

May 4, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion.”

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

The purpose of this hearing is to investigate the role of wholesale drug distribution and diversion in the opioid epidemic in the U.S. Specifically, the hearing will examine whether any breakdowns occurred in the closed system for controlled substance distribution, established under the Controlled Substances Act (CSA), resulting in massive amounts of prescription opioids being shipped to small-town pharmacies in rural West Virginia while the opioid crisis continued to worsen throughout the U.S., but particularly in West Virginia.

I. WITNESSES

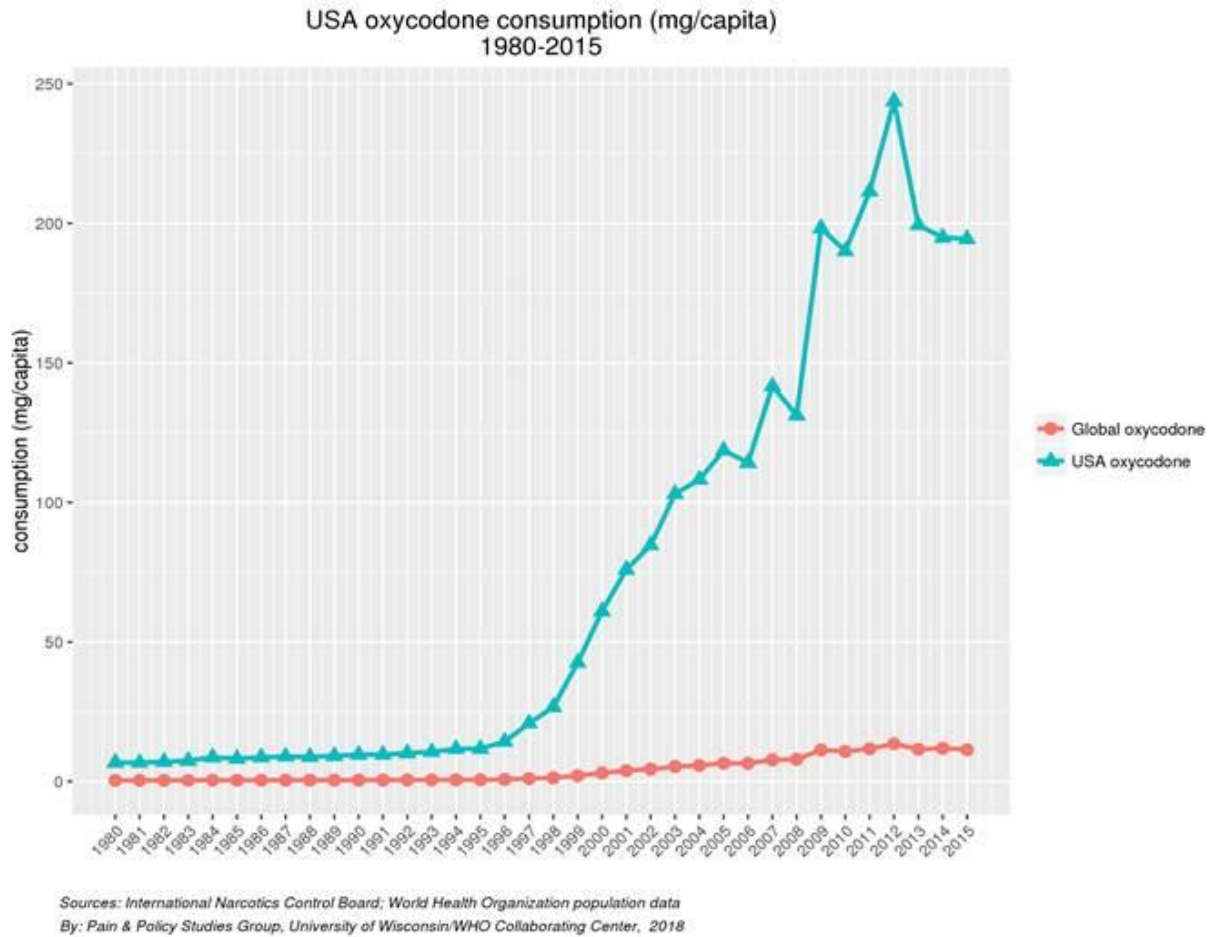
- George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc.;
- Steven H. Collis, Chairman, President and Chief Executive Officer, AmerisourceBergen Corporation;
- John H. Hammergren, Chairman, President and Chief Executive Officer, McKesson Corporation;
- Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc.; and
- J. Christopher Smith, Former President and Chief Executive Officer, H.D. Smith Wholesale Drug Co.

