

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 run around 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

vote on a pure disclosure provision anytime this calendar year. In that spirit, I have an alternative.

I ask unanimous consent that all remaining time on the motion to proceed to H.R. 3204, the compounding bill, be yielded back; that the Senate proceed to H.R. 3204; that the bill be read a third time and passed right now and the motion to reconsider be considered made and laid upon the table; I further ask that the Senate then proceed to the consideration of S. 1197, the Defense authorization bill; that my amendment which is at the desk be called up and that a Democratic side-by-side amendment be in order to be called up; that notwithstanding rule XXII, those amendments remain in order and that both amendments be subject to a 60-vote affirmative threshold for adoption.

The PRESIDING OFFICER. Is there objection?

The majority leader is recognized.

Mr. REID. Reserving the right to object, the Senator from Louisiana has been holding up things in the Senate for weeks. What he has now requested of the Senate is that every other Senator take second fiddle to him. I object.

The PRESIDING OFFICER. Objection is heard.

Mr. VITTER. Madam President, again, I am open to any reasonable path forward that would produce this one, simple, straightforward vote on pure disclosure, information that I think should clearly be public information. So as a third alternative, I ask unanimous consent that the Homeland Security and Governmental Affairs Committee be discharged from further consideration of S. 1629 and the Senate proceed to its immediate consideration; I further ask consent that there be 60 minutes of debate divided in the usual form; that upon the use or yielding back of time, the bill be read a third time and the Senate proceed to a vote on passage of the bill; and that a 60-affirmative vote threshold be required for passage.

The PRESIDING OFFICER. Is there objection?

Mr. REID. I object.

The PRESIDING OFFICER. Objection is heard.

Mr. VITTER. Madam President, reclaiming the floor and wrapping up, I continue to find that very unfortunate and, frankly, really unreasonable. We, each of us as Members of the Senate, made an important election about how to handle this ObamaCare exemption issue. Some folks have classified a good part of their staff as not official staff—magic wand, somehow. They work here, they get a paycheck, they are on government property, they do official business, but they are not official staff. This is a charade, and at a minimum I think the public should know how each office and each Member is handling that situation. That is the only thing my disclosure proposals, which I have been asking for a vote on, would require. That is the only thing I am ask-

ing for a vote on this calendar year. I think offering these three unanimous consent routes to that is very reasonable and would also expedite consideration of many other matters, including the bill on the Senate floor right now. It is unfortunate that that reasonable route forward was not chosen and blocked in multiple ways, but I will certainly continue pursuing this important objective.

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

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

The legislative clerk proceeded to call the roll.

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

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

The Senator from Connecticut is recognized.

Mr. BLUMENTHAL. I thank the Chair.

(The remarks of Senator BLUMENTHAL pertaining to the introduction of S. 1714 are printed in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

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

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

#### HEALTH CARE REFORM

Mr. NELSON. Madam President, I think the President did the right thing today. The whole idea of health insurance reform was to get people into health insurance that do not have health insurance. The idea was not for those who had insurance, unless they wanted to improve that insurance or they did not have the insurance they needed.

The idea, certainly, was not that if they had insurance they were satisfied with, that they were not going to be able to keep that. That is what the President had said. That is what the President reaffirmed today. I think the President did the right thing.

Insurance is a very complicated subject. In all that we are hearing about in the setting up of those different health insurance exchanges in each of the States, you are creating a new pool of people, both young and old, both sick and healthy, and you spread that health risk over a larger number of people. If it is a typical population of young and old, not just all old, and not just all sick, the more you can spread that health risk over an average population, the more you can bring down the cost of that health insurance. That is basically the principle of health insurance.

So, unless we can get the young and healthy people who need health insurance—by the way, they may think they are invincible, but they may also have an accident. Instead of them ending up in the emergency room at the time that they have the accident, or when they really get sick and they do not have health insurance, and they do not pay—guess who pays. All the rest of us pay in our health insurance premiums.

So the whole idea is to reform this by getting as many of the 45 million people that do not have health insurance into the health insurance system. That is what these 50 State insurance exchanges are designed to be. So the issue today did not directly affect that, but for the fact that if those who have health insurance, and they say that they are happy with it, but they are really not because it is a subpar health insurance policy—I call them dog policies. If they realize they have a dog policy, then they see what they can really get in the exchange in a comprehensive policy that will cover maternity and all of the other things, on top of the guarantees that an insurance company cannot cancel them, on top of the guarantees that if they had a pre-existing condition, their insurance is not only not going to be canceled but that they will, in fact, be able to get insurance.

What I have described—guess what it is. It is the Affordable Care Act. It is the ability to have health insurance when a big part of our population—45 million people in this country—has not been able to have it.

The narrow little issue addressed today by the President was that some people have health insurance that they like. They ought to be able to keep it. Some people who have health insurance don't realize how much better it could be with much more comprehensive coverage. Once they see the difference, those folks who the President said today can keep those subpar policies are going to want to go into the health insurance exchange. That is what this is all about.

Unfortunately, this has become all balled up in politics. It is a complicated subject. Most of us don't even want to think about it. We want to leave it to our insurance agent, someone who is skilled.

Now, as we are making our own individual choices, which we are able to do by going on a Web site and designing a policy for ourselves, we are empowering ourselves to have the health care coverage we want. In the meantime, we have a lot of turmoil, a lot of strife, and a lot of politics.

Give it some time. And this is a former insurance commissioner speaking, and I know most of the tricks the insurance companies will pull. But give it some time. Down the road, with the insurance companies I have seen, as I have talked with the CEOs, they want to cooperate because they realize this is good for their business as well because now they will be able to offer so