

We demand that this problem be dealt with on a timely basis, and we are going to keep the feet to the fire of the administration and our friends in the House to make sure they follow up on their commitments to deal with the victims of Hurricanes Harvey, Irma, and Maria.

I yield the floor.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Madam President, I ask unanimous consent that the Senator from Florida be granted the floor as soon as I finish.

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

ENSURING PATIENT ACCESS AND EFFECTIVE
DRUG ENFORCEMENT ACT

Mr. HATCH. Madam President, over the weekend, the Washington Post ran an article about a piece of legislation I helped negotiate last Congress. It was entitled the "Ensuring Patient Access and Effective Drug Enforcement Act" and was intended to encourage greater collaboration between DEA and the regulated community in the fight against opioid abuse. The Post article was sharply critical of this legislation, suggesting that it effectively gutted DEA's ability to do its job. It also suggested the pharmaceutical industry put one over on Congress. I rise to set the record straight on these allegations and to provide a fuller account of how this legislation passed the Senate and became law.

First, some background. The Controlled Substances Act requires drug distributors to obtain a "registration" from DEA in order to distribute controlled substances, including prescription drugs. The act further authorizes DEA to suspend a distributor's registration in certain circumstances, such as where a distributor has been convicted of a crime involving controlled substances or had a State license suspended. Before suspending a registration, DEA must issue a show cause order directing the distributor to explain why its registration should not be suspended. A court then decides whether DEA has met its burden to suspend the registration.

The Controlled Substances Act empowers DEA to bypass this standard suspension process in cases where DEA determines there is "an imminent danger to the public health or safety." In such cases, DEA can issue an immediate suspension order that immediately and without court process terminates the distributor's ability to distribute prescription drugs. Prior to last Congress, the Controlled Substances Act did not define what constitutes an imminent danger to the public health or safety. This left DEA's ability to immediately suspend a party's ability to distribute prescription drugs essentially unfettered. Such unfettered discretion concerned the patient advocacy and drug manufacturing community because an immediate suspension order cuts off all drugs from a distributor, including those intended for legitimate

users. A balance is needed to ensure that individuals who need prescription drugs for treatment receive them but that such drugs are not diverted for improper purposes.

So the bill I helped negotiate last Congress, for the first time, defined what constitutes an imminent danger to the public health or safety. In doing so, it created a standard for when DEA may suspend a party's registration to distribute prescription drugs without any prior court process, and that standard is that there must be a "substantial likelihood of an immediate threat" that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension.

In both committee and floor statements, I made clear that this standard is intended to cover situations where evidence of diversion indicates there is a substantial likelihood that abuse of a controlled substance or of any controlled substances will occur.

The Washington Post article glosses over much of this background. It does not explain that the immediate suspension order is intended to be an extraordinary measure. It does not explain that prior to the bill, DEA had basically carte blanche authority to impose this measure. It does not explain the DEA has other enforcement tools available, including show cause orders which are supposed to be the agency's standard operating procedure. Equally problematic, the article barely even mentions the patient advocacy concerns that motivated the bill to begin with.

I want to quote from a letter that a coalition of patient and health advocacy groups sent to Congress in support of the legislation:

Federal agencies, law enforcement, pharmaceutical industry participants and prescribers each play a role in working diligently to prevent drug abuse and diversion. However, it is also imperative that legitimate patients are able to obtain their prescriptions without disruption. Your legislation addresses both goals by fostering greater collaboration, communication and transparency between industry stakeholders and regulators, leading to more effective efforts to combat abuse while protecting patients.

The letter was signed by, among others, the American Academy of Pain Management, the Fibromyalgia & Chronic Pain Support Network, and the Drug Free America Foundation.

Madam President, I ask unanimous consent that the letter be printed in the RECORD.

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

MARCH 4, 2015.

HON. ORRIN HATCH,
U.S. Senate,
Washington, DC.

HON. SHELDON WHITEHOUSE,
U.S. Senate,
Washington, DC.

DEAR SENATORS HATCH AND WHITEHOUSE: On behalf of the patient and health professional groups listed below we would like to express our support for the Ensuring Patient

Access and Effective Drug Enforcement Act of 2015 (S. 483). We appreciate your leadership and commitment to combating the inappropriate use of prescription medicines. Your legislation will help improve the balance between effective enforcement against prescription drug diversion and abuse, while ensuring patients who are appropriately prescribed medications continue to have access to their treatments.

