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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

May 8, 2017

The Honorable Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Acting Administrator Rosenberg:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the opioid epidemic in the U.S. that is taking 78 lives per day, according to a recent report of the U.S. Surgeon General. As part of this investigation, the Committee is seeking information to understand distribution practices for various opioids in West Virginia in light of reports that distributors may have supplied the state with questionably high quantities of drugs. The possible oversupply described in this reporting suggests that such practices may have exacerbated the opioid addiction problem currently facing the state. For example, a December 2016 investigation by the *Charleston Gazette-Mail* reported:

> In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two painkillers… The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia.[1]

In 2015, West Virginia had the highest opioid overdose death rate in the nation.[2] The opioid crisis in West Virginia has led to numerous deaths and social challenges for its residents. The state and federal government have also incurred costs of important social and addiction treatment services.

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[1] *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, CHARLESTON GAZETTE-MAIL (Dec. 17, 2016).

[2] Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015* (Dec. 30, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

The *Gazette-Mail* cited additional examples regarding distribution practices in West Virginia that, if true, cause great concern. For example, in the small community of Kermit, West Virginia, with a population of 392, a single pharmacy received nearly nine million hydrocodone pills over two years. The *Gazette-Mail*'s reporting also cited another example of what they called a "mom-and-pop pharmacy" in the small town of Oceana, West Virginia that received an unusually high level of prescription medicines relative to a nearby pharmacy. In that case, the *Gazette-Mail* reported this single pharmacy "received 600 times as many oxycodone pills" as a Rite Aid drugstore that was "just eight blocks away."[3]

The *Washington Post* has also reported on the heavy distribution of opioids in the State of West Virginia. For example, the *Post* indicated some officials within the state believe the practices of certain distributors may have violated state laws.[4] Additionally, the *Post* also quoted W. Kent Carper, the president of the Kanawha County Commission, who stated, "[t]he impact is beyond words." Citing Carper, the *Post* further reported, "distributors sent 66 million doses of oxycodone and hydrocodone into Kanawha County, population 190,000."[5] CNN similarly reported on drug distribution practices in West Virginia, noting the state "has become ground zero for the opioid epidemic here in the United States."[6]

If these reports are true, it would appear that the State of West Virginia may have received extraordinary amounts of opioids from distributors beyond what that population could safely use. As one of the agencies that oversees distributors, the Drug Enforcement Administration (DEA) plays a critical role in tracking and monitoring the supply chain of our nation's prescription drugs.

According to the *Washington Post*, while DEA pursued cases against some of the largest opioid distributors in the country, the agency's "initiative was sharply curtailed in the face of pressure from the pharmaceutical industry beginning in 2013."[7] This claim is illustrated by reports that, in 2011, DEA's civil case filings against distributors, manufacturers, pharmacies, and doctors had reached 131. Yet, in 2014, that number had fallen to only 40.[8] The *Washington Post* also noted, "The number of immediate suspension orders, the DEA's strongest weapon of enforcement, dropped from 65 to nine during the same period."[9]

The *Gazette-Mail* also reported that DEA "agency lawyers had put the brakes on enforcement actions against drug distributors, starting in 2013," and that there was a "sharp drop in enforcement actions."[10] Furthermore, a current DEA official cited in the article stated that a Department of Justice lawyer directed DEA agents to halt an ongoing investigation against

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[3] CHARLESTON GAZETTE-MAIL, *supra* note 1.
[4] *Opioid Distributors Sued by West Virginia Counties Hit by Drug Crisis*, WASH. POST (Mar. 9, 2017).
[5] *Id.*
[6] *The Lead with Jake Tapper*, CNN (Dec. 20, 2016), *available at* http://transcripts.cnn.com/TRANSCRIPTS/1612/20/cg.02.html.
[7] *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse,* WASH. POST (Dec. 22, 2016).
[8] *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control,* WASH. POST (Oct. 22, 2016).
[9] *Id.*
[10] *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017).

Cardinal Health, the nation's second-largest drug wholesaler, instead directing them to "process" the case.[11] Considering that this reported decline in enforcement action occurred in the midst of the opioid epidemic—with the number of opioid prescriptions in the U.S. increasing from 112 million in 1992 to 249 million in 2015—it is imperative that the Committee gather the facts about DEA's actions.

All players in the health care and enforcement community have a responsibility to help prevent opioid abuse, addiction, and diversion, and DEA has been at the forefront of these efforts. With the collective data that DEA has access to, the agency can help identify and respond to suspicious order trends for addictive opioids that appear problematic or excessive. Federal regulation requires distributors to report suspicious orders of narcotics to DEA, which include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[12] Therefore, to understand the drug industry's distribution practices and to further evaluate the troubling concerns raised by the above-cited reports, we request that you provide the Committee with the following information, as well as a briefing on these matters, by June 8, 2017:

1. Please provide the number of pills of hydrocodone and oxycodone distributed in West Virginia each year from 2005 through 2016.

2. Does DEA have monitoring systems in place to detect unusual or suspicious patterns or quantities of opioid orders, and does DEA believe they are effective? If so, please describe those monitoring systems and provide the date(s) for when these systems went into effect.

