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# **Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia**

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*Prepared by the Energy and Commerce Committee, Majority Staff*

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## II. Executive Summary

The opioid epidemic is the worst drug crisis in America's history. According to the Centers for Disease Control and Prevention, more than 351,000 lives have been lost to opioid overdoses since 1999, with no signs of abating. Far more people die from the misuse of opioids in the United States each year than from road traffic accidents or violence. Public health officials are alarmed that the opioid problem has helped drive a decline in U.S. life expectancy at a time when life expectancy is improving in many places around the world.

As part of its legislative responsibilities to help protect public health, the House Energy and Commerce Committee in the 115th Congress intensified efforts to understand how the nation got to a crisis point with the opioid epidemic, and to find solutions to address this problem. In early 2017, the Committee became interested in allegations of "opioid-dumping," a term to describe inordinate volumes of opioids shipped by wholesale drug distributors to pharmacies located in rural communities, such as those in West Virginia. These allegations were highlighted in reports by the *Charleston Gazette-Mail* in West Virginia and the *Washington Post*.

In May 2017, the Committee opened a bipartisan investigation into the allegations. From press reports and this investigation, the Committee learned of opioid shipments in West Virginia that shocked the conscience:

- Over 10 years, 20.8 million opioids were shipped to pharmacies in the town of Williamson, home to approximately 3,000 people.
- Another nearly 9 million opioids were distributed in just two years to a single pharmacy in Kermit, West Virginia, population 406.
- Between 2007 and 2012, drug distributors shipped more than 780 million hydrocodone and oxycodone pills to West Virginia.

These troubling examples raised serious questions about compliance with the Controlled Substances Act (CSA), administered by the Drug Enforcement Administration (DEA).

In undertaking this investigation, the Committee sought an in-depth, unprecedented look into what happened that led to inordinate shipments of opioids to small, rural pharmacies in southwestern West Virginia, part of the epicenter of the nation's opioid epidemic and the state with the highest drug overdose death rate in the country. This examination was intended to review evidence, mostly documents, from the three largest wholesale drug distributors in the U.S. as well as those from two other regional distributors that were significant suppliers to West Virginia pharmacies. The companies whose distribution was reviewed are AmerisourceBergen Drug Corp., Cardinal Health, Inc., H.D. Smith Wholesale Drug Co., McKesson Corp., and Miami-Luken, Inc. The investigation also included review of some internal documents from the DEA. From this review, the Committee sought to determine the effectiveness of DEA enforcement and to evaluate the extent that distributors implemented controls to prevent diversion of opioids. This investigation is a start to establish some accountability and

understanding about the epidemic, but this inquiry is only a look at a piece of the overall puzzle. There are other actors involved in the epidemic including manufacturers, pharmacies, physicians, and drug traffickers.

This report presents case studies of opioid distribution to southwestern West Virginia pharmacies over the last decade. The findings from these individual case studies are not necessarily generalizable of the conduct of the distributors more broadly. However, the case studies—taken altogether with the sheer number of opioids sent to these small towns—raise sufficient concerns as to whether these companies fulfilled their legal obligations to prevent drug diversion.

The DEA is the federal agency tasked with administering and enforcing the CSA and regulating more than 1.73 million registrants licensed to manufacture, distribute, and prescribe controlled substances in the United States. This law established schedules of controlled substances and provided the authority for the DEA to register entities engaged in the manufacture, distribution, or dispensation of controlled substances. 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 specifically require all distributors to report suspicious orders of controlled substances, in addition to the statutory responsibility to exercise due diligence to avoid filling suspicious orders. In addition, federal regulations impose additional security control requirements on nonpractitioner DEA registrants, such as distributors including, but not limited to:

- “Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State-controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.”<sup>1</sup>
- “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division of the Administration in his region of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>2</sup>

As the opioid epidemic began to surge, the DEA by 2005 realized that traditional policing of individual doctors and pharmacies was no longer an effective approach against the oncoming avalanche of opioids from rogue internet pharmacies and pill mills. Instead, DEA’s focus turned to the drug wholesale distributors, a chokepoint in the pharmaceutical supply chain, who transfer drugs from manufacturers to businesses such as clinics, hospitals, and pharmacies where they

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<sup>1</sup> 21 C.F.R. § 1301.74(a).

<sup>2</sup> 21 C.F.R. § 1301.74(b).

can be dispensed to patients. Distributors in previous years had not received enforcement attention from the DEA. The new focus looked for greater impact with a highly consolidated industry given that the three major drug distributors—AmerisourceBergen, Cardinal Health, and McKesson—control about 85 percent of the drug supply.

Beginning in 2005, the DEA undertook a series of initiatives meant to educate wholesale drug distributors about their legal obligations to prevent controlled substance diversion. The DEA's "Distributor Initiative" included one-on-one meetings with wholesale distributors in which DEA officials provided specific examples regarding distributors' own customers whose ordering habits were suggestive of trends indicating the presence of diversion and illicit internet pharmacies. Of the five distributors investigated by the Committee, AmerisourceBergen, Cardinal, H.D. Smith and McKesson each had one-on-one meetings with DEA as part of this initiative. In addition, during 2006 and 2007, the DEA sent a series of three letters sent to all DEA-registered distributors, outlining their legal obligations to conduct due diligence and report suspicious orders.

Apparently, the DEA soon realized that the largest distributors were not taking their compliance requirements with sufficient seriousness. In 2007 and 2008, the DEA took enforcement action through legal settlements against the three largest wholesale distributors in the U.S. for alleged violations of the CSA, with multi-million-dollar fines involving two of them.

Despite these settlement agreements, and the subsequent policy enhancements that the three distributors made in their aftermath, the Committee found the distributors continued to ship large volumes of opioids into West Virginia. The three largest wholesale drug distributors in the United States, AmerisourceBergen, Cardinal Health, and McKesson, sent more than 900 million doses of hydrocodone and oxycodone to West Virginia between 2005 and 2016. Cardinal Health was the largest supplier of controlled substances to West Virginia out of the five companies examined as part of the Committee's investigation and distributed more than 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016. From April 2006 through 2016, McKesson supplied 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies. AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016. Likewise, regional distributors, H.D. Smith and Miami-Luken also made inordinate shipments during this timeframe.

According to DEA analysis of market data, the hydrocodone disbursements to some pharmacies were as many as six times higher than the annual amount an average rural West Virginia pharmacy received. At the same time large amounts of opioids were being supplied to West Virginia, the DEA had data demonstrating the increasing problem with controlled substance diversion in the state.

As explained in greater detail in this report, the extraordinary volume of shipments in West Virginia was a signal of possible breakdowns in distributors' oversight of their customers, including their suspicious order monitoring systems. Yet the actions taken by both distributors and the DEA contributed to—and failed to stop—this problem.

Among the Committee's findings, distributors suffered a series of breakdowns or had a lack of follow through in their due diligence evaluations of prospective pharmacy customers. As demonstrated in the report, the Committee found instances of insufficient due diligence by distributors who merely required pharmacies to complete new customer applications. There were cases where data submitted by a new customer was not critically analyzed to identify any red flags of controlled substance diversion. For example, potential red flags regarding a pharmacy's prescribing physicians that raised concerns about possible diversion were not questioned.

After distributors brought pharmacies on board as customers, the investigation found instances where there were failures to monitor the volume of controlled substances sold to customers. Some distributors used thresholds to track customers' purchases of controlled substances and flag orders as suspicious when purchases exceed those limits. But some of the thresholds were assigned arbitrarily, and not effective. The Committee found instances in which distributors set thresholds but failed to enforce them, assigned artificially high hydrocodone threshold limits with little to no documented justification, or continued to raise threshold levels without thoroughly investigating or documenting the justifications presented by a customer pharmacy.

Despite efforts by DEA to educate distributors about their responsibility to report suspicious orders, the companies reviewed by the Committee failed to address suspicious order monitoring in critical ways. Rather than reporting individual suspicious orders as they were identified, some distributors reported a variety of other types information to DEA over the years. This information included excessive orders encompassing drug shipments that had already been shipped, and suspicious customers such as pharmacies with which distributors had terminated business relationships. Neither of these types of reports informed DEA about suspicious orders in real-time nor did they guarantee the suspicious orders reported to DEA were also blocked by the distributors. The Committee also found that one distributor lacked any formal order monitoring program. Rather, the distributor's employees relied on subjective criteria to identify orders it considered suspicious.

Another critical failure identified by the Committee involved instances in which distributors appeared to turn a blind eye to red flags of possible drug diversion. Despite available information, distributors, at times, took only minimal steps to investigate possible warning signs of diversion and continued to ship controlled substances to suspect pharmacies. In several cases, distributors either failed to fully investigate potentially troubling information they obtained from customer pharmacies or willfully ignored it. These failures raise substantial concern given that DEA has said existing knowledge of a geographic area's problem with controlled substance abuse is a factor that distributors should take into account when evaluating customers. West Virginia has the highest drug overdose rate in the country—meaning distributors should have been particularly attuned to any red flags encountered when conducting due diligence on pharmacies in the state.

Many suspect pharmacies highlighted throughout this report remain open. And while some of the distributors featured in this report have stopped doing business with these pharmacies, other distributors have stepped in to supply them. Even when one distributor

determines a pharmacy poses a risk of diversion, another may not investigate thoroughly enough to uncover the same red flags, or it may choose to ignore them. This revolving door of suppliers highlights the need for the DEA to provide oversight of DEA registrants—both distributors willing to turn a blind eye to signs of diversion and pharmacies engaged in pill mill operations.

Just as the Committee found failures in distributors' anti-diversion efforts, so too did it uncover gaps in the DEA's enforcement posture, both related to its capabilities nationwide and its oversight in West Virginia. One element that hindered DEA's ability to proactively identify diversion trends and target enforcement actions was the difficulty of utilizing data collected through its Automation of Reports and Consolidated Orders System (ARCOS). Pharmaceutical manufacturers and distributors are required to report their controlled substance transactions to the DEA under the CSA. The DEA relies on ARCOS to record and track the approximately 90 million controlled substance transactions reported every year. The system enables DEA to review the data so it can detect abnormal distribution patterns involving individual pharmacies and distributors or larger controlled substances sales trends across the U.S. At the time the opioid epidemic was worsening, however, DEA did not proactively use ARCOS data to investigate diversion trends. Rather, the data were used reactively to strengthen cases once DEA identified targets through other means.

In 2015, DEA created a new online reporting system meant to simplify the ARCOS reporting process and immediately flag errors in registrants' reports. Improvements have enabled DEA to proactively analyze ARCOS and, in 2017, DEA headquarters began sending target packages to field divisions that included analysis of ARCOS data, including drug sales trends within the division, and top pharmacy purchasers. Despite these improvements, DEA still lacks a centralized suspicious order reporting system. Unless dictated by a memorandum of agreement, distributors report suspicious orders to local DEA offices that hold varying regulatory interpretations, resulting in inconsistent handling of the reports. The Committee found evidence that this may have led to confusion on the part of distributors regarding reporting requirements.

The Committee also uncovered several factors that constrained DEA's administrative enforcement actions during the timeframe reviewed. DEA's use of Immediate Suspension Orders (ISOs) dropped precipitously in recent years, from 58 ISOs in Fiscal Year (FY) 2011 to 46 in FY 2012, reaching a low of five in FY 2015. ISOs are an enforcement action the agency relies on to immediately revoke the registrations of entities like doctors, pharmacies, and distributors suspected of drug diversion that pose an imminent danger. The DEA conceded that it had deferred ISOs against registrants—potentially jeopardizing the ability to protect public safety—to allow prosecutors to develop criminal cases. The delays happen often enough that DEA has indicated that it is exploring with DOJ a way to eliminate the indefinite delay. Thus far, DEA has not set any limit on the length of time it is willing to delay an ISO.

Another factor that appears to have limited DEA's use of ISOs was the evolution of the agency's enforcement strategy. In reaction to its interpretation of certain administrative or court rulings, DEA lawyers developed a more cautious approach and began to require additional levels of evidence on the front end of investigations before they would approve administrative action. This manifested, for example, in requests for medical expert testimony to support ISOs and other administrative action.

DEA officials have indicated that more could have been done in West Virginia to investigate and prevent controlled substance diversion, particularly in the 2006-2009 timeframe. However, DEA has not indicated in detail to the Committee what lessons were learned and how DEA could have acted sooner. In 2006, DEA had only two diversion investigators assigned to West Virginia and did not begin to devote significant resources to the state until 2015. Since then, the agency has increased personnel in the state, including through the assignment of an Assistant Special Agent in Charge who is based in Charleston, West Virginia rather than Washington, D.C. as was the case prior to 2016. Tactical diversion squads have also been deployed to West Virginia and in January 2018, DEA opened a new field division that oversees DEA's efforts in the Appalachian region, including Kentucky, Tennessee, and West Virginia.