As patient advocacy and health professional organizations, we are committed to combating illegal use of prescription drugs. Millions of Americans depend on prescription drugs to treat and cure illness, alleviate pain, and improve quality of life, yet prescription drug abuse remains a persistent problem that requires collaboration from all those with a stake in improving patient care and protecting against abuse. In considering the burden on patients, it is important to remember that the vast majority of patients who use prescription drugs do so legitimately to address a variety of health issues. Efforts to prevent drug abuse should also consider legitimate users so that actions do not impede patient access or lessen the effectiveness of patient care.

Federal agencies, law enforcement, pharmaceutical industry participants and prescribers each play a role in working diligently to prevent drug abuse and diversion. However, it is also imperative that legitimate patients are able to obtain their prescriptions without disruption. Your legislation addresses both goals by fostering greater collaboration, communication and transparency between industry stakeholders and regulators, leading to more effective efforts to combat abuse while protecting patients. We commend you for including a report to congress, which will illuminate the issue and ultimately benefit patient care. Including patient advocacy groups in the process will ensure those involved in patient care will be able to identify challenges and will emphasize appropriate and workable policy approaches to preventing diversion and abuse of controlled substances.

We commend you for your leadership on this important issue.

Sincerely,

Alliance for Patient Access; American Academy of Pain Management; American Pharmacists Association; American Society of Consultant Pharmacists; American Society for Pain Management Nursing; Center for Lawful Access and Abuse Deterrence; Drug Free America Foundation, Inc.; Fibro Warriors Living Life; Fibro Friends of Tennessee; Fibromyalgia & Chronic Pain Support Network; Fibromyalgia-ME/CFS Support Center, Inc; Florida Fibromyalgia & Chronic Pain Network.

Hematology/Oncology Pharmacy Association; Interstitial Cystitis Association; Kentuckiana Fibromyalgia Support Group; Lake Oswego Health Center; National Association of Chain Drug Stores; National Community Pharmacists Association; National Fibromyalgia & Chronic Pain Association; The Pain Community; Pain Connection-Chronic Pain Outreach Center, Inc.; Project Lazarus; Richmond Fibromyalgia & Chronic Pain Association; Save Our Society From Drugs; U.S. Pain Foundation; Virginia Fibromyalgia & Chronic Pain Support Group.

Mr. HATCH. Madam President, the Washington Post article discusses virtually none of this. Rather, it baldly asserts that Congress cut out DEA's legs from underneath it through a sinister conspiracy of deep-pocketed drug companies and their cunning allies in Congress. Nothing could be further from the truth.

To begin with, I have spent 40 years of my life in the Senate fighting the scourge of drug abuse. I stood side by side with Ronald Reagan in the War on Drugs. In 2000, I coauthored the Drug Addiction Treatment Act, or DATA 2000, one of the first efforts in Congress to address the opioid epidemic. Last year, I led conference negotiations on the Comprehensive Addiction Recovery Act, a landmark piece of legislation that is making a real difference in the fight against opioid and heroin abuse. Currently, I am working on legislation to address opioid addiction in the veteran community. I am no patsy when it comes to drug abuse—prescription or otherwise—and neither are my colleagues.

Indeed, forget me for a moment. Let's take Senator WHITEHOUSE, who helped me negotiate the bill with DEA and DOJ. Are we to believe that Senator WHITEHOUSE, a former Rhode Island attorney general and a former U.S. attorney, a crusader against corporate interests, is somehow in the pocket of the drug companies? Of course not. The charge is laughable on its face.

How about the fact that this bill passed both Houses of Congress by unanimous consent? Did the entire U.S. Congress decide to shield its eyes to the true sinister intent of this legislation? Did the Senate Judiciary Committee, which approved the bill by voice vote, decide to look the other way? This is a committee that includes former prosecutors, state attorneys general, and U.S. attorneys who, at the time, included both the current Attorney General of the United States and the current Senate minority leader.

Are we seriously to believe that Jeff Sessions, the toughest foe of illegal drugs I have ever known in my entire life, sat on his hands while Congress eviscerated the DEA's enforcement authority? No, of course not.

To merely state these allegations is to make clear how utterly ridiculous they really are. Not one Senator or Member of the House opposed this bill. Do you know why? Because DEA, the very agency the bill impacts, the very agency that supposedly can no longer do its job because of this legislation, agreed to let it go forward.

Let me be clear. The DEA could have stopped this bill. They could have stopped it at any time. In fact, they did stop a previous version in 2014 that had different language. I spent months negotiating with DEA and with DOJ until they were at a point they were comfortable allowing the bill to proceed. If they had asked me to hold the bill or to continue negotiations, I would have done so.

