

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

November 17, 2017

Mr. Neil Doherty  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, VA 22152

Dear Mr. Doherty:

Thank you for appearing before the Subcommittee on Health on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [zack.dareshori@mail.house.gov](mailto:zack.dareshori@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,



Greg Walden  
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

## **Attachment — Additional Questions for the Record**

### **The Honorable Adam Kinzinger**

1. With respect to Prescription Drug Monitoring Programs, what issues should we be aware of regarding PDMP access by law enforcement personnel?

### **The Honorable Bill Flores**

A serious problem in the opioid epidemic is synthetic drugs. The DEA released it's 2017 National Drug Threat Assessment Monday. One of the findings was, and I quote, "Overdose deaths, already at high levels, continue to rise. The increased mixing of heroin with analogues of the highly-potent synthetic opioid fentanyl and other synthetic opioids has exacerbated this situation."

Our colleague, Mr. Katko of New York, testified before this committee earlier this month about a bill he has that help protect our communities from synthetics and analogues. Now, there is still work to be done on his proposal – which has passed the Judiciary Committee, I should note.

1. Mr. Doherty, has the DEA focused any attention on providing technical comments on the Katko bill, titled the Stop the Importation and Trafficking of Synthetic Analogues Act – or SITSA for short?
2. Are there tools that the DEA has requested from Congress to help combat synthetics?

I understand law enforcement desires additional scheduling authorities, while researchers have concerns with how this may unintentionally impact the scientific community's ability to study compounds for groundbreaking medications.

3. Is there a way we can strike a balance of scheduling these rapidly-multiplying analogues in a timelier manner while also protecting the important work being done by scientific researchers?

### **The Honorable Chris Collins**

1. As PDMPs have evolved in recent years, incorporating PDMP data into a prescriber or pharmacist's clinical workflow seems to be the key to ensuring that the data is used effectively while also increasing efficiency and saving time for providers. What are the barriers currently preventing more states from incorporating PDMP data into clinical workflow?
2. We know that the "moment of clarity" when a patient realizes they need to go into treatment can be short-lived, and having resources in place to immediately connect patients to treatment is critical to the chances of recovery. When a PDMP does indicate a patient has been "doctor shopping" and potentially has a substance use disorder, what policies are in place to direct them to treatment if they wish to go? If none exist, how could we help encourage them to access treatment at that time?

3. Some states such as Massachusetts have started using data as a weapon in the fight against opioids. They are combining data from prescription records, death records, medical examiners... even prisons. For example, they found that a person who is released from jail in Massachusetts has a 56 times greater chance of dying from an overdose than the average person. They are using that information to make better policy decisions, as well as to identify specific individuals who are in need of services. States are supposed to be the laboratories of democracy. What has the CDC learned from states in their use of data analytics? Is there a plan to use data to fight the opioid crisis?"

### **The Honorable Buddy Carter**

Under CARA, prescribers can write up to three 30-day prescriptions without any refills. You can look into how pharmacists could play a larger role and ways to address prescriber behavior. Additionally, you can ask questions about limiting prescriptions for acute pain needs, such as dental work or minor surgeries with the possibility for a limited refill.

1. Mr. Doherty, under CARA, prescribers were allowed to write up to three 30-day prescriptions for a patient but no refills. While CARA took some great steps forward, I think it's worth taking another look at its progress and ways to improve the program. One area I'd like to raise would be limiting prescriptions for acute pain procedures and needs. As a pharmacist, I've seen people come in with 30 day prescriptions for minor dental procedures. Have you looked in to that possibility and what would be the DEA's outlook on such a move?
2. Would the DEA be willing to look at reducing the number of prescriptions for opioids and allowing for one, limited refill of the prescription? I believe it could help to reduce the amount in circulation as well as address some of these accessibility needs we've brought up through take-back programs.

October 28th is the 14th National Drug Take-Back Day. During your tenure in the state legislature, you helped create the program that turned in 9,630 pounds of unwanted medications during the April drive in Georgia.

3. How would the DEA approach a national mail-in take-back program across the country? What sort of security concerns and guidelines would need to be addressed to make it effective?
4. On top of those concerns, would a nominal fee paid by the patient be able to cover the costs of such a program?

### **The Honorable Pete Olson**

1. Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)? Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?

### **The Honorable Susan Brooks**

1. I have heard you say that preventing drug use before it begins is the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

### **The Honorable Markwayne Mullin**

1. I introduced H.R.3528, the Every Prescription Conveyed Securely Act, with Katherine Clark (D-MA), to require e-prescribing of controlled substances (EPCS) under Medicare Part D. As you may know, the President's Commission on Opioids recommended that the use of e-prescribing of opioids should be encouraged. Since the DEA relaxed its prohibition of e-prescribing for controlled substances in 2010, e-prescribing has expanded for Medicare beneficiaries and six states have mandated its use specifically for controlled substances. Does the DEA have a position on this legislation? Please explain the DEA's position and any concerns it may have with EPCS.

### **The Honorable Ben Ray Lujan**

In the U.S., we still have too few locations to drop off unwanted and expired medication – some of which can be dangerously addictive or fatally lethal in even small doses – like fentanyl. According to the 2017 National Drug Threat Assessment, in 2015, over half of people who misused prescription pain relievers, like opioids, got them from a friend or relative while roughly 34% got them from one doctor.