Taken altogether, the Committee's report outlines a series of missteps and missed opportunities that contributed to the worsening of the opioid epidemic in West Virginia. This investigation identified flaws limiting the effectiveness of the distributors' compliance programs and DEA's enforcement. While focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide. The recently enacted SUPPORT for Patients and Communities Act, (H.R. 6), included several provisions to respond to these concerns. In addition, this report concludes with recommendations to help improve such programs and enforcement, including administrative changes and suggested legislative approaches.

### III. Findings

- In 2002, DOJ OIG found that “DEA’s enforcement efforts [had] not adequately addressed the problem of controlled pharmaceutical diversion” and that diversion investigators accounted for only 10 percent of the agency’s total field investigator positions.
- In 2007, a DEA fact sheet indicated that diversion was a significant problem in West Virginia, which led the nation in methadone-related deaths per capita and had the fastest-growing rate of methadone overdoses.
- In 2011, DEA was aware that distribution of diverted controlled substances was on the rise in West Virginia and that drug trafficking organizations selling the diverted drugs were “particularly active” in the state.
- In 2006, the DEA had two diversion investigators assigned to West Virginia. That year, West Virginia, along with New Mexico, had the highest overdose death rate in the United States.
- Prior to 2010, DEA primarily used ARCOS data reactively in enforcement cases. According to DEA, technical limitations and data errors made it difficult for the DEA to utilize ARCOS data to identify investigative leads.
- Had DEA more proactively used ARCOS data, it could have discovered that between 2006 and 2012 distributors shipped more than 13 million doses of hydrocodone and oxycodone to Sav-Rite Pharmacy No. 1. By contrast, four Rite Aid pharmacies in the same zip code prefix area each received between 1.48 and 2.66 million doses of hydrocodone and oxycodone between 2006 and 2016.
- According to DEA, an analysis of ARCOS data from distributors who sold controlled substances to West Virginia pharmacies “demonstrates similar patterns that DEA observed in Florida in 2011 and 2012.”
- DEA received suspicious order reports regarding sales to Tug Valley Pharmacy as early as 2008 and cited controlled substance sales to the pharmacy in an OTSC against a distributor in 2015, yet never issued an ISO or OTSC against the pharmacy.
- Distributors have expressed concern about the lack of guidance or feedback provided by the DEA, including on how it utilizes information provided by distributors, such as suspicious order reports.
- For due process reasons, it is current DEA practice not to inform distributors or other registrants about customers that “may have engaged in improper behavior.”

- The number of ISOs issued by DEA declined from a high of 58 in FY 2011 to a low of five in FY 2015. In FY 2018, DEA issued the same number of ISOs as it had in all of 2015, 2016 and 2017 combined.
- DEA's Chief Administrative Law Judge first highlighted the decline of DEA enforcement actions in a quarterly report issued in June 2013. He hypothesized that the reason for the decline was a new vetting and quality assurance initiative instituted by DEA's Office of Chief Counsel.
- In April 2015, DEA's Chief Administrative Law Judge noted that the decline in administrative cases did not appear to be the product of the DEA bringing larger or more complicated cases, rather there were simply fewer cases being brought to trial before the DEA ALJs.
- Memoranda drafted by DEA's Chief Administrative Law Judge documents an increased reliance by the DEA on no-state authority cases. This led the judge to deduce in January 2016 that "states have reacted to the reduction in the DEA enforcement actions since FY2012 by attempting to pick up the slack with their own administrative enforcement actions."
- In February 2013, the Chief of DEA's Office of Diversion Control's Pharmaceutical Investigations Section noticed a change in the way the Chief Counsel's Office handled administrative cases, including downgrades of ISOs to OTSCs and a trend of declinations.
- In 2013 the DEA's Office of Chief Counsel's policy toward requiring expert witnesses in ISO or OTSC cases was circumstance dependent. While experts were not required in every case, cases where DEA prevailed without medical expert testimony were "the exception rather than the rule."
- In May 2013, the DEA's Associate Chief Counsel was of the legal opinion that a delay in the issuance of an ISO may weaken DEA's ability to successfully argue that a registrant's conduct constituted an imminent danger to the public health or safety.
- E-mails between the DEA's Office of Chief Counsel and the Office of Diversion Control demonstrate an acrimonious relationship over the proper handling of enforcement actions, which impacted relationships within the agency as well as dealings with the DOJ.
- Federal prosecutors ask the DEA to postpone enforcement actions against registrants with such frequency that the requests became an "ongoing theme" behind delays in DEA enforcement actions.
- DEA allowed Sav-Rite No. 1 to maintain its registration for more than two years after the 2009 raid and forced closure of the same owner's Sav-Rite No. 2, during which time the pharmacy received somewhere between one to two million doses of hydrocodone and oxycodone.



- Distributors can obtain dispensing data from pharmacies that show the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription.
- McKesson supplied Sav-Rite No. 1 with more than 5.66 million doses of hydrocodone and oxycodone in 2006 and 2007. Based on these two years alone, Sav-Rite No. 1 was McKesson's third largest hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.
- McKesson's due diligence file for Sav-Rite No. 1 contained only one document, a November 2007 written declaration from the pharmacy's owner representing that the pharmacy sells only legitimate prescriptions.
- Family Discount Pharmacy in Mount Gay-Shamrock was McKesson's biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017. McKesson supplied the pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014, including more than 3.82 million doses in 2006 and 2007 alone.
- McKesson did not retain sufficient due diligence files documenting its relationship with Family Discount Pharmacy in Mount Gay-Shamrock during 2006 and 2007, including documentation regarding the company's apparent decision to terminate the pharmacy as a customer for "compliance reasons."
- McKesson did not consider its prior relationship with Family Discount Pharmacy when evaluating the pharmacy's new customer application in 2010, with a member of McKesson's regulatory affairs division at one point stating, "I cannot see any reason we should be hesitant" with respect to the pharmacy.
- In 2010, McKesson set the hydrocodone threshold for Family Discount Pharmacy, a pharmacy previously terminated by McKesson for compliance reasons, at a level that was 31 times higher than what the company determined warranted supplementary explanation on its new customer questionnaire.
- McKesson established a business relationship with Tug Valley Pharmacy in July 2015, despite knowledge of pending litigation against the pharmacy related to the alleged diversion of controlled substances. McKesson did not address the litigation with the pharmacy's owner while conducting its due diligence. McKesson later cited the litigation as the reason it suspended Tug Valley's ability to purchase controlled substances after the pharmacy and litigation were featured on *CBS News* in January 2016.
- In February 2016, McKesson received a new customer application from Tug Valley Pharmacy, representing that it was under new ownership. The application contained multiple

errors. McKesson also received a pharmacy questionnaire in which the new owner was unable to answer basic questions about the pharmacy.

- In February 2016, Tug Valley Pharmacy was sold through a financing arrangement under which the former owner retained a security interest in the pharmacy as collateral for making a loan to the new owner to facilitate the purchase.
- Despite McKesson policies stating that invalid, inaccurate, or inconsistent answers on a questionnaire are a cause for concern, it does not appear McKesson sought further explanation from Tug Valley Pharmacy's new owner as to why he was unable to answer several basic questions about the pharmacy as posed in McKesson's pharmacy questionnaire.
- In February 2016, Tug Valley Pharmacy's new owner told McKesson that the former owner no longer had an association with the pharmacy. Not only was this statement not true, but McKesson was in possession of a document at the time of its 2016 approval indicating that the former owner maintained a security interest in the pharmacy. The Committee has seen no indication to suggest that McKesson asked the pharmacy about the former owner's continuing security interest.
- AmerisourceBergen's due diligence documents for Westside Pharmacy included a list of six "Pain Doctors." Two of the doctors were located a four-hour and eleven-and-a-half-hour round-trip drive from the pharmacy respectively. Five of the six doctors have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing, or are currently under federal investigation.
- Based on documents provided to the Committee, in 2011, AmerisourceBergen did not investigate why Westside Pharmacy filled prescriptions for physicians located hours away from the pharmacy.
- AmerisourceBergen told the Committee that it placed stricter limits on Westside Pharmacy's purchasing of controlled substances in late 2012. The Committee received no documents that reference these limitations or the pharmacy's apparent decision to subsequently end its business relationship with AmerisourceBergen.
- AmerisourceBergen began doing business with Westside Pharmacy again in January 2016. Documents produced to the Committee give no indication to suggest that AmerisourceBergen considered the company's 2012 decision to place stricter limits on the pharmacy's ability to purchase controlled substances.
- Prior to onboarding Westside Pharmacy as a customer in January 2016, AmerisourceBergen does not appear to have consulted public news reports that would have alerted the company to red flags related to some of the pharmacy's top prescribing physicians. According to AmerisourceBergen, "[n]ews searches for prescribing physicians are not a standard part of ABDC's new customer review[.]"

- In December 2015, when Westside Pharmacy submitted a prospective customer application to AmerisourceBergen, two of the pharmacy's top prescribers of opioids were located four-hour round-trip drives from the pharmacy.
- In February 2011, H.D. Smith suspended Family Discount Pharmacy's ability to order hydrocodone, after controlled substances constituted nearly 80 percent of the pharmacy's overall purchases the month prior.
- In 2015, Family Discount Pharmacy disclosed to H.D. Smith that it had "10 days of over 1000 Rx's filled" in January 2015. The dispensing volume was despite the pharmacy's location across the street from two other pharmacies in a town of less than 2,000 people.
- When H.D. Smith onboarded Family Discount Pharmacy for a second time in 2015, the pharmacy had recently been terminated by two other wholesale distributors – with the pharmacy disclosing that one termination was based on the volume of the pharmacy's hydrocodone orders.
- Between 2007 and 2009, H.D. Smith distributed more than more than 5.65 million doses of hydrocodone to two pharmacies located approximately four blocks apart in Williamson, a town of 3,191 people.
- H.D. Smith's distribution of hydrocodone to Tug Valley Pharmacy increased more than 1,000 percent in a five-month-period in 2007, from 19,100 hydrocodone doses to 224,400 hydrocodone doses. Information H.D. Smith provided the Committee did not include documentation to justify or explain the dramatic increase in its distribution of hydrocodone to Tug Valley Pharmacy.
- H.D. Smith began implementing controlled substance thresholds for its customers, including Tug Valley Pharmacy, in 2008. The thresholds limited Tug Valley's hydrocodone purchases to under 50,000 doses a month, less than a quarter of what the pharmacy purchased in November 2007 when no thresholds were in place.
- Between 2006 and 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley Drug Company, located in Williamson, West Virginia.
- From June 2008 to March 2011, Cardinal set Hurley Drug Company's hydrocodone threshold at 155,000, three times higher than its average monthly purchases in 2009 and 14 times higher than its average monthly purchases in 2010.
- Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley Drug Company on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month. This was a fifteen-fold increase in the threshold in two weeks.

- Cardinal's due diligence and threshold documentation for Hurley Drug Company provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008.
- Based on documentation provided to the Committee, Hurley Drug Company did not hit its hydrocodone threshold in the approximately three years it was set at 155,000 dosage units a month.
- Cardinal did not reevaluate the threshold between June 2008 and March 2011 to determine whether it was accurately set. This includes after learning of derogatory information regarding Dr. Katherine Hoover, a doctor for whom Hurley Drug Company filled prescriptions.
- Cardinal reviewed Hurley Drug Company's account before the pharmacy's switch from a secondary to primary customer, initially anticipating that thresholds would need to be increased to accommodate growth. However, as a result of the review, Cardinal cut Hurley's hydrocodone threshold from 155,000 to 66,501 dosage units.
- Between 2006 and 2012, Cardinal Health distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, population 1,779. This amount made the pharmacy Cardinal Health's top purchaser of hydrocodone and oxycodone products in West Virginia between 2006 and 2017.
- In June 2008, Family Discount Pharmacy cited an increase in hydrocodone prescriptions written by a single doctor—Dr. Katherine Hoover—in requesting an increase to its thresholds. Based on documents provided to the Committee, Cardinal did not inquire further about Dr. Hoover's prescribing at that time and raised the hydrocodone thresholds for the pharmacy.
- In September 2008, Cardinal learned of derogatory information regarding Dr. Hoover, specifically, that two pharmacists in Kentucky would not fill prescriptions for Dr. Hoover based on concerns about her practice. Documents provided by Cardinal do not indicate the company reevaluated Family Discount Pharmacy's hydrocodone thresholds after learning of this information.
- On at least three occasions, Family Discount Pharmacy cited the closure of another pharmacy as a reason why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims.
- After Cardinal formed a Large Volume – Tactical and Analytical Committee, it reviewed and reduced Family Discount Pharmacy's hydrocodone threshold limit from 154,500 dosage units to 75,005 dosage units.