II. BACKGROUND

Opioid prescription drugs are used for pain management. In the U.S., about 6.9 percent of all adults have used an opioid analgesic during the last 30 days.¹ Opioid prescribing rates

¹ Kristen Kenan, Karin Mack, and Leonard Paulozzi, *Trends in prescriptions for oxycodone and other commonly used opioids in the United States, 2000-2010*, 6 *Open Med.*e41 (2012) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3659213/>.

peaked in 2012 with more than 255 million prescriptions written in that year. In 2016, the number decreased to slightly more than 214 million.²



The U.S. continues to experience an opioid epidemic, which has worsened over the last two decades. Opioid-involved overdose deaths are the leading cause of injury death in the U.S. and take the lives of 115 Americans per day.³ According to a recent report issued by the Centers for Disease Control and Prevention (CDC), prescription or illicit opioids were involved in nearly two-thirds of all drug overdose deaths in the U.S. during 2016 – a 27.7 percent increase from 2015.⁴ In total, more than 351,000 people have died since 1999 due to an opioid-involved

² Centers for Disease Control and Prevention, U.S. prescribing rate maps. Opioid overdose, updated July 31, 2017, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

³ Centers for Disease Control and Prevention, Understanding the Epidemic, Opioid Overdose, Aug. 30, 2017, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

⁴ Centers for Disease Control and Prevention, Vital Signs: Trends in Emergency Department Visits for Suspected Overdoses – United States, July 2016-September 2017, Mar. 9, 2018, available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm>.

overdose.⁵ The crisis has become so severe that the average life expectancy declined in 2016 from the previous year, largely because of opioid overdoses.⁶

Beginning in April 2014, through numerous hearings, the Subcommittee on Oversight and Investigations has undertaken a comprehensive examination into the root causes of the opioid epidemic and explored possible solutions to enable greater access to effective, evidence-based treatment for substance use disorders. On May 8, 2017, the Committee launched an investigation into the distribution of prescription opioids, initially sending letters to the Drug Enforcement Administration (DEA) and the three largest wholesale drug distributors in the U.S., AmerisourceBergen, Cardinal Health, and McKesson.⁷ The Committee has since expanded its investigation to include regional wholesale distributors, H.D. Smith Drug Co.,⁸ and Miami-Luken, Inc.⁹ The Committee also sent follow-up letters to the three national distributors on February 15, 2018.¹⁰ The Committee sent a second letter to the DEA on October 13, 2017,¹¹ and held a hearing with the DEA's Acting Administrator Robert Patterson on March 20, 2018, which examined DEA's efforts to combat prescription drug diversion and the agency's response to the opioid epidemic.¹²

Role of the Wholesale Drug Distributors

In general, the role that wholesale drug distributors play in the pharmaceutical supply chain is to purchase pharmaceuticals from manufacturers and distribute the drugs to downstream

⁵ Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016, available at https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.

⁶ Catherine Roberts, *Opioid Overdoses Are Major Cause Behind Life Expectancy Decline*, CDC Report Says, Consumer Reports, Dec. 21, 2017, available at <https://www.consumerreports.org/drug-use/opioid-overdoses-life-expectancy-decline/>.

⁷ See H. Comm. on Energy & Commerce, *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia*, May 9, 2017, available at <https://energycommerce.house.gov/news/letter/letters-distributors-and-dea-regarding-alleged-pill-dumping-west-virginia/>.

⁸ On Nov. 21, 2017 AmerisourceBergen announced its intention to acquire H.D. Smith for \$815 million. See Press Release, AmerisourceBergen Corporation, AmerisourceBergen to Acquire HD Smith, Nov. 21, 2017, available at <https://www.amerisourcebergen.com/abcnew/newsroom/press-releases/amerisourcebergen-to-acquire-hd-smith>. AmerisourceBergen announced that it had completed its acquisition of H.D. Smith on Jan. 3, 2018. See Press Release, AmerisourceBergen Corporation, AmerisourceBergen Completes Acquisition of HD Smith, Jan. 3, 2018, available at <https://www.amerisourcebergen.com/abcnew/newsroom/press-releases/amerisourcebergen-completes-acquisition-of-hd-smith>.

