

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 free-standing 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