

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

March 17, 2018

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “The Drug Enforcement Agency’s Role in Combating the Opioid Epidemic”

On **Tuesday, March 20, 2018, at 10:00 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled “The Drug Enforcement Agency’s Role in Combating the Opioid Epidemic.”

I. THE OPIOID EPIDEMIC CONTINUES TO HARM PUBLIC HEALTH

Opioid overdose is the leading cause of unintentional, non-traumatic deaths in the United States. According to the Centers for Disease Control and Prevention (CDC), opioid-related overdose deaths quintupled between 1999 and 2016. Opioids now cause an average of 115 deaths every day.¹ Nearly half of these overdose deaths are caused by prescription opioids.² This crisis has devastated communities across the country, killing approximately 300,000 people between 1999 and 2015, and costing more than \$1 trillion between 2001 and 2017.³

¹ Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic* (www.cdc.gov/drugoverdose/epidemic/index.html).

² Centers for Disease Control and Prevention, *Opioid Overdose: Prescription Opioid Overdose Data* (www.cdc.gov/drugoverdose/data/overdose.html).

³ Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report – International Overdose Awareness Day – August 31, 2017* (www.cdc.gov/mmwr/volumes/66/wr/mm6634a1.htm?s_cid=mm6634a1_w); *Economic Toll of Opioid Crisis in U.S. Exceeded \$1 Trillion Since 2001*, Altarum (Feb. 13, 2018).

II. ENERGY AND COMMERCE COMMITTEE INVESTIGATION INTO OPIOID DISTRIBUTION PRACTICES IN WEST VIRGINIA

West Virginia has the highest opioid overdose death rate per capita in the nation, at 52 opioid deaths for every 100,000 people. It is also among the states with the highest rate of pain reliever use disorder, according the Substance Abuse and Mental Health Services Administration.⁴

The opioid epidemic costs the state of West Virginia an estimated \$8.8 billion annually, equal to one-eighth of its entire economy.⁵ At the same time, West Virginia has received considerable volumes of opioids over the past decade. For example, according to a 2016 news investigation, drug wholesalers distributed about 780 million opioids to pharmacies throughout the State of West Virginia between 2007 and 2012.⁶

In May of 2017, the Committee sent bipartisan letters to three wholesale drug distributors and to the Drug Enforcement Agency (DEA) regarding opioid pill distribution practices in West Virginia.⁷ Among other things, these letters sought information on the quantity of opioids shipped to the state, how DEA and distributors tracked such shipments, and whether mechanisms to stop shipments for orders deemed “suspicious” were used in accordance with the Controlled Substances Act and applicable regulations.⁸ The Committee also identified some concerning trends upon analyzing DEA’s publicly-available Automation of Reports and Consolidated Orders System (ARCOS) data on the amount of opioids shipped to West Virginia, broken down into particular regions. The Committee subsequently requested and obtained from DEA more granular ARCOS data on the amount of opioids shipped to every pharmacy in what had been reported as high opioid volume areas of the state.

⁴ National Center for Health Statistics, *Drug Overdose Mortality by State* (www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm); Substance Abuse and Mental Health Services Agency, *2015-2016 National Survey on Drug Use and Health* (www.samhsa.gov/data/sites/default/files/NSDUHsaeMaps2016/NSDUHsaeMaps2016.htm).

⁵ *Opioid epidemic costs WV \$8.8 billion annually, study says*, Charleston Gazette-Mail (Feb. 6, 2018).

⁶ *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016); *‘Suspicious’ drug order rules never enforced by state*, Charleston Gazette-Mail (Dec. 18, 2016).

⁷ Letter from House Committee on Energy and Commerce to Steven Collis, Chairman, President and Chief Executive Officer, AmerisourceBergen Corporation (May 8, 2017); Letter from House Committee on Energy and Commerce to George S. Barrett, Chairman and Chief Executive Officer, CardinalHealth (May 8, 2017); Letter from House Committee on Energy and Commerce to Hon. Chuck Rosenberg, Acting Director, Drug Enforcement Agency (May 8, 2017); Letter from House Committee on Energy and Commerce to John Hammergren, Chairman, President and Chief Executive Officer, McKesson Corporation (May 8, 2017).

⁸ 21 U.S.C. §§ 801 et seq.; 21 C.F.R. §1301.74(b).

The Committee's analysis of this DEA data suggested that distributors shipped what appear to be high volumes of opioids to pharmacies in towns with relatively small populations between 2006 and 2016. For example, DEA's ARCOS data indicated that in 2007 alone, distributors shipped 4.3 million doses of opioids to a town of 406, and another 20.8 million prescription opioids between 2008 and 2015, to two pharmacies in a town of three thousand people.

