

March 16, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic.”

The Subcommittee on Oversight and Investigations will hold a hearing on March 20, 2018, at 10:00 a.m. in 2322 Rayburn House Office Building, entitled “The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic.” The purpose of this hearing is to discuss the response of the Drug Enforcement Administration (DEA) to the opioid crisis, including the detection and investigation of suspicious orders of opioids, and DEA’s enforcement approach to the opioid epidemic.

I. WITNESS

- Robert W. Patterson, Acting Administrator, U.S. Drug Enforcement Administration.

II. BACKGROUND

The U.S. continues to experience an opioid epidemic, with opioid-involved overdose deaths currently being the leading cause of injury death in the U.S., taking the lives of 115 Americans per day.¹ 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 2015.² In total, more than 351,000 lives have been lost since 1999 due to an opioid-involved overdose.³

Beginning in April 2014, through numerous hearings, the Subcommittee 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 three largest wholesale drug distributors in the

¹ Centers for Disease Control and Prevention, Understanding the Epidemic, Opioid Overdose, Aug. 30, 2017, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

² 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, <https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm>.

³ Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016, https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.

U.S. as well as the DEA.⁴ The Committee expanded this investigation to include two additional wholesale drug distributors, and sent a second letter to the DEA on October 13, 2017.

Role of the DEA in Combatting the Opioid Epidemic

The DEA was established within the Department of Justice by Executive Order on July 1, 1973, when the Office of National Narcotics Intelligence and the Office for Drug Abuse Law Enforcement were merged, and the Attorney General was granted additional authority to coordinate federal efforts to combat illicit drug abuse.⁵ Today, the DEA is the federal agency principally responsible for enforcement of the Controlled Substances Act (CSA), enacted under Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.⁶ The CSA established the schedules for controlled substances⁷ and provided authority for the DEA to register entities engaged in the manufacture, distribution, or dispensation of these substances as well.⁸ The CSA also established registration requirements⁹ and provided the authority for the DEA to deny, revoke, or suspend such registration(s) if it determined the registrant to be out of compliance with the mandates of the CSA.¹⁰ 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. The DEA regulations require all distributors to report suspicious orders of controlled substances.¹¹ In addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted to non-medical, scientific, or industrial channels. Failure to exercise such due diligence could provide a statutory basis for revocation or suspension of a DEA registration.¹²

The CSA also authorized the DEA to establish annual production quotas for controlled substances.¹³ According to the CDC, the number of prescription opioids sold to pharmacies, doctors' offices, and hospitals in the U.S. nearly quadrupled from 1999 to 2010, yet there was no increase in the the number of patients treated for pain during this time period.¹⁴ In August 2017, the DEA announced its intention to reduce the amount of controlled substances, including opioids, manufactured in the U.S. by 20 percent in 2018.¹⁵ The reduced 2018 production figures

⁴ See H. Comm. Energy & Commerce, *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia*, May 9, 2017, <https://energycommerce.house.gov/news/letter/letters-distributors-and-dea-regarding-alleged-pill-dumping-west-virginia/>.

⁵ Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) *reprinted at* 21 U.S.C. § 801.

⁶ Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91 – 513, 84 Stat. 1236, 1296 (1970).

⁷ 21 U.S.C. § 812.

⁸ 21 U.S.C. § 822.

⁹ 21 U.S.C. § 823.

¹⁰ 21 U.S.C. § 824.

¹¹ 21 C.F.R. 1301.74(b).

¹² 21 U.S.C. § 823(e) and 21 U.S.C. § 824(a).

¹³ 21 U.S.C. § 826.

¹⁴ Centers for Disease Control and Prevention, *supra* note 1.

¹⁵ Press Release, U.S. Drug Enforcement Admin, DEA proposes reduction to amount of controlled substances to be manufactured in 2018 (Aug. 4, 2017) *available at* <https://www.dea.gov/divisions/hq/2017/hq080417.shtml>.

were finalized by DEA in November 2017.¹⁶ Recently, the Attorney General issued a memorandum to DEA, directing the agency to examine its regulations governing aggregate production quotas and noting “[s]tudies have indicated that the United States is an outlier in the number of opioid prescriptions issued each year.”¹⁷

According to its Fiscal Year (FY) 2019 budget request, the DEA regulates more than 1.73 million registrants that are licensed to manufacture, distribute, and prescribe controlled substances.¹⁸ Among the tools available to DEA to ensure compliance with the CSA, and to protect the public health and welfare, are Immediate Suspension Orders (ISOs) and Orders to Show Cause (OTSCs), the latter of which require a registrant to prove to the DEA Administrator why the registrant’s DEA registration should not be revoked or suspended.¹⁹ 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.²⁰