⁹ See H. Comm. on Energy & Commerce, *Letters to Regional Distributors Expanding Alleged Pill Dumping Investigation*, Jan 30, 2018, available at <https://energycommerce.house.gov/news/letter/letters-regional-distributors-expanding-alleged-pill-dumping-investigation/> and H. Comm on Energy & Commerce, *Letter to Miami-Luken Regarding Alleged Pill Dumping in West Virginia*, Sept. 26, 2017 available at <https://energycommerce.house.gov/news/letter-miami-luken-regarding-alleged-pill-dumping-west-virginia/>.

¹⁰ See H. Comm. on Energy & Commerce, *Follow-Up Letters to Distributors Regarding Ongoing Pill Dumping Investigation*, Feb. 15, 2018, available at <https://energycommerce.house.gov/news/follow-letters-distributors-regarding-ongoing-pill-dumping-investigation/>.

¹¹ Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al. to Robert W. Patterson, Acting Adm'r, U.S. Drug Enforcement Admin., Oct. 13, 2017, available at <https://energycommerce.house.gov/wp-content/uploads/2017/10/20171013DEA.pdf>.

¹² *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the H. Comm on Energy & Commerce, Subcomm. on Oversight and Investigations*, 115th Cong., Mar. 20, 2018.

customers, such as pharmacies, where they are dispensed to patients.¹³ Wholesale drug distributors engaged in interstate commerce are required, pursuant to regulations issued by U.S. Food and Drug Administration (FDA) and authorized under the Prescription Drug Marketing Act of 1987,¹⁴ to be licensed by a state where the distributor has a presence.¹⁵ FDA's regulations also established minimum federal requirements necessary for state licensure.¹⁶ In addition, Title II of the Drug Quality and Security Act, also referred to as the Drug Supply Chain Security Act, which was enacted on November 27, 2013, directed FDA to develop federal licensure standards for wholesale pharmaceutical distributors.¹⁷

It is common for wholesale drug distributors to purchase and distribute both controlled and non-controlled substances as part of their general course of business. However, distributors who engage in the purchase and distribution of controlled substances are subject to additional legal obligations under the Controlled Substances Act (CSA). Wholesale drug distributors that distribute controlled substances must be registered with the DEA¹⁸ and such registrations shall be granted so long as the DEA determines they are in the public interest.¹⁹ Currently, 947 entities are registered with the DEA to distribute controlled substances in the U.S.²⁰ While there are a large number of registrants, McKesson, Cardinal Health, and AmerisourceBergen are the predominant wholesale drug distributors in the U.S., accounting for approximately 85 percent to 90 percent of domestic pharmaceutical wholesaling revenue.²¹

The CSA was designed to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion. Prior to the establishment of the DEA, the Bureau of Narcotics and Dangerous Drugs issued regulations in 1971 in accordance with the objectives of the CSA.²² These regulations, among other things, require distributors to "design and operate a system to disclose . . . suspicious orders of controlled substances."²³ The regulations also require distributors to report suspicious orders of controlled substances to the DEA when they are discovered.²⁴ According to the regulations, suspicious

¹³ 21 C.F.R. § 203.3(cc).

¹⁴ Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 98 (1988).

¹⁵ 21 C.F.R. § 205.4.

¹⁶ 21 C.F.R. § 205.5.

¹⁷ 21 U.S.C. § 360eee-2.

¹⁸ 21 U.S.C. § 822.

¹⁹ 21 U.S.C. § 823.

²⁰ *Registrant Population by Business Activity*, U.S. Drug Enforcement Admin., available at <https://apps.deadiversion.usdoj.gov/webforms/odrBusActReportSelect.do;jsessionid=EA9E06C5D86689DF265FE8B8CCB8C39B>, last visited May 1, 2018.

²¹ Scott Higham and Lenny Bernstein and Scott Higham, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.2608027cefa6.

²² The DEA was established within the Department of Justice by Executive Order on July 1, 1973, when various Executive Branch agencies were merged and the Attorney General was granted additional authority to coordinate federal efforts to combat illicit drug abuse. See Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) reprinted at 21 U.S.C. § 801.

²³ 21 C.F.R. 1301.74(b).