3. What policies and procedures does DEA have in place to take action in response to such patterns, including notification of the manufacturers, distributors, pharmacies, physicians, and other authorities?

4. Does DEA receive investigative leads from manufacturers, wholesale distributors, pharmacies, or state pharmacy boards? If so, what policies and procedures are in place to process and investigate those leads? Please provide any examples of accomplishment from these leads.

5. Federal regulation requires distributors to report suspicious orders of narcotics to DEA. Please provide the number of suspicious orders reported by distributors to DEA each year from 2005 through 2016, the characteristics of the suspicious orders reported, and any trends or patterns identified in these reports. Further, what steps or actions does DEA take, as a matter of course, following the submission of a suspicious order report from a distributor?

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[11] *Id.*

[12] 21 C.F.R. § 1301.74(b).

6. Did DEA identify any patterns of opioid distribution in West Virginia that caused the agency to take enforcement action? If so, when did DEA become aware of those patterns?

7. Please describe what actions were taken after identifying such patterns, including a timeline for these actions.

8. If the reporting in the *Gazette-Mail* on opioid distribution to West Virginia is accurate, is DEA taking any specific action to examine sales and monitoring processes in West Virginia and nationwide? If so, what actions has the agency taken to date and what additional actions are planned?

9. What data could DEA share with wholesale distributors, as appropriate given law enforcement and commercial confidential information sensitivities, that would help improve detection of suspicious orders of opioids?

10. According to a December 2016 article in the *Charleston Gazette-Mail*, opioid wholesale distributors shipped massive quantities of opioid medicines that appeared to be far in excess of what certain communities in West Virginia should have received based on sound medical needs. The article said:

> In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two pain killers [...] The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia.

a. Does DEA agree with the accuracy of the above statements? If not, please explain and provide the accurate information.

b. If DEA agrees that the statements are accurate, what action, if any, has DEA taken on this issue with respect to supply chains into West Virginia? Please include information on any joint effort with other federal, state, local law enforcement or public health agencies, or state pharmacy boards.

c. Similarly, has DEA identified specific public safety issues stemming from the possible oversupply of opioids as described in the 2016 Charleston Gazette-Mail reporting?

d. What additional insights does DEA have into the alleged practices as indicated in this reporting?

11. MSNBC also ran a story about the substantial influx of opioids into West Virginia. More specifically, it reported on the small town of Kermit, West Virginia with an estimated population of only 392 people. MSNBC reported that one pharmacy in Kermit received nine million hydrocodone pills in two years. We note that DEA indicated during testimony at the March 21, 2017 hearing before the Subcommittee

on Oversight and Investigations, that DEA is familiar with reports of possible oversupply of opioids in West Virginia.

a. Does DEA agree with the accuracy of the MSNBC report? If not, please explain and provide the number of hydrocodone pills provided to pharmacies in Kermit, West Virginia during the period in question.

b. If DEA agrees that the MSNBC report is accurate, what actions, if any, has DEA taken to date in response to the reported oversupply in the Kermit, West Virginia case?

12. The reports of possible oversupply of addictive opioids into West Virginia may raise additional concerns regarding whether there are systemic weaknesses in our regulatory and enforcement systems that could allow abusive oversupply patterns to go unnoticed or unaddressed.

a. Has DEA identified any systemic failures surrounding the oversupply of opioids in West Virginia?

b. If yes, what issues did DEA identify?

c. What has DEA concluded were the causes of these issues?

d. What solutions has DEA identified, and what efforts to date has DEA taken to implement these solutions?

13. If true, the reported oversupply of these addictive pills to the State of West Virginia raises significant concern that the same problem could be occurring elsewhere.

a. What monitoring systems are in place to detect potential oversupply of opioids nationwide?

b. Does DEA have sufficient insight into the supply patterns of other states hard-hit by the opioid epidemic to identify and respond to suspicious patterns occurring elsewhere?

14. The October 22, 2016 *Washington Post* article asserts that DEA headquarters delayed and blocked enforcement actions that led to a steep decline in enforcement actions between 2011 and 2014. Does DEA agree with this description? Please explain.

a. Similarly, was there a decline in suspension orders as the *Washington Post* article indicates? Please explain.

b. Please provide all documents since January 1, 2011 related to delayed or blocked enforcement actions and suspension orders.

15. The October 22 *Washington Post* article also suggests that, beginning in 2013, DEA lawyers began requiring a "higher standard of proof before cases could move forward." If this reporting is accurate, please explain how the standard of proof changed and the rationale for this change.

16. Were concerns raised by drug companies or wholesale distributors regarding DEA's approach to ongoing enforcement actions? If complaints were made, please describe their general nature, when they were made, and whether DEA agreed with them.

17. What additional tools or authorities does DEA need to identify and respond to suspicious order trends of opioids, and to help prevent the oversupply of opioids?

An attachment to this letter provides additional information about responding to the committee's request. If you have any questions, please contact Alan Slobodin or Brittany Havens of the Majority staff at (202) 225-2927 or Kevin McAloon of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this matter.

Sincerely,

Greg Walden
Chairman
Committee on Energy and Commerce

Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

David B. McKinley
Member
Committee on Energy and Commerce

Attachment