- In 2007, McKesson shipped an average of 9,650 hydrocodone pills a day to the Sav-Rite No. 1 pharmacy in Kermit, West Virginia. This was 36 times the threshold amount set by the Lifestyle Drug Monitoring Program.
- McKesson continued to supply Sav-Rite No. 1 with massive quantities of opioids for five months after representing to the DEA that it had reviewed all customers pursuant to the Lifestyle Drug Monitoring Program.
- McKesson supplied just under 300 million doses of hydrocodone and oxycodone to West Virginia pharmacies between April 2006 and 2016.
- McKesson did not submit suspicious order reports to the DEA regarding orders placed by West Virginia pharmacies until August 1, 2013.
- Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.
- McKesson devoted “substantial resources to enhance and revise” its Controlled Substance Monitoring Program in 2013, the same year the DEA served the distributor an Administrative Inspection Warrant and an Administrative Subpoena to obtain records from its Aurora, Colorado distribution facility.
- Cardinal was West Virginia’s largest supplier of oxycodone and hydrocodone between 2005 and 2016, distributing approximately 366 million doses during that time.
- Cardinal did not have a consolidated suspicious order reporting system in place until 2012 and was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012.
- Since 2008, Cardinal’s policies have required notification of DEA regarding suspicious orders. The company was unable to provide comprehensive data prior to 2012 demonstrating compliance with these reporting policies in West Virginia.
- Cardinal issued a “complete rewrite” of its Detecting and Reporting Suspicious Orders and Responding to Threshold Events policy in April 2012. This was done a month before it entered into a settlement agreement with DEA to resolve allegations the company failed to report suspicious orders.
- AmerisourceBergen distributed nearly 250 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.
- In June 2007, AmerisourceBergen reached a settlement to resolve allegations it failed to maintain effective controls to prevent controlled substance diversion. A month later, the company began to block suspicious orders and submit suspicious order reports to the DEA.

Prior to July 2007, AmerisourceBergen mailed copies of suspicious order reports to the DEA on a monthly basis but did not block any orders deemed suspicious.

- The number of suspicious order reports regarding West Virginia pharmacies that AmerisourceBergen submitted to DEA and blocked from shipment ranged from a high of 792 orders in 2013 to a low of three orders in 2016.
- AmerisourceBergen responded inconsistently when pharmacies triggered repeated suspicious orders. In 2009, the company investigated and terminated its relationship with Tug Valley Pharmacy after reporting 36 suspicious orders in one month. However, AmerisourceBergen continued to supply Beckley Pharmacy for nearly a year after reporting 109 suspicious orders in five months from 2013 to 2014.
- Before providing DEA with order-specific suspicious order reports, Miami-Luken previously reported customers it stopped doing business with. Documents provided to the Committee appear to indicate the first customer termination report was made to DEA in October 2012.
- Based on documents produced to the Committee, the first order-specific suspicious order report Miami-Luken made because a pharmacy hit a monthly threshold was submitted to DEA on May 14, 2014.
- Miami-Luken provided DEA with at least two suspicious order reports in 2014, 10 in 2015, 33 in 2016, and one in 2017. The company also stopped selling controlled substances to at least 20 pharmacies.
- According to Miami-Luken's Chairman of the Board, prior to 2013, the company made "rudimentary efforts" to monitor suspicious orders and decisions on what constituted a suspicious order were made based on "one's feeling."
- Miami-Luken did not implement a functional suspicious order monitoring system until 2015.
- In 2008 and 2009, H.D. Smith submitted individual suspicious order reports to DEA for every transaction that triggered its Controlled Substance Order Monitoring Program. The company altered its practices in subsequent years, and instead of reporting individual orders, it alerted DEA when it stopped selling controlled substances to a pharmacy or identified other suspicious customer activity.
- All but one of the 393 suspicious order reports H.D. Smith submitted to the DEA in 2008 and 2009 related to orders placed by Family Discount Pharmacy, Hurley Drug Company, Sav-Rite No. 1, and Tug Valley Pharmacy.
- H.D. Smith terminated business relationships with 15 West Virginia pharmacies over compliance concerns or failure to cooperate with due diligence efforts, but only provided documentation indicating it informed DEA about six of the terminations.

- H.D. Smith's 2009 policy states that suspicious order information will be sent to DEA Headquarters and DEA field offices. The policy does not indicate the company changed its reporting procedures to focus on suspicious activity and customers rather than order-specific suspicious order reports.
- When McKesson reinstated Tug Valley Pharmacy as a customer in February 2016, the pharmacy's new owner assured McKesson that its former owner no longer had any association with the pharmacy. However, after learning in October 2017 the former owner was employed by the pharmacy, as was a pharmacist with a felony conviction related to controlled substances, McKesson did not terminate or restrict Tug Valley's ability to purchase controlled substances.
- During a November 1, 2017 conversation between McKesson's Director of Regulatory Affairs and Tug Valley's new owner, the pharmacy owner made representations about the former owner and the convicted pharmacist that McKesson did not attempt to verify until February 28, 2018.
- McKesson's February 28, 2018 site visit to Tug Valley, which resulted in the pharmacy's termination, was initiated by a third-party request, not by McKesson's own proactive due diligence.
- At various times during a ten-year period, McKesson shipped more than 8.29 million doses of opioids to two commonly owned pharmacies, located just three miles apart in rural West Virginia.
- Family Discount Pharmacy in Mount Gay-Shamrock purchased nearly five times the amount of hydrocodone from McKesson than a nearby Rite Aid Pharmacy. McKesson fulfilled the orders placed by Family Discount Pharmacy during a time when the surrounding area had "serious prescription drug abuse issues" per a local law enforcement officer.
- McKesson terminated Family Discount's Mount Gay-Shamrock pharmacy in April 2014, but did not undertake an on-site regulatory review of the co-owned Stollings location until sixteen months later. McKesson did review purchase data from the Stollings pharmacy around the time it terminated the Mount Gay-Shamrock location, however, documentation produced to the Committee regarding that review consisted of only a single page of handwritten notes.
- An H.D. Smith analysis found a single doctor prescribed more than 158,000 doses of hydrocodone dispensed by Tug Valley Pharmacy in February 2008. During the same month, a second doctor was responsible for prescribing more than 40,000 doses of hydrocodone dispensed by the pharmacy. Combined, these two doctors prescribed, and Tug Valley Pharmacy dispensed, nine times the then-monthly volume for an average retail pharmacy in rural West Virginia.

- H.D. Smith reported its concerns regarding Tug Valley Pharmacy and Hurley Drug Company to the DEA in April 2008, including that two doctors wrote 87 percent of the hydrocodone prescriptions filled by Tug Valley Pharmacy, and that a single doctor wrote 69 percent of the hydrocodone prescriptions filled by Hurley Drug Company. But the company did not stop doing business with either pharmacy at that time.
- Approximately six months after the company reported concerns about Hurley Drug Company's opioid dispensing to the DEA, an H.D. Smith representative recommended increasing the pharmacy's thresholds for controlled substances purchases, noting that the pharmacy did not "appear to [have] a high degree of risk to mitigate."
- Between December 2007 and April 2009, H.D. Smith provided Sav-Rite No. 1 in Kermit, population 406, with more than 1.48 million doses of hydrocodone and oxycodone.
- H.D. Smith reported Sav-Rite No. 1 to the DEA in April 2008 "because it was ordering a significant amount of hydrocodone and approximately 25% of the hydrocodone prescriptions were written by Dr. Katherine Hoover." The company did not stop doing business with Sav-Rite No. 1 at that time.
- H.D. Smith conducted a site visit at Sav-Rite No. 1 in November 2008 that presented numerous red flags, including the pharmacy's owner telling H.D. Smith he inferred diversion from the pharmacy was likely. H.D. Smith did not terminate Sav-Rite No. 1 as a customer or restrict its ability to purchase controlled substances at that time.
- In 2008, the first full year of its relationship with Family Discount Pharmacy in Mount-Gay Shamrock, H.D. Smith supplied the pharmacy with more than 1.13 million doses of hydrocodone and oxycodone. The pharmacy estimated it would purchase 50 percent of its controlled substances purchases from H.D. Smith, meaning the company would have had reason to believe the pharmacy was receiving far more opioids than those H.D. Smith supplied.
- In November 2009, H.D. Smith documented that Family Discount Pharmacy was continuing to reach its hydrocodone threshold and that 51 percent of the hydrocodone prescriptions filled at the pharmacy were written by Dr. Katherine Hoover.
- Upon discovering that Dr. Hoover was responsible for 51 percent of the hydrocodone prescriptions filled at Family Discount Pharmacy, documents produced to the Committee give no indication that H.D. Smith examined, or considered its earlier findings and actions related to Dr. Hoover and other nearby pharmacies.
- Between 2009 and 2015, Miami-Luken shipped more than 4.38 million doses of hydrocodone and oxycodone to Westside Pharmacy, located in Oceana West Virginia, population 1,394.



- As early as 2011, Miami-Luken was aware that Westside Pharmacy was filling prescriptions for doctors located hours away, and that a large number of prescriptions for hydrocodone and oxycodone were paid for with cash. Despite this knowledge, the company continued to supply the pharmacy with more than 3.36 million opioids over the next four years.
- Miami-Luken's May 2015 analysis of Westside Pharmacy's dispensing data showed that three doctors wrote 74 percent of the oxycodone prescriptions filled by the pharmacy between February 2015 and April 2015. Following the company's analysis, the pharmacy pledged it would no longer fill prescriptions written by several doctors identified by Miami-Luken, including Drs. David Morgan and Sanjay Mehta.
- In October 2015, after determining that Westside Pharmacy continued to fill prescriptions written by Drs. Morgan and Mehta, Miami-Luken did not immediately terminate the pharmacy or restrict its ability to order controlled substances.
- In November 2015, Miami-Luken approved an increase to Westside Pharmacy's oxycodone threshold despite being aware of the pharmacy's prior deceit and red flags related to its dispensing practices and prescribing physicians.

## IV. Background

### A. Origins of the Modern Opioid Epidemic

The United States' history of battling opioid abuse and addiction dates back more than 150 years to the Civil War-era, when doctors liberally used morphine and other opioids to treat soldiers injured in battle.<sup>3</sup> As illustrated in the chart below, the modern opioid epidemic's origins can be traced back to the late 1990s when, according to the National Institute on Drug Abuse, "pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates."<sup>4</sup> According to the Centers for Disease Control and Prevention (CDC), more than 351,000 lives have been lost to opioid overdoses since 1999.<sup>5</sup>

The dramatic growth in opioid consumption is unique to the United States. In a 2017 technical report, published in accordance with Article 15 of the Single Convention on Narcotic Drugs of 1961, the International Narcotics Control Board wrote, "[i]n 2016, the country with the highest consumption of hydrocodone continued to be the United States, with 33.4 tons, equivalent to 99.1 per cent of total global consumption."<sup>6</sup> The report also noted "consumption of oxycodone was concentrated in the United States (72.9 per cent of the world total)."<sup>7</sup> In May 2017, the United Nations Office of Drugs on Crime issued its *World Drug Report*, and noted that

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<sup>3</sup> See Erick Trickey, *Inside the Story of America's 19<sup>th</sup>-Century Opiate Addiction*, SMITHSONIAN.COM, Jan. 4, 2018, <https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/>. See also Janet Woodcock, M.D., Dir., Center for Drug Evaluation and Research, U.S. Food and Drug Admin., *The Larger Landscape of Pain Management: Seeking Balance*, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM489201.pdf> (last visited Nov. 19, 2018).

<sup>4</sup> Nat'l Inst. On Drug Abuse, *Opioid Overdose Crisis*, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#three> (last visited Nov. 19, 2018). It has also been postulated that the modern opioid crisis is actually a sub-epidemic of a larger overall drug overdose epidemic in the United States, based upon data analysis of mortality records between 1979 and 2016. See Hawre Jalal, et al., *Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016*, 361 *Science* 6408, eaau1184 (2018) available at <http://science.sciencemag.org/content/361/6408/eaau1184>.