²⁴ *Id.*

orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.²⁵

In addition to the regulatory requirements incumbent upon controlled substance distributors, the distributors also have a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted to non-medical, scientific, or industrial channels.²⁶ The CSA also provides DEA with authority to deny, revoke, or suspend a distributor's registration if it determines the distributor's actions to be to be in violation of the mandates of the CSA or inconsistent with the public interest.²⁷ A distributor's failure to exercise adequate due diligence could provide a statutory basis for revocation or suspension of the distributor's DEA registration.²⁸

Federal Efforts to Combat Illicit Prescription Drug Diversion

Over the last 13 years, the DEA has undertaken numerous efforts to educate drug distributors, pharmacies, and doctors about their roles and responsibilities to prevent drug diversion. Amid a dramatic increase in the trafficking and abuse of prescription controlled substances, the DEA identified distributors as a chokepoint in the drug supply chain that could monitor and analyze orders of controlled substances and report orders as suspicious as defined in 21 CFR 1301.74. Recognizing that wholesale distributors played a key role in the pharmaceutical supply chain, the DEA launched an industry-specific anti-diversion initiative in 2005, called the "Distributor Initiative Program." According to the DEA, the goal of the initiative is to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."²⁹ DEA initially designed this program to educate drug distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. Through the program, the DEA "educates distributors about their obligations under the CSA, as well as provides registrants with current trends and 'red flags' that might indicate that an order is suspicious."³⁰ The initiative remains active and as of September 2017, the DEA has briefed at least 99 firms that hold 309 separate distributor registrations about concerns regarding illegal Internet pharmacy operations and rogue pain clinics.³¹

In addition to the briefings, the DEA also sent letters in 2006 and 2007 to every DEA-registered distributor to spell out their legal obligations. The initial letter, sent on September 27, 2006, emphasized that, under the CSA, distributors have a responsibility not just to report all

²⁵ *Id.*

²⁶ 21 U.S.C. § 823(b) and 21 U.S.C. § 823(e).

²⁷ 21 U.S.C. § 824.

²⁸ 21 U.S.C. § 823(b), 21 U.S.C. § 823(e), and 21 U.S.C. § 824(a).

²⁹ *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., 2014, Statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.

³⁰ *Id.*

³¹ *DEA Trends & Updates – Connecticut/Rhode Island Pharmacy Diversion Awareness Conference*, U.S. Drug Enforcement Admin., Sept. 24-25, 2017, available at https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2017/sept_2017/carrion.pdf#search=distributor%20initiative.

suspicious orders to the DEA but also to exercise due diligence to avoid filling suspicious orders that might be diverted. In the letter, the DEA also provided examples of circumstances that might be indicative of controlled substance diversion and offered several suggested questions that distributors could ask pharmacy customers as they try to determine whether or not the customer is engaged in drug diversion.³² These points were largely reiterated in the letter the DEA sent to distributors on February 7, 2007.³³

The letter the DEA sent to distributors on, December 20, 2007, however, provided more specific guidance to wholesale distributors about their obligation to report suspicious orders under the CSA. The letter warned that it is the responsibility of the registrant to design and operate a suspicious order monitoring system and that suspicious orders must be reported to local DEA officers “when discovered by the registrant.”³⁴ Monthly reports submitted after orders were already filled and sent to customers would not meet the regulatory requirement, according to the DEA. Nor would providing daily, weekly, or monthly “excessive purchases” reports.³⁵ In the same letter, the DEA also specifically referred distributors to a July 3, 2007, final order issued by the DEA’s Deputy Administrator that revoked the DEA registration of Southwood Pharmaceuticals Inc.³⁶ The final order included discussion of distributors’ obligations to maintain effective controls against diversion and required action when distributors discover a suspicious order.

The DEA has also hosted several distributor conferences in the past, most recently in 2016, that had the purpose of providing distributors with “an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, Automation of Reports and Consolidated Orders System (ARCOS), and suspicious order reporting.”³⁷ Despite receiving significant guidance from the agency, some wholesale distributors have been subject to enforcement actions initiated by the DEA, alleging the distributors failed to adhere to their legal obligations under the CSA. Some of the enforcement actions taken against wholesale distributors, and related settlement agreements, include:

- April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order³⁸ against the AmerisourceBergen Orlando, Florida distribution center alleging

³² Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Sept. 27, 2006, (On file with the Committee).

³³ Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007, (On file with the Committee).

³⁴ Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Dec. 20, 2007, (On file with the Committee).

³⁵ *Id.*

³⁶ See 72 Fed. Reg. 36,487, July 3, 2007.

³⁷ *Distributor Conference – May 10 & 11, 2016; Indianapolis, Indiana*, U.S. Drug Enforcement Admin., https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2016/index.html.