Based on this analysis, the Committee extended its investigation to include two additional distributors. In January and February of this year, the Committee sent letters to all five distributors, asking for additional documents and information regarding opioids shipments to West Virginia pharmacies.⁹

III. KEY HEARING ISSUES

Some key questions likely explored by the Committee include whether DEA believes that distributors adequately exercised due diligence over their pharmacy customers as federal law and regulations require. For example, the regulatory requirements of the Controlled Substance Act oblige distributors to "design and operate a system" to track "suspicious orders of controlled substances," and to report these suspicious orders to DEA.¹⁰ Nonetheless, the Department of Justice (DOJ), acting on behalf of DEA, has filed multiple civil cases against the distributors for failure to report suspicious orders, and ultimately reached four settlements with the distributors for violations of this Act. Notably, McKesson Corporation agreed to pay DOJ \$13 million in 2008 and \$150 million in 2017 for failing to detect and disclose suspicious orders, and Cardinal Health agreed to pay \$34 million in 2008 and \$44 million in 2016.¹¹ DOJ continues to litigate a

⁹ Letter from House Committee on Energy and Commerce to J. Christopher Smith, President and CEO, H.D. Smith (Jan. 26, 2018); Letter from House Committee on Energy and Commerce to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. (Jan. 26, 2018); Letter from House Committee on Energy and Commerce to Steven Collis, Chairman, President and Chief Executive Officer, AmerisourceBergen Corporation (Feb. 15, 2018); Letter from House Committee on Energy and Commerce to George Barrett, Executive Chairman of the Board, and Mr. Michael Kaufmann, Chief Executive Office, Cardinal Health, Inc. (Feb. 15, 2018); Letter from House Committee on Energy and Commerce to John Hammergren, Chairman, President and Chief Executive Officer, McKesson Corporation (Feb. 15, 2018).

¹⁰ 21 C.F.R. §1301.74(b).

¹¹ U.S. Department of Justice, *McKesson Corporation Agrees to Pay More than \$13 Million to Settlement Claims that it Failed to Report Suspicious Sales of Prescription Medications* (May 2, 2008) (press release); *McKesson to Pay \$150 Million for Failing to Report 'Suspicious' Drug Orders*, Wall Street Journal (Jan. 17, 2017); U.S. Department of Justice, *Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008) (press release); U.S. Department of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of the Controlled Substances Act* (Dec. 23, 2016) (press release).

lawsuit to revoke Miami-Luken, Inc.'s registration to distribute controlled substances based on similar allegations.¹²

The State of West Virginia has also reached settlements with Cardinal Health and AmerisourceBergen for \$20 million and \$16 million, respectively, both to resolve allegations that these distributors shipped excessive quantities of opioids, relative to the population of West Virginia.¹³ West Virginia is currently prosecuting a similar civil lawsuit against McKesson Corporation.¹⁴

Other questions that will likely be examined include whether DEA adequately used its resources such as ARCOS data to review distribution practices in West Virginia, and whether these tools made it possible for DEA to recognize these seemingly high distribution practices as they occurred. In addition, news reports suggested that DEA may have reduced the number of immediate suspension orders it issued to stop shipments from wholesale distributors and pill dispensing by pharmacies.¹⁵ The Committee has asked DEA for information as to whether this decrease did in fact take place, and if so, for documents and communications related to the decline.¹⁶

IV. WITNESS

Hon. Robert Patterson
Acting Administrator
United States Drug Enforcement Agency

¹² *Miami-Luken Inc. v. United States Department of Justice, Drug Enforcement Administration*, No. 1-16-mc-012 (S.D. Ohio filed May 18, 2016).

¹³ *Cardinal Health, AmerisourceBergen settle pain pill lawsuit for \$36 million*, West Virginia Record (Jan. 10, 2017); Second Amended Complaint at ¶ 15a (iii), *State of West Virginia ex rel. Patrick Morrissey et al. v. Amerisourcebergen Drug Corp. et al.*, Civ. No. 12-c-141 (Boone County, WV Circuit Court, Jan. 2, 2014).

¹⁴ Amended Complaint at ¶ 12, *State of West Virginia ex rel. Patrick Morrissey et al. v. McKesson Corporation*, Civ. No. 16-C-1 (Boone County, WV Circuit Court, Jan. 21, 2016).

¹⁵ *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse*, Washington Post (Dec. 22, 2016); *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, Washington Post (Oct. 22, 2016); *DEA Agent: 'we had no leadership' in WV amid flood of pain pills*, Charleston Gazette-Mail (Feb. 18, 2017).

¹⁶ Letter from House Committee on Energy and Commerce to Hon. Chuck Rosenberg, Acting Director, Drug Enforcement Agency (May 8, 2017).