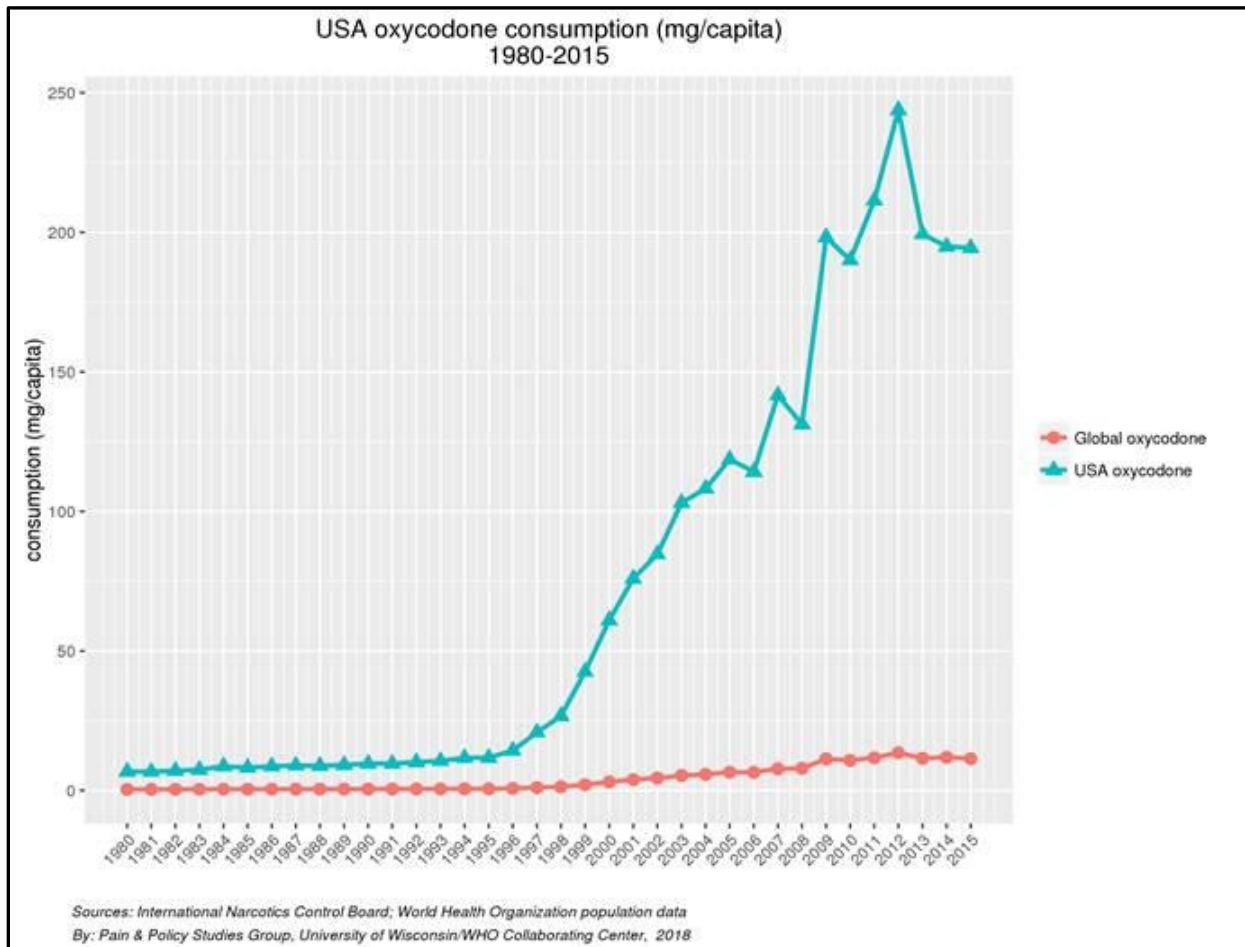
<sup>5</sup> Centers for Disease Control and Prevention, *Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016*, available at [https://www.cdc.gov/nchs/data/databriefs/db294\\_table.pdf#page=4](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4).

<sup>6</sup> Int'l Narcotics Control Bd., *Narcotic Drugs: Estimated World Requirements for 2018; Statistics for 2016*, 36 (2017) available at [https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic\\_drugs\\_technical\\_publication\\_2017.pdf](https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic_drugs_technical_publication_2017.pdf). The International Narcotics Control Board is an independent expert body, established by the Single Convention on Narcotic Drugs of 1961, and is responsible for the monitoring the implementation of United Nations international drug control conventions. See Single Convention on Narcotic Drugs of 1961, *opened for signature* Jan. 24, 1961, 520 U.N.T.S. 7515 (entered into force Aug. 8, 1975) available at [https://www.unodc.org/pdf/convention\\_1961\\_en.pdf](https://www.unodc.org/pdf/convention_1961_en.pdf).

<sup>7</sup> Int'l Narcotics Control Bd., *Narcotic Drugs: Estimated World Requirements for 2018; Statistics for 2016*, 37 (2017) available at [https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic\\_drugs\\_technical\\_publication\\_2017.pdf](https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic_drugs_technical_publication_2017.pdf).

while the harm caused by opioids is a problem for many countries, it is “particularly evident in the United States of America.”<sup>8</sup> The reported also stated:

The United States accounts for approximately one quarter of the estimated number of drug-related deaths worldwide, including overdose deaths, which continue to rise. Mostly driven by opioids, overdose deaths in the United States more than tripled during the period 1999-2015, from 16,849 to 52,404 annually, and increased by 11.4 per cent in the past year alone, to reach the highest level ever recorded. Indeed, far more people die from the misuse of opioids in the United States each year than from road traffic accidents or violence.<sup>9</sup>



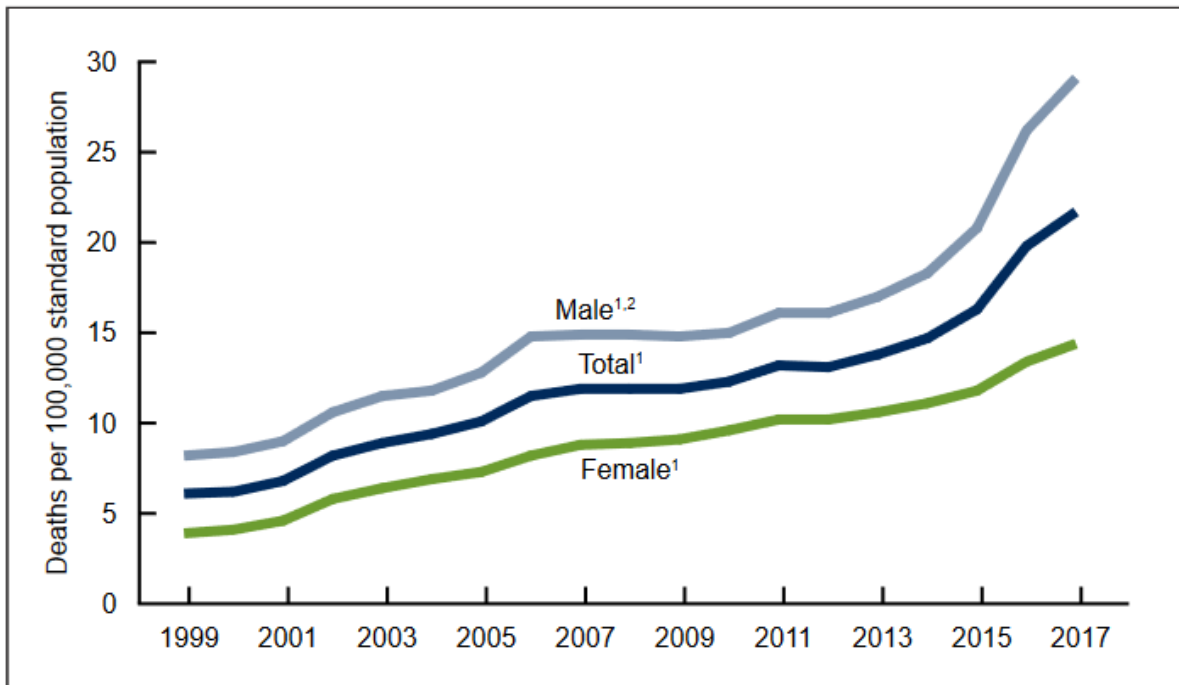
The rate of drug overdose deaths has increased dramatically since 1999. According to the CDC, and as illustrated in the chart below, the “age-adjusted rate of drug overdose deaths increased from 6.1 per 100,000 standard population in 1999 to 21.7 in 2017.”<sup>10</sup>

<sup>8</sup> United Nations Office on Drugs and Crime, *World Drug Report 2017 – Exec. Summary, Conclusions and Policy Implications*, (May 2017) 10 available at [http://www.unodc.org/wdr2017/field/Booklet\\_1\\_EXSUM.pdf](http://www.unodc.org/wdr2017/field/Booklet_1_EXSUM.pdf).

<sup>9</sup> *Id.*

<sup>10</sup> Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999-2017*, NCHS Data Brief (Nov. 2008) available at <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>.

Figure 1. Age-adjusted drug overdose death rates: United States, 1999–2017



Source: Centers for Disease Control and Prevention

In November 2018, the Centers for Disease Control and Prevention released data which showed that overall life expectancy in the United States decreased during 2017, which the agency attributes to increases in suicides and overdose deaths.<sup>11</sup> Dr. Robert R. Redfield, CDC Director, stated:

The latest CDC data show that the U.S. life expectancy has declined over the past few years. Tragically, this troubling trend is largely driven by deaths from drug overdose and suicide. Life expectancy gives us a snapshot of the Nation’s overall health and these sobering statistics are a wakeup call that we are losing too many Americans, too early and too often, to conditions that are preventable.<sup>12</sup>

In 1999, shortly after opioid prescriptions began to increase precipitously, rogue internet pharmacies began to emerge in the United States.<sup>13</sup> These internet sites used a variety of different tactics to entice individuals to order controlled substances, irrespective of any

<sup>11</sup> Betsy McKay, *U.S. Life Expectancy Falls Further*, WALL ST. J., Nov. 29, 2018, <https://www.wsj.com/articles/u-s-life-expectancy-falls-further-1543467660>.

<sup>12</sup> Press Release, Centers for Disease Control and Prevention, CDC Director’s Media Statement on U.S. Life Expectancy (Nov. 29, 2018) available at <https://www.cdc.gov/media/releases/2018/s1129-US-life-expectancy.html>.

<sup>13</sup> See U.S. Gov’t Accountability Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69 (Oct. 2000) available at <https://www.govinfo.gov/content/pkg/GAOREPORTS-GAO-01-69/pdf/GAOREPORTS-GAO-01-69.pdf>.

underlying medical need, and then facilitated fulfillment of these orders through kickback agreements made with unscrupulous doctors and traditional retail pharmacies.<sup>14</sup> The volume of opioids dispensed in fulfillment of internet pharmacy orders was massive. For example, in 2006 alone, the DEA identified 34 pharmacies that were fulfilling orders placed on rogue internet sites and dispensed a combined total of more than 98 million dosage units of hydrocodone, an average of approximately 2.9 million dosage units per pharmacy.<sup>15</sup> By comparison, each of these pharmacies dispensed approximately 3,195 percent more hydrocodone than the average retail pharmacy in the United States dispensed at that time, which, according to the DEA, was approximately 88,000 dosage units annually.<sup>16</sup>

In the mid-2000s, the DEA dedicated a significant amount of resources to combating rogue online pharmacies. During this time, the DEA initiated enforcement actions against distributors alleged to have supplied controlled substances to pharmacies that were fulfilling orders placed on the internet,<sup>17</sup> as well as doctors<sup>18</sup> and retail pharmacies<sup>19</sup> that were also engaged in internet pharmacy diversion schemes.

In response to the proliferation of rogue internet pharmacies, Congress enacted the Ryan Haight Online Pharmacy Consumer Protection Act on October 15, 2008 (hereinafter “Ryan Haight Act” or the “Act”).<sup>20</sup> The Ryan Haight Act amended the CSA and required, among other things, that practitioners conduct at least one in-person medical evaluation of a patient before they are permitted to prescribe that patient controlled substances.<sup>21</sup> The Act also effectively legislated rogue internet pharmacies out of existence as it required existing DEA pharmacy registrants to obtain a modification of their registration to operate as an “online pharmacy” which the Act broadly defined.<sup>22</sup> The only entities permitted to operate as online pharmacies were those that obtained such a modification. Since the rogue internet sites that facilitated the orders of controlled substances were not registered with the DEA, they were ineligible to obtain the required modification and thus were no longer able to operate.