I brought the bill to markup only after DEA and DOJ agreed with me on a path forward. Anyone who claims that I or anyone else steamrolled DEA and DOJ on this bill is either ignorant or woefully misinformed.

That brings me to another point that was largely lost in all the insinuations

in the Washington Post article. The language that purportedly eviscerated DEA's enforcement power—that is, the requirement that the DEA show a substantial likelihood of immediate threat before issuing an immediate suspension order—was written by DEA and DOJ lawyers and provided to Hill staff as a proposed compromise.

So let's get this straight. Congress took language that DEA and DOJ wrote, inserted it into the bill, and now Congress is the bad guy? I should note that other aspects of DEA and DOJ's proposed language changed, but that key phrase “substantial likelihood of an immediate threat”—the phrase that critics now point to as gutting DEA's enforcement authority—came from DEA and DOJ. And lest we forget, President Obama signed the bill into law on the advice of his own DEA Administrator.

I think we need to be candid about what is going on here. Opponents of the current administration are trying to derail the President's nominee to be head of the Office of National Drug Control Policy, Representative TOM MARINO, by mischaracterizing and trying to rewrite the history of a bill that he championed. They are being aided in their efforts by a group of former DEA employees who took an extremely hard line against drug companies when they were at the Agency and who are upset that the DEA chose to pursue a more collaborative approach after they left. I don't fault these individuals for their passion, but I do reject the notion that there was some sort of sinister conspiracy at play. And I find it unconscionable that critics of the bill and of Representative MARINO would flat-out ignore the very real patient concerns that motivated this bill and motivated my personal involvement with it. You think this bill was a sop to the drug industry? Tell that to the Fibromyalgia and Chronic Pain Network. Tell that to the American Academy of Pain Management. Tell that to the Drug Free America Foundation.

If we are going to make this bill a political football and try to use it to sink Representative MARINO's nomination, let's tell the full story. Let's be fair. Let's at least be honest. Let's not gin up a one-sided narrative based entirely on the statements of former Agency officials who disagreed with the change of leadership.

No matter how you try to spin it, this is not the latest episode of “House of Cards.” Rather, let's be clear that Members of this body negotiated this bill in good faith with the DEA and the Department of Justice. Let's be clear—the DEA and DOJ themselves generated the language that critics now claim is so problematic. Let's remember that this bill passed by unanimous consent and that every single Member of this body and the House of Representatives agreed to it. Let's remember, too, that the DEA and DOJ could have stopped this bill at any time if they had wanted to but instead chose

to allow it to proceed. After all, they stopped an earlier version in 2014 that had different language. They could have stopped it again. And even after the bill passed Congress, they could have advised President Obama not to sign on. Don't forget that the bill bears his signature. Let's not pretend that DEA, both Houses of Congress, and the Obama White House all somehow wilted under Representative MARINO's nefarious influences.

Provocative headlines and clever framing may drive page hits, but this body's decisions should be based on the full story. It should be based on all the facts. A single news article that tells only one side of the story should not derail a nominee who has a long history of fighting illegal drug use and of helping individuals with chronic conditions obtain treatment. Let's not ignore the full story here in the rush toward easy politics.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Florida.

PUERTO RICO RECOVERY EFFORT

Mr. NELSON. Madam President, I want to talk about a matter of life and death. It is happening, as we speak, in Puerto Rico. I went there yesterday. I didn't want to have a flyover of the island, but at the invitation of Governor Rosselló, I got into a helicopter so that I could get up into the mountains and into the areas that have been closed because people hadn't been able to get there on the roads. That is what I wanted to see.

We have had colleagues come back and, because of a flyover in a helicopter, say that they say don't see a lot of damage. Of course not, because they are flying over parts of towns in which most of the structures are concrete blocks. But if you get down there on the ground and go into the structure, then you will see a different story.

First of all, you will smell a different story because the water has accumulated, and now it is turning to mold and mildew—inhabitable conditions. But when you get up into the mountains, you see the places that were cut off. Not until a week ago did they have the roads cleared so that people could get up there. And as we speak, as of yesterday, they are still reconstructing the roads so that people can get on these narrow, winding, little dirt roads that go up through the mountains. So for 2 and a half weeks, communities have been completely cut off, like the one that I saw yesterday, Utuado, which is way up in the mountains.

I want to show you some pictures, but I want you to realize that today is Monday. Next Wednesday will be 4 weeks since the hurricane hit. Can you imagine going into a State with 3.5 million people and 85 percent of the people do not have electricity? And by the way, these are our fellow American citizens; they are just in a territory. Can you imagine going into a State where a month after the hurricane, 50