³⁸ Immediate Suspension Orders (ISOs) and Orders to Show Cause (OTSCs) are administrative tools available to DEA to ensure compliance with the CSA, and to protect the public health and welfare. An OTSC requires a registrant to prove to the DEA Administrator why the registrant’s DEA registration should not be revoked or suspended. See 21 U.S.C. § 824(c) and 21 C.F.R. § 1301.37(b). If, however, the DEA Administrator determines that a DEA registrant’s activities constitute an imminent danger to the public health or safety, the Administrator may issue an ISO, which requires the immediate surrender of the registrant’s DEA registration, pending the final resolution of an accompanying OTSC. See 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e)(f).

failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency;³⁹

- November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;⁴⁰
- December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;⁴¹
- December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;⁴²
- January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;⁴³
- On September 30, 2008, Cardinal Health agreed to pay a \$34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California, and Denver, Colorado;⁴⁴
- May 2, 2008, McKesson Corporation agree to pay a \$13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”⁴⁵

³⁹ *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with the Committee).

⁴⁰ *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Nov. 28, 2007, (On file with the Committee).

⁴¹ *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 5, 2007, (On file with the Committee).

⁴² *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 7, 2007, (On file with the Committee).

⁴³ *In re Cardinal Health*, Order to Show Cause, Jan. 30, 2008, (On file with the Committee).

⁴⁴ *In re Cardinal Health*, Settlement and Release Agreement, Sept. 30, 2008, (On file with the Committee).

⁴⁵ *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008, (On file with the Committee).

- February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;⁴⁶
- May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years;⁴⁷
- November 23, 2015, DEA Issued an Order to Show Cause against Miami-Luken for failure to maintain effective controls against the diversion of controlled substances, particularly hydrocodone and oxycodone, between 2007 and 2015. This enforcement action remains pending with DEA;⁴⁸
- December 23, 2016, Cardinal Health agreed to pay a \$34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligations under the CSA in Florida, Maryland, New York, and Washington;⁴⁹ and
- January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.⁵⁰

Prescription Opioid Distribution Investigation

As noted, in May 2017, the Committee opened an investigation into the distribution of prescription opioids by wholesale drug distributors, with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia. Between 2007 and 2012, distributors sent more than 780 million hydrocodone and oxycodone pills to the state – or 433 doses per person. AmerisourceBergen, Cardinal Health, and McKesson delivered more than half of that amount, about 423 million pills.⁵¹ In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.⁵²

⁴⁶ *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Feb 2, 2012, (On file with the Committee).

⁴⁷ *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012, (On file with the Committee).

⁴⁸ *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015, (On file with the Committee).

⁴⁹ Press Release, U.S. Dep't of Justice, United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under the Controlled Substances Act, Dec. 23, 2016, *available at* <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

⁵⁰ *In re McKesson*, Administrative Memorandum of Agreement, Jan. 5, 2017, (On file with the Committee).

⁵¹ Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail, Dec. 17, 2016, *available at* https://www.wvgazette.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.

⁵² *Id.*

While the investigation is still ongoing, the Committee has uncovered additional information that raises questions about the adequacy of due diligence performed by wholesale drug distributors, and the companies' adherence to the CSA's requirement that they implement a suspicious order monitoring program and report any suspicious orders to DEA.⁵³ The information also raises questions about the DEA's oversight of its registrants in West Virginia as the opioid crisis continued to worsen.

Among the Committee's findings: a single pharmacy in Mount Gay-Shamrock, West Virginia—population 1,779—received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016; distributors sent 20.8 million opioid pills to Williamson, West Virginia—population 2,900—during the same period; a pharmacy in Kermit, West Virginia—population 406—ranked 22nd in the entire country in 2006 in the overall number of hydrocodone pills it received, with a single distributor supplying 76 percent of its hydrocodone pills that year. Over a two-year period, distributors shipped approximately 9 million opioids to Kermit, West Virginia.

III. ISSUES

The following issues may be examined at the hearing:

- The policies and procedures wholesale distributors had in place to mitigate controlled substance diversion amid the opioid epidemic and whether such policies and procedures were followed;
- The actions taken by wholesale distributors when presented with “red flags” for possible diversion; and
- The lessons wholesale distributors learned from past experiences in West Virginia that will enable them to safeguard against controlled substance diversion more effectively.

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Christopher Santini, Brittany Havens, or Andrea Noble of the Committee staff at (202) 225-2927.

⁵³ See 21 C.F.R. § 1301.74.