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<sup>14</sup> *Online Pharmacies and the Problem of Internet Drug Abuse, Hearing Before Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary*, 110th Cong. Serial No. 110-186 at 3 (2008) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin.) available at <https://judiciary.house.gov/wp-content/uploads/2008/06/Rannazzisi080624.pdf>.

<sup>15</sup> See 74 Fed. Reg. 15,597, Apr. 6, 2009.

<sup>16</sup> 74 Fed. Reg. 15,597, Apr. 6, 2009.

<sup>17</sup> See 72 Fed. Reg. 36,487, July 3, 2007. See also *In re Richie Pharmaceutical*, Memorandum of Agreement (Aug. 7, 2007) available at <https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Richie%20Pharmaceutical%20-%202007.pdf> and Press Release, U.S. Drug Enforcement Admin., Long Island Co. Pays \$800k for Failing To Report Suspicious Orders to Web Pharmacies (July 10, 2007) available at <https://web.archive.org/web/20151009051552/http://www.dea.gov/divisions/nyc/2007/nyc071007p.html>.

<sup>18</sup> See 71 Fed. Reg. 77,791, Dec. 27, 2006.

<sup>19</sup> See 72 Fed. Reg. 50,397, Aug. 31, 2007.

<sup>20</sup> Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. 110-425, 122 Stat. 4820 (2008).

<sup>21</sup> 21 U.S.C. § 829(e).

<sup>22</sup> 21 U.S.C. § 802 and 21 U.S.C. § 823(f).

## B. The Opioid Epidemic's Impact in West Virginia

The opioid epidemic's impact has been particularly acute in West Virginia, beginning with the influx of OxyContin to the state during the late 1990s.<sup>23</sup> The sudden influx of prescription opioids, leading to the resulting increases in abuse and addiction, has had profound effects on West Virginia. Between 1999 and 2004, the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent, giving West Virginia the highest unintentional drug overdose death rate in the United States at the time.<sup>24</sup> A study published in the *Journal of the American Medical Association* in December 2008 found that, in 2006, 93 percent of the unintentional overdose deaths attributable to prescription drugs in West Virginia involved opioids.<sup>25</sup> The study also found that 63 percent of the overdose deaths were associated with pharmaceutical diversion, and 21 percent exhibited evidence of doctor shopping.<sup>26</sup> Citing a DEA report entitled, *DEA Appalachian Report: West Virginia 2007*, the study also noted “[t]he Drug Enforcement Administration confirms that drug diversion was widespread in West Virginia and the Appalachian region during this period.”<sup>27</sup>

In 2017, West Virginia continued to have the highest overdose death rate in the country,<sup>28</sup> and a report issued by the West Virginia Department of Health and Human Resources found that the number of overdose deaths in the state increased by more than 316 percent between 2001 and 2016, with most overdose deaths involving at least one opioid.<sup>29</sup> Reporting by the *Charleston Gazette-Mail* found that distributors sent more than 780 million doses of hydrocodone and oxycodone to West Virginia between 2007 and 2012, with AmerisourceBergen, Cardinal Health, and McKesson responsible for more than half of that amount, approximately 423 million doses.<sup>30</sup> In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.<sup>31</sup>

The opioid crisis in West Virginia has also caused many societal challenges for its residents and has had a deleterious impact on the state's economy. Press reports indicate the

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<sup>23</sup> See U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, 9 (Dec. 2003) available at <https://www.gao.gov/new.items/d04110.pdf>.

<sup>24</sup> Memorandum from Aron J. Hall, DVM, Epidemic Intelligence Service Officer, W. Va. Dep't of Health & Human Res., et al. to Douglas H. Hamilton, M.D., PhD, Dir., Epidemic Intelligence Service, Centers for Disease Control and Prevention, 2 (Oct. 12, 2007) (On file with Committee).

<sup>25</sup> Aron J. Hall, DVM, MSPH, et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, Vol. 300 No. 22, JAMA, 2613, 2619 (2008).

<sup>26</sup> *Id.* at 2616.

<sup>27</sup> *Id.* at 2619.. With respect to the Appalachian region, generally, the study cites to a 2008 report issued by the DOJ's National Drug Intelligence Center, entitled, *Drug Market Analysis 2008: Appalachia High Intensity Drug Trafficking Area*.

<sup>28</sup> Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999-2017*, NCHS Data Brief (Nov. 2008) available at <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>.

<sup>29</sup> W. Va. Dep't of Health and Human Res., *2016 West Virginia Overdose Fatality Analysis: Healthcare Systems Utilization, Risk Factors, and Opportunities for Intervention*, at 9, Dec. 20, 2017 available at [https://dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis\\_004302018.pdf](https://dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf).

<sup>30</sup> 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](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).

<sup>31</sup> *Id.*

opioid epidemic has “caus[ed] a void” in West Virginia’s economy of nearly \$1 billion.<sup>32</sup> An American Enterprise Institute study, released in March 2018, concluded that West Virginia’s economy suffered more economic harm on a per capita basis from the opioid epidemic than any other state in the country in 2015 when mortality costs are factored in.<sup>33</sup> The study also found that of the 20 counties in the United States that had been most severely impacted by the opioid crisis from an economic perspective, 11 were located in West Virginia.<sup>34</sup>

### C. Statutory and Regulatory Framework

Federal efforts to address the proliferation of opioids and drug abuse in the United States can largely be traced back to the early twentieth century when Congress enacted the Harrison Narcotics Tax Act (Harrison Act) in 1914.<sup>35</sup> The Harrison Act required, among other things, that manufacturers and distributors of opium, from which opioids are derived, and cocaine register with the Bureau of Internal Revenue, pay a special tax, and keep records of their transactions on forms issued by the Bureau of Internal Revenue.<sup>36</sup> Congress created the Federal Bureau of Narcotics within the Department of the Treasury in 1930 for purposes of enforcing the Harrison Act and to assume the responsibilities of the Federal Narcotics Control Board, a body established under the Narcotic Drugs Import and Export Act of 1922 to oversee the import and export of opiates and other drugs for medical and legitimate purposes only.<sup>37</sup>

Over the next several decades, Congress enacted a number of statutes to address drug manufacturing and distribution in the United States.<sup>38</sup> In 1968, the Department of Justice (DOJ) assumed principal authority to enforce federal drug laws when the Bureau of Narcotics merged with the Bureau of Drug Abuse Control, which had recently been established within the U.S. Food and Drug Administration (FDA), to form the Bureau of Narcotics and Dangerous Drugs.<sup>39</sup> In a special message to Congress, proposing the formation of the Bureau of Narcotics and

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<sup>32</sup> *WVU chief economist: Opioid crisis has cost West Virginia nearly \$1 billion*, WVU Today, Nov. 28, 2017, <https://wvutoday.wvu.edu/stories/2017/11/28/wvu-chief-economist-opioid-crisis-has-cost-west-virginia-nearly-1-billion>.

<sup>33</sup> Alex Brill and Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis* at 4, American Enter. Inst., Mar. 20, 2018, available at [https://www.aei.org/wp-content/uploads/2018/03/Geographic\\_Variation\\_in\\_Cost\\_of\\_Opioid\\_Crisis.pdf](https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf).

<sup>34</sup> *Id.* at 8.

<sup>35</sup> LISA N. SACCO, CONG. RESEARCH SERV., R43749, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS (2014).

<sup>36</sup> Harrison Narcotics Tax Act, Pub. L. No. 63-223, 38 Stat. 785 (1914). The Bureau of Internal Revenue was established within the Department of the Treasury in 1862 and was responsible for the assessment and collection of internal revenue in the United States. The Bureau was reorganized in 1953 and was renamed the Internal Revenue Service. See U.S. Dep’t of the Treasury, *History – Internal Revenue Service* (last updated Oct. 3, 2010) available at <https://www.treasury.gov/about/history/Pages/irs.aspx>.

<sup>37</sup> See Pub. L. 71-357, 46 Stat. 585 (1930). See also Narcotic Drugs Import and Export Act, Pub. L. No. 67-227, 42 Stat. 596 (1922).

<sup>38</sup> See Narcotics Act of 1946, Pub. L. No. 79-320, 60 Stat. 39 (1946); Boggs Act of 1952, Pub. L. No. 82-255, 65 Stat. 767 (1952); Narcotic Control Act of 1956, Pub. L. No. 84-728, 70 Stat. 567 (1956); Narcotics Manufacturing Act of 1960, Pub. L. No. 86-429, 74 Stat. 55 (1960); Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, 79 Stat. 226 (1965).

<sup>39</sup> Reorganization Plan No. 1 of 1968, 33 C.F.R. 5611 (1966 – 1970 Comp.) reprinted at 28 U.S.C. § 509.

Dangerous Drugs, President Lyndon Johnson stated that such an action was necessary due to the fact that, at the time, “investigation and enforcement of our narcotics laws [were] fragmented” and that consolidating enforcement authority under the DOJ would result in the “most efficient and effective” enforcement of federal laws relating to narcotics and dangerous drugs.<sup>40</sup>

On July 14, 1969, President Richard Nixon sent a special message to Congress, calling for comprehensive federal legislation to address drug abuse, which the President called a “serious national threat to the personal health and safety of millions of Americans[,]” and stated that “[a] national awareness of the gravity of the situation is needed; a new urgency and concentrated national policy are needed at the Federal level to begin to cope with this growing menace to the general welfare of the United States.”<sup>41</sup> The following year, Congress enacted the Controlled Substances Act (CSA) as a part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, which was signed in to law and became effective on May 1, 1971.<sup>42</sup>

The CSA established schedules for controlled substances, ranging from schedule I to schedule V, based on a number of different factors.<sup>43</sup> For example, controlled substances classified as schedule I: (a) have a high potential for abuse; (b) lack a currently accepted medical use in treatment in the United States; and (c) have a lack of accepted safety for use of the drug or other substance under medical supervision.<sup>44</sup> Conversely, controlled substances classified as schedule V: (a) have a low potential for abuse relative to the drugs or other substances in schedule IV; (b) have a currently accepted medical use in treatment in the United States, and (c) abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.<sup>45</sup> Opioids such as hydrocodone and oxycodone are classified as schedule II-controlled substances, which are drugs that, among other things, have a high potential for abuse and may lead to severe psychological or physical dependence, if abused.<sup>46</sup>

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 registration and, as a condition of maintaining such registration, take steps to ensure their registration is not being used as a source of diversion.<sup>47</sup> To that end, the CSA requires entities engaged in the manufacture, distribution, or dispensation of controlled substances to obtain a registration (license) from the Attorney General,<sup>48</sup> and establishes registration requirements thereto.<sup>49</sup> With

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<sup>40</sup> *Id.*

<sup>41</sup> UNITED STATES GOV'T PRINTING OFFICE, PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES 1969 513-518 (1971).

<sup>42</sup> The Controlled Substances Act was enacted under Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

<sup>43</sup> 21 U.S.C. § 812.

<sup>44</sup> 21 U.S.C. § 812(b)(1).

<sup>45</sup> 21 U.S.C. § 812(b)(5).

<sup>46</sup> *See* 21 C.F.R. § 1308.12. *See also* 21 U.S.C. § 812. Hydrocodone was rescheduled from schedule III to schedule II by the U.S. Drug Enforcement Administration (DEA) in 2014. *See* 79 Fed. Reg. 49,661, Aug. 22, 2014.

<sup>47</sup> *See* 21 U.S.C. § 823.

<sup>48</sup> 21 U.S.C. § 822. Pursuant to 21 U.S.C. § 871(a), the Attorney General has delegated administration and enforcement of the CSA to the Administrator of the Drug Enforcement Administration. *See* 28 C.F.R. § 0.100.