Decline in Enforcement Actions Initiated by DEA

Throughout the last two decades, the opioid epidemic has worsened. In 2016, opioids were involved in 42,249 overdose deaths – an amount five times higher than the number of opioid-involved deaths reported in 1999.²¹ The impact of the opioid epidemic has become so pronounced that it has caused the overall life expectancy in the U.S. to decline during the past two consecutive years.²² The opioid epidemic has also received widespread media coverage and elicited responses at every level of government. Yet, since 2011, the number of ISOs issued by the DEA has significantly declined.

According to data provided by the DEA, the number of ISOs issued by the agency declined from 65 in 2011, to six in 2017.²³ The DEA has publicly stated that the high number of ISOs issued during the 2011 and 2012 time frame were due to actions the DEA took to shut

¹⁶ Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2018, 82 Fed. Reg. 51873 (Nov. 8, 2017).

¹⁷ Memorandum from Hon. Jefferson Sessions, Attorney Gen., United States of America, to Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin., Mar. 1, 2018, <https://www.justice.gov/file/1040226/download>.

¹⁸ U.S. Dep’t of Justice, FY 2019 Budget and Performance Summary – Drug Enforcement Administration (DEA), <https://www.justice.gov/jmd/page/file/1033151/download> (last visited Mar. 11, 2018).

¹⁹ See 21 U.S.C. § 824(c) and 21 C.F.R. § 1301.37(b).

²⁰ See 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36.

²¹ Centers for Disease Control and Prevention, Drug Overdose Death Data, Dec. 19, 2017, <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

²² Lenny Bernstein and Christopher Ingraham, *Fueled by drug crisis, U.S. life expectancy declines for a second straight year*, WASH. POST, Dec. 21, 2017, https://www.washingtonpost.com/national/health-science/fueled-by-drug-crisis-us-life-expectancy-declines-for-a-second-straight-year/2017/12/20/2e3f8dea-e596-11e7-ab50-621fe0588340_story.html?utm_term=.9b960a164076.

²³ See Office of Sen. Orrin Hatch, DEA Immediate Suspension Orders 2008-2017, https://www.hatch.senate.gov/public/_cache/files/80f96e98-6c08-4bd8-bdec-ee8c99cf7596/ISO%20&%20Show%20Cause%20Order%20Charts%20for%20the%20Record.pdf.

down numerous rogue “pill mill” pharmacies in Florida.²⁴ However, statements and allegations made by current and former DEA officials suggest the number of ISOs issued by the agency also declined because of internal policy changes.²⁵ To date, the DEA has not addressed these allegations directly.

Prescription Opioid Distribution Investigation

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.²⁶ In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.²⁷

While the investigation is ongoing, the Committee uncovered additional statistics that raise 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.²⁸ The statistics also raise 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.

²⁴ See *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act Before S. Comm. on the Judiciary*, 115th Cong. (2017) (statement of Demetra Ashley, Acting Assistant Adm’r, U.S. Drug Enforcement Admin). In her written testimony, Acting Assistant Administrator Ashley stated, “DEA issued 104 ISOs between FY2011 and FY 2012, with all but four being issued against practitioners . . . and pharmacies. Those actions were largely attributed to significant efforts to combat pill mills in Florida . . . The number of ISOs issued in FY 2011 and FY2012 were seen as atypical by historical DEA data.”

²⁵ See e.g. Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.f19aef7fe849; Bernstein and Higham, *‘We feel like our system was hijacked’: DEA agents say a huge opioid case ended in a whimper*, WASH. POST, Dec. 17, 2017, https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?hpid=hp_rhp-banner-low_mckesson-603am-hed%3Ahomepage%2Fstory&utm_term=.f620afa9efdc; and Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country’s Largest Drug Distributor*, CBS News 60 Minutes, Dec. 17, 2017, <https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/>.

²⁶ Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail, Dec. 17, 2016, 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.

²⁷ *Id.*

²⁸ See 21 C.F.R. § 1301.74

III. ISSUES

The following issues may be examined at the hearing:

- What is DEA's role in responding to the opioid epidemic?
- Why did the number of enforcement actions initiated by DEA decline while the opioid epidemic continued to worsen?
- What changes, if any, did DEA make to the evidentiary standards or policies related to Immediate Suspension Orders or Orders to Show Cause?
- How has DEA learned from past practices in order to improve its response to the opioid epidemic?

IV. STAFF CONTACTS

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