1. Administrator Doherty, what is the DEA doing to combat the misuse of pain relievers that are given by, bought from, or stolen from family friends?
2. What is the DEA doing to make it harder to misuse of prescription drugs attained directly from doctors?
3. I'm aware of private sector organizations such as CVS and Walgreen's that are working diligently to provide more drop-off locations in their stores and local communities. What would it take to have drop-off locations for controlled substances in every community in the United States? What is the public sector doing to aid the private sector in these efforts?

Addressing the opioid epidemic is going to require a multi-faceted approach. We cannot cure opioid addiction through law enforcement or treatment alone. We must also work to address the problem at the start. This means we should also be adopting policies and practices to reduce the amount of opioids that are available in circulation, and educating health care providers on opioids, pain management, and non-opioid pain alternatives.

Approximately 80 percent of the legal global opioid supply is consumed in the United States. Based on 2015 sales, the top five opioid products were made by Purdue Pharma, Johnson & Johnson, Insys Therapeutics, Mylan and Depomed, according to sales. A 2016 survey by the National Safety Council revealed that about 99 percent of physicians exceed the recommended

three-day dosage limit, with a quarter of them writing prescriptions for a full month and thus overprescribing these types of medications.

Members of this Committee have called for additional prescriber education and training to this effect and I want to learn more about what role FDA and DEA can play in this process.

4. Mr. Doherty, as you know, a number of stakeholders have called for mandatory prescriber training on opioids to be a requirement of DEA registration. What role do you see prescriber education playing in addressing the opioid crisis, and what role has, or can, DEA play in ensuring health care practitioners are properly informed about the benefits and risks of opioids and the role appropriate prescribing can play in addressing the opioid epidemic?

In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. *The New York Times* reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The *Times* and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long-term investments in prevention, treatment, recovery, and monitoring.

The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.

5. Deputy Assistant Administrator Doherty, do you have all of the tools you need to stop the opioid epidemic?
6. How will the DEA allocate its 3.7 percent boost in funding in the President's budget proposal to fight the opioid epidemic?

Opioid addiction is not a new problem. Misuse of and addiction to pharmaceuticals has existed for centuries, ever since morphine was heralded in the 1850s as a solution to our opium addiction problem— until it, in turn, morphine became a larger problem, as did heroin, and then methadone. Today, we understand the importance of pain relieving agents, but as my constituents continue to perish at alarming rates due to these drugs, we need to be working together to address the crisis. The public and private sectors can and should work together to swiftly address the opioid epidemic. The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science that is necessary to helping the FDA accomplish its mission. The Foundation was created by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to address regulatory science challenges of the 21st century. The central focus of the Foundation is to assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to

evaluate products more effectively, predictably, and efficiently, and thereby enhance the agency's ability to protect and promote the health of the American public.

7. Understanding what we know now about this issue, what further information or support do you need from pharmaceutical manufacturers to more aggressively combat this crisis?

Stopping the flow of opioids into the U.S. will require a decrease in demand. People who are at highest risk of overdose use prescription opioids nonmedically for 200 or more days a year. These highest-risk users are approximately four times more likely than the average user to buy the drugs from a dealer or other stranger. From a supply perspective, the ways for illicit opioids and heroin to enter the U.S. are ever-changing and creative, driven by the rise of e-commerce and outpacing our current abilities to monitor what enters across our borders.

Opioids and heroin illicitly enter the U.S. through the U.S. Postal Service and traditional drug smuggling channels. Illicit synthetics are largely manufactured in China and smuggled into the United States via traditional channels and through the U.S. Postal Service. Fentanyl is a synthetic opioid that Americans can order online through illicit drug marketplaces. Online ordering of counterfeit prescription drugs is possible via e-commerce websites and through dark web markets on the Tor network. Because fentanyl is potent, it is easy to hide in letters and small packages that are sent by post. Overseas labs in China are mass-producing fentanyl and fentanyl-related compounds and marketing them to drug trafficking groups in Mexico, Canada, and the United States. Mexico often serves as a transshipment point for fentanyls shipped from China. In 2017, fentanyl is being trafficked through Mexico into the U.S. alongside heroin and cocaine, though it is largely produced in Asia. Customs and Border Protection officers search packages entering the U.S. through the John F. Kennedy International Airport mail center for fentanyl and other synthetic opioids using an old X-ray machine, a borrowed handheld laser that can peek into packages, and a dog trained to detect fentanyl. In fiscal year 2016, the CBP team at JFK airport seized seven fentanyl packages. This year, they have seized 64 as of September 17, 2017.

Not all illicit synthetics enter the U.S. from other countries. A DEA intelligence brief published in July 2016 noted that people within the U.S. are also making and selling fentanyl pills. In January 2016, DEA agents seized 6,000 fentanyl pills made to look like oxycodone from a dealer who was manufacturing them in his New York residence. A similar pill pressing operation was discovered in Los Angeles in March 2016.

Heroin consumed in the U.S. comes mainly from Afghanistan and Mexico, according to the UN's International Narcotics Control Board (INCB). As much as 94 percent of the heroin entering America comes from Mexico, estimated William R. Brownfield, assistant secretary of the Bureau of International Narcotics and Law Enforcement Affairs.

8. Why can't the U.S. stop and dramatically reduce trafficking of opioids and heroin into the U.S.?
9. If Congress was to allow for international drug importation writ large, does that have the potential to impact either positively or negatively the ability for nefarious actors to increase illegal opioid trafficking in the US?