<sup>49</sup> 21 U.S.C. § 823.



respect to distributors specifically, the CSA requires distributors maintain effective controls against diversion in order to mitigate against controlled substances being diverted into non-medical or other illegitimate channels.<sup>50</sup> The Attorney General has the authority to deny, revoke, or suspend a registration under the CSA if he or she determines the registrant to be out of compliance with the mandates of the CSA or that maintaining a registration would be inconsistent with the public interest.<sup>51</sup>

Shortly after the CSA became effective, the Bureau of Narcotics and Dangerous Drugs issued a number of regulations in furtherance of the CSA's objectives.<sup>52</sup> The CSA's implementing regulations include specific security control requirements for nonpractitioner registrants, such as distributors, requiring:

- “Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Bureau or with the appropriate State-controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.”<sup>53</sup>
- “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Regional Office of the Bureau in his region of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>54</sup>

These regulations have remained largely unchanged since first issued in 1971, with the exception that the regulations were updated in 1973 to reflect that the Drug Enforcement Administration (DEA), which was established within the DOJ by Executive Order in 1973, replaced the Bureau of Narcotics and Dangerous Drugs as the federal agency charged with enforcing the CSA.<sup>55</sup> The DEA remains the federal agency tasked with administering and

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<sup>50</sup> 21 U.S.C. § 823(b)(1) and 21 U.S.C. § 823(e)(1). The CSA defines “distribute” as “to deliver (other than by administering or dispensing) a controlled substance or listed chemical[.]” and defines “distributor” as “a person who so delivers a controlled substance or a listed chemical.” 21 U.S.C. § 802(11).

<sup>51</sup> 21 U.S.C. § 824.

<sup>52</sup> See 36 Fed. Reg. 7,778 Apr. 24, 1971, redesignated at 38 Fed. Reg. 26,609 Sept. 24, 1973. After the DEA was established in 1973 to enforce the CSA, references to the Bureau of Narcotics and Dangerous Drugs were replaced in the regulations.

<sup>53</sup> 36 Fed. Reg. 7,785 Apr. 24, 1971 *reprinted at* 21 C.F.R. § 1301.74(a).

<sup>54</sup> 36 Fed. Reg. 7,785 Apr. 24, 1971 *reprinted at* 21 C.F.R. § 1301.74(b). According to a 2015 order issued by the DEA's Acting Administrator, the definition of “suspicious” is not limited to orders of unusual size, frequency, or those that deviate substantially from typical ordering patterns as a pharmacy could have characteristics that “might make an order suspicious, despite the particular order not being of unusual size, pattern or for frequency.” See 80 Fed. Reg. 55,417, Sept. 15, 2015. See also *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).

<sup>55</sup> Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) *reprinted at* 21 U.S.C. § 801. In October 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), which, among other things, amended the CSA, codifying the definition of a suspicious order and the associated reporting requirement. Pursuant to Section 3292 of the SUPPORT for Patients and Communities Act, “[t]he term ‘suspicious order’ may include, but is

enforcing the CSA and, according to its Fiscal Year (FY) 2019 budget request, the agency regulates more than 1.73 million registrants that are licensed to manufacture, distribute, and prescribe controlled substances in the United States,<sup>56</sup> 910 of which are distributors.<sup>57</sup>

In addition to the requirement to report all suspicious orders, the CSA requires that distributors 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 registration issued under the CSA.<sup>58</sup> If the DEA takes action to deny, revoke, or suspend a registration, it must “serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.”<sup>59</sup> The Order to Show Cause (OTSC) shall:

- “[C]ontain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;”<sup>60</sup>
- “[D]irect the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and”<sup>61</sup>
- “[N]otify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.”<sup>62</sup>

If, however, the DEA Administrator determines that a registrant’s activities constitute “an imminent danger to the public health or safety[.]” the Administrator may issue an Immediate Suspension Order (ISO), which requires the immediate surrender of the registrant’s DEA

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not limited to (A) an order of a controlled substance of unusual size; (B) an order of a controlled substance deviating substantially from a normal pattern; and (C) orders of controlled substances of unusual frequency.” With respect to reporting requirements, and also pursuant to Section 3292, “[e]ach registrant shall (1) design and operate a system to identify suspicious orders for the registrant; (2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and (3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.” SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

<sup>56</sup> 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 Nov. 19, 2018).

<sup>57</sup> U.S. Drug Enforcement Admin., *Registrant Population by Business Activity, October 2018*, <https://apps.deadiversion.usdoj.gov/webforms/jsp/odrReports/odrBusActReportSelect.jsp> (last visited Nov. 19, 2018).

<sup>58</sup> 21 U.S.C. § 823(b), 21 U.S.C. § 823(e), and 21 U.S.C. § 824(a)(4). *See also* 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 Committee).

<sup>59</sup> 21 U.S.C. § 824(c)(1) and 21 C.F.R. § 1301.37.

<sup>60</sup> 21 U.S.C. § 824(c)(2)(A).

<sup>61</sup> 21 U.S.C. § 824(c)(2)(B).

<sup>62</sup> 21 U.S.C. § 824(c)(2)(C). Upon review of any correction plan submitted pursuant to this section, the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan. *See* 21 U.S.C. § 824(c)(3).

registration during the pendency of an underlying action to revoke or suspend a DEA registration subject to an OTSC.<sup>63</sup> The ISO “shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.”<sup>64</sup>

#### **D. Role of Wholesale Pharmaceutical Distributors**

Wholesale pharmaceutical distributors fulfill a critical role in the pharmaceutical supply chain – transferring drugs from manufacturers to businesses such as clinics, hospitals and pharmacies where they can be dispensed to patients. According to the Healthcare Distribution Alliance (HDA), “pharmaceutical distributors purchase prescription medicines and other medical products directly from manufacturers for storage in warehouses and distribution centers across the country.”<sup>65</sup> After acquiring prescription drugs from manufacturers, distributors will receive, process, and distribute orders to downstream customers such as pharmacies or hospitals.<sup>66</sup>

To prevent drug diversion and ensure the controlled substance orders are safely and securely processed and shipped, distributors are required to abide by numerous legal obligations, including obligations promulgated under the CSA. When wholesale distributors engage in interstate commerce, they are required to be licensed by each state where the distributor has a presence.<sup>67</sup> Distributors that handle controlled substances must also be registered with the DEA,<sup>68</sup> and such registrations shall be granted so long as the DEA determines they are in the public interest.<sup>69</sup>

More than 900 entities are registered with the DEA to distribute controlled substances in the United States.<sup>70</sup> Three national wholesale distributors—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—control the majority of the controlled substances market. Combined, these companies account for approximately 85 percent of the wholesale pharmaceutical distribution in the United States.<sup>71</sup> The three companies had

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<sup>63</sup> 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36.

<sup>64</sup> *Id.*

<sup>65</sup> Healthcare Distribution Alliance, *Role of Distributors*, <https://www.healthcaredistribution.org/about/role-of-distributors> (last visited Nov. 19, 2018). There are also “secondary wholesale distributors” which are firms that acquire pharmaceuticals from other wholesale distributors, but not directly from manufacturers. See SUSAN THAUL, CONG. RESEARCH SERV., R43106, PHARMACEUTICAL SUPPLY CHAIN SECURITY (2013).

<sup>66</sup> SUSAN THAUL, CONG. RESEARCH SERV., R43106, PHARMACEUTICAL SUPPLY CHAIN SECURITY (2013).

<sup>67</sup> Regulations were issued by the U.S. Food and Drug Administration (FDA) and authorized under the Prescription Drug Marketing Act of 1987, Pub. L. 100-293, 102 Stat. 95(1988). See 21 C.F.R. § 205.4.

<sup>68</sup> 21 U.S.C. § 822.

<sup>69</sup> 21 U.S.C. § 823.

<sup>70</sup> U.S. Drug Enforcement Admin., *Registrant Population by Business Activity, October 2018*, <https://apps.deadiversion.usdoj.gov/webforms/jsp/odrReports/odrBusActReportSelect.jsp> (last visited Nov. 19, 2018).

<sup>71</sup> Scott Higham and Lenny Bernstein, *The Drug Industry’s Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, [https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.2608027cefa6](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.2608027cefa6).

combined revenues of more than \$480 billion in 2017, and each ranked among the top 14 businesses in the United States as featured in the 2018 *Fortune* 500 list.<sup>72</sup>

The Committee's investigation focused on the actions of five distributors that were active in West Virginia: the three aforementioned national distributors, as well as two regional distributors, H.D. Smith Wholesale Drug Company and Miami-Luken, Inc. H.D. Smith was estimated to have brought in \$4 billion in drug distribution-related revenue in 2015,<sup>73</sup> and was acquired by AmerisourceBergen in January 2018.<sup>74</sup> According to company documents, Springboro, Ohio-based Miami-Luken, Inc., recorded a net revenue of \$165 million in Fiscal Year 2015.<sup>75</sup> In June 2018, the company informed the Committee that it "no longer sells any controlled substances to retail customers."<sup>76</sup> Later, in October 2018, the company told the Committee it had discontinued operations altogether, saying, "as a result of the ongoing DEA administrative proceeding and multiple lawsuits that have been filed against the Company, the Company has been forced to shut its doors and go out of business."<sup>77</sup>

## E. DEA Distributor Initiative

In 2005, prior to the enactment of the Ryan Haight Act, the DEA established the Distributor Initiative Program (hereinafter "Distributor Initiative" or the "Initiative"), recognizing the unique role distributors play in the CSA's closed system of distribution.<sup>78</sup> According to Joseph Rannazzisi, former Deputy Assistant Administrator in the DEA's Office of Diversion Control, the Initiative was established to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."<sup>79</sup> To do this, the DEA conducted individual, in-person meetings with certain wholesale distributors, reviewing each distributor's legal responsibilities under the CSA and providing specific examples from the distributor's own customers where the DEA identified that the customer's ordering habits and characteristics were suggestive of diversion.<sup>80</sup> In the meetings, the DEA warned distributors that

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<sup>72</sup> *Fortune*, *Fortune* 500, <http://fortune.com/fortune500/list/> (last visited Nov. 19, 2018).

<sup>73</sup> Adam Fein, *MDM Market Leaders: 2016 Top Pharmaceutical Distributors*, available at <https://www.mdm.com/2016-top-pharmaceuticals-distributors> (last accessed Nov. 19, 2018).

<sup>74</sup> See Press Release, AmerisourceBergen Corp., 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>.

<sup>75</sup> Miami Luken, Inc., Consolidated Statement of Operations (Attached as Exhibit to Minutes of the Annual Meeting of the Board of Directors of Miami-Luken Holding Company, Inc., Mar. 30, 2016) (On file with Committee).

<sup>76</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Counsel to Miami-Luken, Inc.)

<sup>77</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>78</sup> See *Improving Predictability and Transparency in DEA and FDA Regulation*, Hearing Before Subcomm. on Health of the H. Comm. on Energy and Commerce, 113th Cong. Serial No. 113-137, 5 (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin) available at <https://docs.house.gov/meetings/IF/IF14/20140407/102093/HHRG-113-IF14-Wstate-RannazzisiJ-20140407.pdf>.

<sup>79</sup> *Id.*

<sup>80</sup> See 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->

failing to exercise effective controls against diversion could result in the distributor's DEA registration being revoked, and that "[a]ny distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately."<sup>81</sup>

Over time, the focus of the Distributor Initiative has shifted from rogue internet pharmacies, which Congress addressed through the enactment of the Ryan Haight Act, to trends and red flags of diversion attributable to rogue pain clinics and pharmacies. For example, in a 2012 hearing before the Senate Caucus on International Narcotics Control, the written testimony of Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, stated, "[t]his program was implemented in late 2005 and was designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and more recently to rogue pain clinics and rogue pharmacies."<sup>82</sup>

The DEA also supplemented the guidance provided during the individual meetings through a series of three letters, sent in 2006 and 2007, reiterating distributors' legal responsibilities to maintain effective controls against diversion, and to report suspicious orders to the DEA when they are discovered by a distributor.<sup>83</sup> In addition, beginning in 2007, the DEA held five separate national conferences for registrants, three of which were exclusively for

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d7c704ef9fd9\_story.html?utm\_term=.af8d3f2847ba. *See also* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee); and Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee).

<sup>81</sup> *See* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee). *See also* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee) and Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee).

<sup>82</sup> *Responding to the Prescription Drug Abuse Epidemic: Hearing Before S. Caucus on Int'l Narcotics Control*, 112th Cong., 9 (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.) *available at* <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>.

<sup>83</sup> *See* 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 Committee); 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 Committee) and 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 Committee).

distributors, where the agency reviewed distributors' legal responsibilities under the CSA and provided updates on DEA's areas of concern and current trends related to controlled substance diversion.

