for example, 129,000 vials of insulin were stolen. These vials later reappeared and were then sold to pharmacies and hospitals. We do not know who was handling these vials after they were stolen, or if they were stored under appropriate conditions—a real threat to patients.

This bill does the following:

First, it establishes a comprehensive, electronic, interoperable framework for tracing the distribution history of every individual unit that passes through the drug supply chain. The effect of this part of the bill is to establish a ''chain of custody'' or ''pedigree'' for each prescription drug dispensed to patients. Should a drug be diverted, this ''chain of custody'' will provide important information to Federal regulators when counterfeit drugs are detected in the supply chain.

Second, it clearly distinguishes the scope of what constitutes the traditional pharmacy practice of drug compounding from those, like NECC, who seek to exploit a patchwork of current Federal laws and regulations to produce large quantities of unsafe drug products under the guise of compounding.

I am proud that California has led the Nation in taking real steps to address the issue of pharmaceutical supply chain safety.

In fact, California passed a law to require more oversight of the drug supply chain in 2004. Since then, the State Board of Pharmacy and State legislators have worked together with representatives from industry to perfect the law.

This action by California has been a key influence in drafting language on the Federal level. The Board of Pharmacy has provided many hours of technical assistance and has really been a team player. I commend the hard work of Chairman HARKIN, Ranking Member ALEXANDER, and his predecessor Senator ENZI, as well as Senators BENNET and BURR and their staff who have worked tirelessly to bring this legislation to the finish line. Many stakeholders were involved in drafting this bipartisan, bicameral solution that addresses the issue of substandard manufacturing practices and drug supply chain safety.

This is a remarkable step toward improved safety of medicine that Americans rely on every day.

Mr. BURR. Mr. President, we worked to ensure that the Drug Quality and

Security Act achieves a balanced approach to strengthen the safety, security and accountability of our Nation's pharmaceutical drug supply chain. This legislation establishes a uniform electronic unit-level system over the next decade that will increase security and ensure a safer pharmaceutical drug supply chain from manufacturers to dispensers. The charitable distribution of prescription drugs from the manufacturer to patients through patient assistance programs, PAPs, is a valuable and unique approach to providing American patients access to critical, lifesaving medicines. As this legislation is implemented, the varied and unique approaches of PAPs should be taken into consideration to ensure patients who access needed treatments through these effective programs are able to continue accessing the prescription drug medications provided through PAPs.

The PRESIDING OFFICER. Is there further debate? If not, the question is on passage of the bill.

The bill (H.R. 3204) was passed.

Mr. REID. I ask unanimous consent that the motion to reconsider be laid upon the table, with no intervening action or debate.

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

● Ms. WARREN. Mr. President, today the Senate passed the Drug Quality and Security Act. I am proud to have worked together with Chairman HARKIN, Ranking Member ALEXANDER, and all of the Senators on the HELP Committee from both sides of the aisle over several months to develop this law, which will create commonsense oversight of the pharmaceutical compounding industry and the pharmaceutical supply chain.

Some politicians use the word ''regulation'' as if it were a curse. Certainly no one wants bad regulations or over regulation, but the impact of failing to regulate when public safety is at risk can be dangerous and even deadly.

We have an example just how deadly right in front of us—and an example of what happens when Congress fails to regulate. It starts with compounding pharmacies.

Compounding pharmacies serve individual patients who need specialized drugs. Without these customized products, some of our most vulnerable patients would not be able to get the precisely formulated medications they need. But customers have no way to evaluate the safety or purity or cleanliness of the compounded medications they receive. That is what regulations are for.

For too long, bad actors in this industry have taken advantage of lax State enforcement and confusion about Federal regulations. The consequences of too little regulation and too little enforcement were brought into sharp focus last year when a compounding pharmacy in Massachusetts, the New England Compounding Center, was identified as the source of a widespread fungal meningitis outbreak that sickened 751 people and killed 64. I wish NECC were an isolated case, but companies like it have engaged in shoddy practices for years practices that have caused sickness and injuries and even death.

There have been many attempts to fix the law and require FDA oversight in this area. In 2007 Senator Kennedy worked with Senator ROBERTS to develop bipartisan legislation that would have addressed this issue. If that effort had succeeded, we might have been able to spare many people great suffering. Sixty-four people from just one incident would probably be alive today. But the industry lobbyists beat back their efforts. The result? People got sick and people died.

This issue is of particular importance to Massachusetts, and I am proud to have worked with my colleagues on the HELP Committee throughout my first year in the Senate to shape earlier versions of this legislation. Throughout the bipartisan development process and the public hearings and votes in the HELP Committee, I pushed for a bill that would subject compounding pharmacies to strong FDA oversight. Those efforts, and negotiations with the House of Representatives, have produced the Drug Quality and Security Act. The bill strengthens current law and establishes tough, new regulations that will keep us all safer.

