

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

May 5, 2018

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion”

On **Tuesday, May 8, 2018, at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled “Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion.”

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, opioid-related overdose deaths quintupled between 1999 and 2016. Opioids now cause an average of 116 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

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

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

² Department of Health and Human Services, *About the U.S. Opioid Epidemic* (<https://www.hhs.gov/opioids/about-the-epidemic/>).

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).

The Committee has been investigating possible causes of the opioid crisis, using the State of West Virginia as a case study of the epidemic. West Virginia has the highest opioid overdose death rate per capita in the nation, at 52 opioid deaths for every 100,000 people.⁴ It is also among the states with the highest rate of pain reliever use disorder, according to the Substance Abuse and Mental Health Services Administration.⁵ This epidemic costs the state an estimated \$8.8 billion annually, equal to one-eighth of its entire economy.⁶

Drug wholesale distributors have shipped West Virginia considerable volumes of opioids over the past decade. A 2016 news investigation reported, for example, that drug wholesalers sold West Virginia pharmacies about 780 million doses of opioids between 2007 and 2012.⁷

In May of 2017, the Committee sent bipartisan letters to three drug wholesalers, McKesson Corporation (McKesson), AmerisourceBergen Drug Corporation (AmerisourceBergen) and Cardinal Health (Cardinal), and to the Drug Enforcement Agency (DEA) regarding opioid pill distribution practices in West Virginia.⁸ 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 (CSA) and applicable regulations.⁹ Upon analyzing DEA’s publicly-available Automation of Reports and Consolidated Orders System (ARCOS) data, the Committee also identified some concerning trends in 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).

⁵ 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).

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

⁷ *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).

⁸ 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, Cardinal Health (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).

⁹ 21 U.S.C. § 801 et seq.; 21 C.F.R. §1301.74(b) (2018).

The Committee's analysis of this DEA data suggests 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 people, and another 20.8 million prescription opioids to two pharmacies in a town of 3,000 people between 2008 and 2015. Based on this information, the Committee extended its investigation to include two additional wholesale distributors, Miami-Luken Inc. and H.D. Smith.

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.¹⁰ Citing DEA data, these letters noted the quantity of pills that each distributor sent to particular pharmacies, and demonstrated that these amounts were in excess of what a rural pharmacy would have been expected to receive, based on market data.

The letters also noted that the CSA and applicable regulations require distributors to "design and operate a system" to track "suspicious orders of controlled substances," and to report these suspicious orders to DEA.¹¹ Past settlements suggest that distributors have not always complied with this requirement. Notably, McKesson Corporation agreed to pay the Department of Justice (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 for the same reason.¹² DOJ continues to litigate a lawsuit to revoke Miami-Luken's

¹⁰ 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); *see supra* note 8. Full letters available at <https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-continues-to-expand-bipartisan-investigation-into-alleged-pill-dumping-in> and <https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-continues-to-probe-national-distributors-about-alarming-number-of-0>.

¹¹ 21 C.F.R. §1301.74(b) (2018).

¹² *See* 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).

registration to distribute controlled substances based on similar allegations.¹³ Accordingly, the letters asked the distributors various questions about their due diligence procedures and suspicious order monitoring systems.

III. KEY HEARING ISSUES

Some key questions likely to be explored by the Committee include lessons to be learned from the rise of the opioid epidemic in West Virginia, including why certain pharmacies received what appear to be high volumes of pills. As part of this investigation, the hearing is likely to examine the due diligence undertaken by distributors prior to shipping pills to particular regions or pharmacies. The hearing is also likely to explore whether the distributors stopped pharmacy orders that were suspicious based on size, frequency, or other factors, and whether they reported these orders to DEA. The hearing might also explore why certain distributors settled with both state and federal authorities for failure to report suspicious orders and to conduct appropriate due diligence of their pharmacy customers.

IV. WITNESSES

Mr. George Barrett
Executive Chairman of the Board
Cardinal Health Inc.

Mr. Steven Collis
Chairman, President, and CEO
AmerisourceBergen Corporation

Mr. John Hammergren
Chairman, President, and CEO
McKesson Corporation

Dr. Joseph Mastandrea
Chairman of the Board
Miami-Luken, Inc.

Mr. J. Christopher Smith
Former President and CEO
H.D. Smith Wholesale Drug Company

¹³ *Miami-Luken Inc. v. United States Department of Justice, Drug Enforcement Administration*, No. 1-16-mc-012 (S.D. Ohio filed May 18, 2016).