The Distributor Initiative remains active at the DEA. In written testimony, submitted for a March 20, 2018 hearing before the Committee's Subcommittee on Oversight and Investigations, then-DEA Acting Administrator Robert Patterson stated that the DEA continues to work with registrants to administer the Initiative "with a goal of educating distributors on how to detect and guard against diversion activities[.]"<sup>84</sup>

## **F. Enforcement Actions Taken by DEA**

Through the educational component of the Distributor Initiative, the DEA provided individual and group guidance to distributors on their legal obligations under the CSA, but also warned distributors that failing to meet these obligations could result in the revocation of a distributor's DEA registration. Despite this guidance, however, the DEA alleged that some distributors failed to operate in accordance with the CSA. To address distributors the DEA believed were continuing to violate the CSA, the agency adopted a more aggressive enforcement posture and undertook actions to revoke their registrations.<sup>85</sup> In accordance with the heightened emphasis on enforcement, the DEA undertook actions to revoke the registrations of various regional and mid-size wholesale distributors including Southwood Pharmaceuticals,<sup>86</sup> Richie Pharmacal,<sup>87</sup> and Keysource Medical,<sup>88</sup> among others.<sup>89</sup>

The enforcement actions undertaken by the DEA were not limited to regional and mid-size distributors, as the agency also took action against major national wholesale distributors for alleged violations of the CSA. For example, on August 4, 2006, the DEA issued an OTSC against McKesson, seeking to revoke the DEA registration for the company's Lakeland, Florida

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<sup>84</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. at 6 (2018) (statement of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Wstate-PattersonR-20180320.pdf>.

<sup>85</sup> *See Responding to the Prescription Drug Abuse Epidemic: Hearing Before S. Caucus on Int'l Narcotics Control*, 112th Cong., 9-10 (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.) available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>.

<sup>86</sup> *See* 72 Fed. Reg. 36,487, July 3, 2007.

<sup>87</sup> *See In re Richie Pharmacal*, Memorandum of Agreement (Aug. 7, 2007) available at <https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Richie%20Pharmaceutical%20-%202007.pdf>.

<sup>88</sup> *See* Press Release, U.S. Drug Enforcement Admin., Cincinnati Pharmaceutical Supplier's DEA License Suspended (June 10, 2011) available at <https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended>.

<sup>89</sup> *See* Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\\_story.html?utm\\_term=.0cbc79264365](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.0cbc79264365).

distribution facility.<sup>90</sup> The DEA issued a second OTSC against McKesson on November 1, 2007, this time seeking to revoke the DEA registration for the company's distribution facility in Landover, Maryland.<sup>91</sup> To resolve these allegations, McKesson reached a settlement with the DEA on May 2, 2008, wherein the company, among other things, agreed to pay a \$13.25 million fine, and be subject to heightened reporting requirements.<sup>92</sup> On January 17, 2017, McKesson entered into another settlement with the DEA, which stated that, at various times, it did not abide by the terms of the 2008 settlement agreement, and that it failed to maintain effective controls against diversion at 12 separate distribution facilities across the country, approximately one-third of the company's distribution facilities overall.<sup>93</sup> McKesson agreed to pay a \$150 million fine, and to temporarily suspend distributing controlled substances at four of its distribution facilities, among other obligations. Unlike 2008, there was no precipitating OTSC associated with the 2017 settlement.<sup>94</sup>

The DEA also initiated enforcement actions against AmerisourceBergen and Cardinal Health for their alleged failures to comply with the CSA. On April 19, 2007, the DEA issued an ISO and OTSC against AmerisourceBergen, seeking to revoke the DEA registration of the company's Orlando, Florida distribution facility for its alleged failure to maintain effective controls against diversion and report suspicious orders to the DEA.<sup>95</sup> The DEA and AmerisourceBergen entered into a settlement agreement to resolve the DEA's allegations on June 22, 2007, wherein the company agreed to be subject to heightened reporting requirements; AmerisourceBergen did not pay a fine in connection with this settlement.<sup>96</sup>

Between November 28, 2007 and January 30, 2008, the DEA brought four enforcement actions to revoke the registrations of Cardinal Health's distribution facilities in Washington, Florida, New Jersey, and Texas, alleging that Cardinal failed to meet its legal obligations under the CSA at each of these facilities.<sup>97</sup> The DEA and Cardinal entered into a settlement agreement

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<sup>90</sup> *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* In the May 2, 2008 settlement agreement, the DEA also alleged that McKesson failed to maintain effective controls against diversion at its Conroe, Texas and Denver, Colorado distribution facilities.

<sup>93</sup> See *In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928471/download>; see also *In re McKesson*, Administrative Memorandum of Agreement, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928476/download>, and Lenny Bernstein and Scott 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?utm\\_term=.b0e352a571e5](https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.b0e352a571e5).

<sup>94</sup> See *In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928471/download>. See also *In re McKesson*, Administrative Memorandum of Agreement, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928476/download>.

<sup>95</sup> *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with Committee).

<sup>96</sup> *Id.*

<sup>97</sup> See U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Nov. 28, 2007 (On file with Committee); U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 5, 2007 (On file with Committee); U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec.

on October 2, 2008 to resolve the allegations, wherein Cardinal agreed to heightened reporting requirements and to pay a \$34 million fine to the federal government.<sup>98</sup> However, on February 2, 2012, the DEA issued an ISO and OTSC against Cardinal, seeking to revoke the DEA registration of the company's distribution facility in Lakeland, Florida, alleging that Cardinal failed to abide by the terms of the 2008 settlement, and that its distribution practices continued to be in violation of the CSA.<sup>99</sup> Cardinal and the DEA entered into another settlement to resolve these allegations on May 14, 2012,<sup>100</sup> with the company once again agreeing to pay a \$34 million dollar penalty.<sup>101</sup>

However, as will be discussed in greater detail later in this report, the number of ISOs initiated by the DEA began to substantially decline in 2013, with the agency failing to bring any ISOs against distributors for nearly a six-year period. On May 2, 2018, the DEA issued an ISO against Morris & Dickson Company, a Louisiana-based wholesale distributor, alleging the company failed to maintain effective controls against diversion, and report suspicious orders to the DEA in relation to the company's sales to several high-volume pharmacies in Louisiana.<sup>102</sup> This was the first ISO issued by the DEA against a wholesale distributor since 2012.<sup>103</sup> However, the DEA rescinded the ISO against Morris & Dickson Company on May 18, 2018, after a federal judge granted a motion brought by the company, enjoining the ISO from being enforced.<sup>104</sup> The rescission of the ISO notwithstanding, Morris & Dickson Company's DEA registration may ultimately still be revoked as the DEA also issued an OTSC against the company, which would revoke the company's DEA registration if the DEA's Administrator determines, after considering all available evidence, that doing so is consistent with the public's interest.<sup>105</sup> The DEA has indicated to the Committee that it is currently in pre-hearing

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7, 2007 (On file with Committee); and U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause, Jan. 30, 2008 (On file with Committee).

<sup>98</sup> *In re Cardinal Health*, Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008, (On file with Committee). In the settlement, the DEA alleged that Cardinal also failed to maintain effective controls against diversion at distribution facilities located in California, Colorado, and Georgia.

<sup>99</sup> See U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Feb. 2, 2012, (On file with Committee).

<sup>100</sup> *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012, (On file with Committee).

<sup>101</sup> Press Release, U.S. Dep't of Justice, M.D. Fla., 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>.

<sup>102</sup> Press Release, U.S. Dep't of Justice, DEA Suspends the Registration of Morris & Dickson Company from Distributing Controlled Substances (May 4, 2018) *available at* <https://www.justice.gov/opa/pr/dea-suspends-registration-morris-dickson-company-distributing-controlled-substances>.

<sup>103</sup> Lenny Bernstein and Sari Horwitz, *DEA issues first immediate suspension of opioid sales to a wholesaler since 2012*, WASH. POST, May 4, 2018, [https://www.washingtonpost.com/national/health-science/dea-issues-first-immediate-suspension-of-opioid-sales-to-a-wholesaler-since-2012/2018/05/04/660f53be-4fe4-11e8-84a0-458a1aa9ac0a\\_story.html?utm\\_term=.a0a203172b0e](https://www.washingtonpost.com/national/health-science/dea-issues-first-immediate-suspension-of-opioid-sales-to-a-wholesaler-since-2012/2018/05/04/660f53be-4fe4-11e8-84a0-458a1aa9ac0a_story.html?utm_term=.a0a203172b0e).

<sup>104</sup> Sari Horwitz and Scott Higham, *Justice Department rescinds order stopping opioid sales by Louisiana distributor*, WASH. POST, May 18, 2018, [https://www.washingtonpost.com/world/national-security/justice-department-rescinds-order-stopping-opioid-sales-by-louisiana-distributor/2018/05/18/d90eee46-5abc-11e8-8836-a4a123c359ab\\_story.html?utm\\_term=.56839c5d6911](https://www.washingtonpost.com/world/national-security/justice-department-rescinds-order-stopping-opioid-sales-by-louisiana-distributor/2018/05/18/d90eee46-5abc-11e8-8836-a4a123c359ab_story.html?utm_term=.56839c5d6911).

<sup>105</sup> Nick Wooten, *Morris & Dickson still faces DEA hearing over opioid orders*, SHREVEPORT TIMES, May 21, 2018, <https://www.shreveporttimes.com/story/news/2018/05/21/morris-dickson-still-faces-federal-hearing-over-opioid-orders/629936002/>.



discussions with Morris & Dickson Company, with a hearing to be held at an unspecified later date.<sup>106</sup>

## **G. The Committee's Investigation**

### **1. The Committee's Investigation into Drug Wholesale Distributors**

In May 2017, the Committee opened a bipartisan investigation into the distribution of prescription opioids by wholesale distributors, with a specific focus on unusually large shipments of opioids to pharmacies located in small West Virginia communities, by sending letters to the three largest wholesale distributors in the United States – AmerisourceBergen, Cardinal Health, and McKesson.<sup>107</sup>

In the initial letters to the companies, the Committee requested that the companies provide information regarding:

- The number of pills of hydrocodone and oxycodone sold by each distributor to purchasers in West Virginia in each year from 2005 through 2016;
- Any monitoring systems in place to detect unusual or suspicious patterns or quantities of opioid orders;
- Policies and procedures in place to detect unusual or suspicious patterns or quantities of opioid orders; and
- Actions taken after identifying such patterns, among other requests.<sup>108</sup>

The Committee expanded its investigation on September 25, 2017, when it sent a letter to Miami-Luken, a regional midwestern wholesale distributor. Miami-Luken received an OTSC from the DEA on November 23, 2015, informing the company the DEA was taking action to revoke its registration to distribute controlled substances for its failure to maintain effective

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<sup>106</sup> E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Aug. 24, 2018 1:28 pm) (On file with Committee).

<sup>107</sup> See Press Release, H. Comm. on Energy and Commerce, Bipartisan Committee Leaders Demand Answers About Alleged Pill Dumping in Midst of Opioid Crisis (May 9, 2017) *available at* <https://energycommerce.house.gov/news/press-release/bipartisan-committee-leaders-demand-answers-about-alleged-pill-dumping/>. On the same day that it opened its investigation into the distribution of opioids by wholesale distributors, the Committee also opened an investigation into the Drug Enforcement Administration's (DEA) efforts to combat the opioid epidemic. The Committee's investigation into the DEA is discussed in greater detail in this section at subsection 2.

<sup>108</sup> See *e.g.* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President, and Chief Exec. Officer, AmerisourceBergen Corp., May 8, 2017, *available at* <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508AmerisourceBergen.pdf>.

controls against diversion, and report suspicious orders to the DEA.<sup>109</sup> The Committee requested that Miami-Luken provide:

- All due diligence documents for selected pharmacies referenced in the DEA OTSC;
- Information and documents related to any personnel terminations taken by Miami-Luken, with any such termination attributable to nonfulfillment of the company's DEA compliance obligations; and
- Copies of suspicious order reports Miami-Luken filed with the DEA, beginning January 1, 2008, among other requests.<sup>110</sup>

During its investigation the Committee also reviewed publicly available DEA Automated Reports and Consolidated Ordering System (ARCOS) data, which provides aggregate drug-specific distribution figures for geographic areas on a three-digit ZIP code prefix basis.<sup>111</sup> Based upon this review, the Committee requested DEA provide ARCOS data for the amount of hydrocodone and oxycodone shipped between 2005 and 2016 to six three-digit ZIP codes in West Virginia, identifying the specific wholesale distributors responsible for the shipments as well as the individual pharmacies that were supplied.<sup>112</sup>

Through its review of the targeted, pharmacy-specific ARCOS data produced by the DEA, the Committee expanded its investigation of wholesale distributors again, on January 26, 2018, when it sent a letter to H.D. Smith, an Illinois-based wholesale distributor that had recently been acquired by AmerisourceBergen.<sup>113</sup> In its letter, the Committee cited the volume of H.D. Smith's hydrocodone and oxycodone shipments to pharmacies in small West Virginia communities. The Committee requested that H.D. Smith provide:

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<sup>109</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Sept. 25, 2017, *available at* [https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami\\_Luken.pdf](https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf). See also U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015, (On file with Committee).