The compounding provisions of this bill are not the final word in what is needed. I believe the FDA should have more authority to inspect the records of compounding pharmacies, and we have included in the bill a GAO study that will assess the impact and effectiveness of this new law and tell us if more work is needed. But this bill is big step forward in making people safer, so I support it strongly.

This legislation has another feature that will help make drugs safer. It creates an important new oversight system to ensure we have a secure supply chain for our pharmaceutical products. Today, we can track a gallon of milk in the grocery store all the way back to its producer, but we can't verify the origins of a prescription drug on the shelves of our pharmacies. Counterfeit or illegally imported drugs can be integrated into the supply chain, and currently there is no detection mechanism. This bill ensures that we can trace a particular drug from its manufacturer all the way to the pharmacy. It will allow consumers to buy prescription medications with greater confidence that the drugs are safe, legal, and free of counterfeit or substandard ingredients. It will allow patients to have greater confidence that the pills in the bottle from the pharmacy are exactly what their doctors have ordered—nothing more and nothing less.

I commend my colleagues for stepping up to the challenge and showing that it is possible for Congress to do what is right—pass commonsense reforms that protect patients and consumers from harm. This is one of the basic functions of government: making sure that markets work by ensuring that no one cuts corners that the customer can't see or that put someone's family at risk. When all the manufacturers have to follow the same standards of cleanliness, when all of them have to account for where they got the chemicals they used in their products, the playing field is level and the customer is free to make good, independent decisions. This is how government should work—through actions to improve public health and public safety through smart, fair, and reasonable regulations that will improve the lives of all Americans. I hope that the Drug Quality and Security Act will do just that. I am proud to support it.●

Mr. HARKIN. Mr. President, today, with final passage of the Drug Quality and Security Act, we have helped to ensure the safety of compounded drug products and secure the pharmaceutical supply chain. We have clarified the law governing traditional compounding and created a new source of high-quality compounded products for hospitals and other providers who need large volumes of compounded drugs. We have also set in motion a revolution in the distribution of pharmaceuticals—within a decade we will know exactly how our drug products travel through the often-complicated distribution system so that we can identify counterfeit and adulterated drugs before they get into American medicine cabinets.

By passing the Drug Quality and Security Act, we have taken an important step to improve American families' access to lifesaving drugs and medical devices.

The bipartisan process that produced this bill has been quite remarkable. I have worked closely with my colleagues on both sides of the aisle and both sides of the Capitol, as well as industry stakeholders, patient groups, and consumer groups, to solicit ideas and improvements on the critical provisions in this bill. We have a better product thanks to everyone's input.

I would like to extend a special thank you to my colleague, Ranking Member ALEXANDER. I have been working with Senator ALEXANDER on this since he became ranking member, and it has been a wonderful and cooperative partnership. I can honestly say that we would not have gotten this done without his excellent leadership and wise council. I thank the Senator.

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

On that note, I specifically thank the staff of Ranking Member ALEXANDER's office. I thank David Cleary, Mary-Sumpter Lapinski, and Grace Stuntz. I

also thank Hannah Katch from Senator FRANKEN's staff, Rohini Kosoglu from Senator BENNET's staff, Jennifer Boyer from Senator ROBERTS staff, and Anna Abram and Margaret Coulter from Senator BURR's staff. I know that they have developed close working relationships with my staff throughout this process, and I am sincerely grateful for your dedicated efforts.

I also thank my own staff on the HELP Committee, who have spent many a night and weekend with Senator ALEXANDER's staff, other member offices, and our colleagues in the House working to come to consensus on the critical policy issues in this legislation. I thank Pam Smith, Jenelle Krishnamoorthy, Elizabeth Jungman, Nathan Brown, Emily Schlichting, Allison Preiss, Kate Frischmann, Abraham White, Jim Whitmire, Chung Shek, Frank Zhang and Evan Griffis.

We would be remiss if we did not also thank the Congressional Budget Office for their knowledgeable and capable team that dedicated many hours to estimating the budgetary effects of this legislation. Finally, we owe an enormous debt of gratitude to the staff members in the Legislative Counsel's Office—specifically Kim Tamber, Stacy Kern-Sheerer, and Bill Baird. They, too, worked long hours, nights, and weekends to assist my staff in drafting this legislation and working out technical issues.

This bill's final passage is a victory for the millions of Americans who need safe medicines—a victory that would not have been possible without the dedicated work of our Senate family. I thank you all for your extraordinary public service.

WELCOMING BACK SENATOR INHOFE

Mr. REID. Mr. President, I see our friend here who has returned from his surgery and the death of his son, if he wishes to say something before I complete my remarks.

Mr. INHOFE. Mr. President, the majority leader should go ahead. My remarks will be longer.

Mr. REID. Mr. President, through the Chair to the senior Senator from Oklahoma, we are glad to have him back. We all empathize with something only a parent can understand. I am grateful to him for the example he sets for all of us.

SCHEDULE

Mr. President, we are going to be in a period of morning business until 5 o'clock today. Following morning business, the Senate will proceed to executive session to consider the nomination of Robert Wilkins to be U.S. Circuit judge for the DC Circuit. At 5:30, there will be up to two rollcall votes, including cloture on the Wilkins nomination. If cloture is not invoked, there will be a second cloture vote on the Defense authorization bill.

NOMINATIONS

Mr. REID. Mr. President, today the Senate will consider yet another qualified nominee to be a DC Circuit Court of Appeals judge, considered by many to be the second highest court in all the land.

It is troubling that Senate Republicans, for the fourth time this year, appear poised to reject an exceedingly capable nominee to this court for blatantly political reasons. Republicans have blocked three highly qualified female DC Circuit nominees in a row: Caitlin Halligan, Patricia Millett, and Nina Pillard. Today they are expected to block confirmation of District Judge Robert Wilkins, an extremely competent and experienced nominee and one who has bipartisan support. I say that because no one has questioned his qualifications or abilities; likewise, no Senator objected to the qualifications of Ms. Halligan, Ms. Millett or Ms. Pillard. Instead, Republicans have blocked these nominees solely to deny President Obama his constitutional right to appoint judges.

In years passed, my Republican colleagues agreed to block judicial nominees only in ''extraordinary circumstances.'' These are their words, not mine.

In 2005, the senior Senator from South Carolina LINDSEY GRAHAM defined extraordinary circumstances for the benefit of this body. Being a highly qualified trial lawyer, I think he is qualified to respond and set this definition that we all agreed with. Here is what he said:

> Ideological attacks are not an ''extraordinary circumstance.'' To me, it would have to be a character problem, an ethics problem, some allegation about the qualifications of a person, not an ideological bent.

No Senator—I repeat, no Senator—has questioned the character, ethics, or qualifications of these three women that have already been rejected for the DC Circuit. No one has questioned the character, ethics or qualifications of Judge Wilkins. So I am frustrated that Republicans would once again filibuster such a highly qualified nominee—a nominee so highly qualified, in fact, that he was confirmed 3 years ago by voice vote to become a district court judge.

Judge Wilkins is an Indiana native who graduated cum laude with a degree in chemical engineering, and then he got a law degree from Harvard Law School. He has worked as a staff attorney for the DC Public Defender Service. He was a partner specializing in white-collar defense, intellectual property, and complex civil litigation at the private law firm of Venable. That is an outstanding law firm with lawyers all over the country.

Judge Wilkins also helped shine a national spotlight on national profiling when he brought a landmark lawsuit against the Maryland State Police in 1992 after he and three family members were stopped and searched. Why? Because they were African Americans. It is landmark litigation.

This nominee has a bright legal mind and a remarkable dedication to the rule of law. Under normal circumstances, such as the circumstances of his 2010 confirmation, he would be quickly confirmed, but now he faces a Republican filibuster. Unfortunately, the type of Republican obstruction we face today has become quite commonplace. President Obama's circuit court nominees, including nominees for the vital DC Circuit, have waited seven times longer than those nominated by President Bush.

Republicans claim they are blocking nominees to this crucial court because the court is underworked and doesn't need to fill its complement of judges. Republicans also claim that filling these three vacancies would amount to court packing. That is absurd on its face. My Republican colleagues were happy to confirm four Bush nominees to this court. In fact, 15 of the last 19 to the DC Circuit were appointed by Republican presidents. Appointing judges to fill vacant judicial seats is not court packing, it is the President's right as well as his duty.

I do not ask Republican Senators to support President Obama's nominees or even that they vote for them, but it is right and proper that they should give President Obama's nominees the same fair consideration afforded the nominees that came before them.

RESERVATION OF LEADER TIME

Would the Chair announce the business of the day.

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 5 p.m. with Senators permitted to speak therein for up to 10 minutes each.

The Senator from Oklahoma.

ORDER OF PROCEDURE

Mr. INHOFE. Mr. President, I ask unanimous consent that my 10 minutes might be extended by about 10 more minutes.

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

THANKS TO THE MAJORITY LEADER

Mr. INHOFE. Mr. President, let me start off, before the leader leaves the floor—and I was hoping to do this before the Chaplain of the Senate, Dr. Barry Black, left. I had a horrible loss eight days ago, losing a son. It was so touching to me—and I thank Barry Black, who included a good bit of some things about my son and about me in his opening prayer. Also, the comments that were made, the very gentle comments, and very helpful, that were made by the majority leader. So, through the Chair, I wish to thank HARRY REID very much for the comments he made.