<sup>110</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Sept. 25, 2017, *available at* [https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami\\_Luken.pdf](https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf).

<sup>111</sup> Pursuant to 21 U.S.C. § 827(d)(1) and 21 C.F.R. § 1304.33, DEA-registered distributors are required to report each controlled substance transaction they make to the DEA on a quarterly basis, at a minimum. The regulations allow distributors to report their transactions to the DEA more frequently, but not more frequently than once a month.

<sup>112</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and 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>.

<sup>113</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to J. Christopher Smith, President and CEO, H.D. Smith Wholesale Drug Co., Jan. 26, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126HDSmith.pdf>.

- All due diligence documents for selected West Virginia pharmacies the Committee identified during its investigation;
- Additional explanation for the company's seemingly high shipments of opioids to selected West Virginia pharmacies;
- Copies of all hydrocodone and oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that the company refused to ship; and
- Copies of any suspicious order reports the company filed with the DEA between 2006 and 2017 regarding orders placed by West Virginia pharmacies as well as the company's protocols for identifying suspicious orders, among other requests.<sup>114</sup>

On the same day it sent its letter to H.D. Smith, the Committee sent a second letter to Miami-Luken, posing additional questions to the company and making supplemental document requests, based upon the Committee's review of the material Miami-Luken provided in response to the Committee's September 25, 2017 letter and a December 13, 2017 transcribed interview of Miami-Luken's Board Chairman, Dr. Joseph Mastandrea.<sup>115</sup> In the January 26, 2017 letter, the Committee requested that Miami-Luken provide:

- Additional explanation for the company's shipments of opioids to selected West Virginia pharmacies as well as the company's explanation for due diligence-related items the Committee identified during its review of the materials previously submitted by the company;
- Copies of all hydrocodone and oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that the company refused to ship; and
- Copies of any suspicious order reports the company filed with the DEA between 2006 and 2017 regarding orders placed by West Virginia pharmacies, among other requests.<sup>116</sup>

On February 15, 2018, the Committee also sent a second letter to AmerisourceBergen, Cardinal Health, and McKesson, each of which were based upon the Committee's review of the distributor and pharmacy specific ARCOS data as well as the companies' responses to the Committee's May 8, 2017 letter.<sup>117</sup>

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<sup>114</sup> *Id.*

<sup>115</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Jan. 26, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126Miami-Luken.pdf>.

<sup>116</sup> *Id.*

<sup>117</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President, and Chief Exec. Officer, AmerisourceBergen Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215AmerisourceBergen.pdf>. See also Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec.

In the letter to AmerisourceBergen, the Committee requested that the company provide:

- All due diligence documents for selected West Virginia pharmacies the Committee identified during its investigation;
- Documents related to the company’s suspicious order monitoring program, beginning in 2006, as well as information on the company’s “Know Your Customer” program;
- Copies of all hydrocodone and oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that the company refused to ship; and
- The five states with the highest number of suspicious orders reported by the company to the DEA each year from 2006 to 2017 as well as copies of any suspicious order reports the company filed with the DEA between 2006 and 2017 regarding orders placed by West Virginia pharmacies, among other requests.<sup>118</sup>

In the letter to Cardinal Health, the Committee requested that the company provide:

- All due diligence documents for selected West Virginia pharmacies the Committee identified during its investigation;
- Additional explanation for the company’s seemingly high shipments of opioids to selected West Virginia pharmacies;
- Details on any orders for hydrocodone or oxycodone, placed by West Virginia pharmacies since January 1, 2006, that exceeded certain thresholds that may have been established by the company; and
- The five states with the highest number of suspicious orders reported by the company to the DEA each year from 2006 to 2017 as well as copies of any suspicious order reports the company filed with the DEA between 2006 and 2017 regarding orders placed by West Virginia pharmacies, among other requests.<sup>119</sup>

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Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf> and Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>.

<sup>118</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President, and Chief Exec. Officer, AmerisourceBergen Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215AmerisourceBergen.pdf>.

<sup>119</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec. Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf>.

In the letter to McKesson, the Committee requested that the company provide:

- All due diligence documents for selected West Virginia pharmacies the Committee identified during its investigation;
- Information and documents related to the company's suspicious order monitoring program between 2006 and 2017;
- A list, broken down by year and dosage unit, of the company's ten largest customers in West Virginia between 2006 and 2017, based upon hydrocodone and oxycodone dosage units; and
- The five states with the highest number of suspicious orders reported by the company to the DEA each year from 2006 to 2017 as well as copies of any suspicious order reports the company filed with the DEA between 2006 and 2017 regarding orders placed by West Virginia pharmacies, among other requests.<sup>120</sup>

The Subcommittee on Oversight and Investigations held a hearing on May 8, 2018, when it received sworn testimony from, and posed questions to representatives of each of the wholesale drug distributors involved in the investigation. The Subcommittee examined the role that each company may have played in contributing to the opioid epidemic as well as distribution practices specific to West Virginia.<sup>121</sup> Appearing at Subcommittee's hearing were:

- George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc.;
- Steven H. Collis, Chairman, President, and CEO, AmerisourceBergen Corporation;
- John H. Hammergren, Chairman, President, and CEO, McKesson Corporation;
- Joseph R. Mastandrea, D.O., Chairman of the Board, Miami-Luken, Inc.; and
- J. Christopher Smith, Former President and CEO, H.D. Smith Wholesale Drug Company<sup>122</sup>

The five distributors provided thousands of pages of documents to the Committee, including due diligence files, suspicious order reports and policy manuals. As will be discussed throughout this report, at times the information produced by the distributors seemed to be incomplete, causing the Committee to request additional explanation or documentation. Upon

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<sup>120</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>.

<sup>121</sup> See *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) *available at* <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>122</sup> As noted, H.D. Smith was acquired by AmerisourceBergen in January 2018.

subsequent requests by the Committee, a distributor either produced additional documentation, or acknowledged that the Committee had received all documents related to a pharmacy.

## **2. The Committee's Investigation into the Drug Enforcement Administration**

In May 2017, at the same time the Committee's first letters were sent to the distributors, the Committee also wrote to the DEA, referencing not only the West Virginia opioid distribution figures, but also reporting from the *Charleston Gazette-Mail* and *Washington Post* that detailed sharp declines in the number of enforcement actions initiated by the DEA, beginning in 2013, while the opioid epidemic was continuing to surge.<sup>123</sup> The Committee requested that the DEA provide:

- Information on any patterns of opioid distribution in West Virginia, identified by the DEA, which caused the agency to take enforcement action as well as a description of any such action;
- Whether the DEA agreed with the accuracy of the opioid distribution figures reported in the *Charleston Gazette-Mail*, and if so, what action did the agency take in response;
- Information on what systems DEA has in place to detect any potential oversupplying of opioids nationwide;
- An explanation for the decrease in enforcement actions; and
- All documents related to delayed or blocked enforcement actions and suspension orders since January 1, 2011, among other requests.<sup>124</sup>

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<sup>123</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Chuck Rosenberg, Acting Adm'r, U.S. Drug Enforcement Admin., May 8, 2017, available at <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508DEA.pdf>. See also 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=.af8d3f2847ba](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=.af8d3f2847ba); Scott Higham et al., *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse*, WASH. POST, Dec. 22, 2016, [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e\\_story.html?utm\\_term=.66ebcc1a0be7](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.66ebcc1a0be7); and Eric Eyre, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, CHARLESTON GAZETTE-MAIL, Feb. 18, 2017, [https://www.wvgazette.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article\\_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html](https://www.wvgazette.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html).

<sup>124</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Chuck Rosenberg, Acting Adm'r, U.S. Drug Enforcement Admin., May 8, 2017, available at <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508DEA.pdf>.

During the course of this investigation, the Committee encountered unnecessary delays on the part of DEA. For instance, it took DEA two months (including a three-week extension granted at DEA's request) to issue a one-page response to the Committee's May 8, 2017 letter. The response disregarded the Committee's questions. Rather, the DEA's July 11, 2017 letter stated the agency "will not be in a position to provide additional information" until the conclusion of a review of its opioid enforcement policies—an action initiated by the DOJ's Office of Inspector General (OIG) on May 31, 2017.<sup>125</sup> In effect, the DEA sought to delay any response to a Congressional oversight investigation while an OIG review, initiated weeks after the Committee opened its investigation, was ongoing.

Bipartisan Committee leaders, including Chairman Greg Walden and Ranking Member Frank Pallone, met with then-Acting Administrator Chuck Rosenberg in July 2017, where he pledged that the DEA would cooperate with the investigation and fully respond to the Committee's May 8, 2017 letter by the end of August. The DEA provided a partial response to the Committee on August 2, 2017.<sup>126</sup> Still outstanding were document requests related to delayed or blocked enforcement actions and immediate suspension orders at DEA dating back to 2011.

While awaiting document production from DEA, and as mentioned earlier in this section, the Committee reviewed publicly available DEA ARCOS data, which appeared to show a considerable increase in the amount of hydrocodone and oxycodone that wholesale distributors provided to West Virginia.<sup>127</sup>

Based upon this review, the Committee sent a second letter to DEA on October 13, 2017, requesting ARCOS data for the amount of hydrocodone and oxycodone shipped between 2005 and 2016 to six three-digit ZIP codes in West Virginia, identifying the specific wholesale distributors responsible for the shipments as well as the individual pharmacies that were supplied.<sup>128</sup> The Committee also requested the DEA provide additional documentation related to the November 23, 2015 Miami-Luken OTSC.<sup>129</sup>

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<sup>125</sup> Letter from Section Chief, Cong. Affairs Section, U.S. Drug Enforcement Admin., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce (July 11, 2017).

<sup>126</sup> See E-Mail from Section Chief, Cong. Affairs Section, U.S. Drug Enforcement Admin., to Staff, H. Comm. on Energy and Commerce (Aug. 2, 2017, 5:44 pm) (On file with Committee).

<sup>127</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and 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>.

<sup>128</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and 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>. On April 26, 2018, the Committee requested that DEA provide ARCOS data for an additional five three-digit ZIP codes in West Virginia, again identifying the specific wholesale distributors responsible for the shipments as well as the individual pharmacies that were supplied. Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, to Robert W. Patterson, Acting Adm'r, U.S. Drug Enforcement Admin., Apr. 26, 2018 (On file with Committee).

<sup>129</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and 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>.

On October 25, 2017, the Energy and Commerce Committee held a full committee hearing entitled “Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives.”<sup>130</sup> At the hearing, Chairman Walden addressed the DEA’s delay in producing documents requested by the Committee and threatened to subpoena the agency. Chairman Walden stated, “I’m going to be very blunt. My patience is wearing thin. Our requests for data from DEA are met with delay, excuses and, frankly, inadequate response. People are dying, lives and families are ruined.”<sup>131</sup>

Neil Doherty, Deputy Assistant Administrator of the Office of Diversion Control, testified on behalf of the DEA, and answered questions about the Committee’s ongoing investigation, including the status of DEA’s responses to the Committee’s questions and document requests.<sup>132</sup>

On Nov. 8, 2017, bipartisan Committee leadership met with then-DEA Acting Administrator Robert Patterson and DOJ Assistant Attorney General for Legislative Affairs Stephen Boyd to discuss the Committee’s outstanding requests. Again, the Acting Administrator pledged the DEA’s cooperation with the Committee’s investigation. Following this meeting, the DEA began to produce larger number of documents and data to the Committee.

The documents DEA produced to the Committee included heavy redactions, however. On February 6, 2018, bipartisan Committee leaders held a press conference about the ongoing investigation and stressed that DEA must supply unredacted documents.<sup>133</sup> The Committee ultimately reached an accommodation with the DEA that provided the Committee with the information needed to complete its investigation.

On March 20, 2018, the Committee’s Subcommittee on Oversight and Investigations held a hearing with then-DEA Acting Administrator Patterson, where the Subcommittee examined the DEA’s efforts to combat diversion and drug abuse as the opioid crisis unfolded across the country, and specifically in West Virginia.<sup>134</sup> The Subcommittee also sought an accounting from DEA on any lessons it may have learned from potential past failings that would enable the agency to more effectively combat diversion, and drug abuse moving forward.

Since opening its investigation, the Committee, through its members and staff, have sent twelve letters requesting documents and information, reviewed more than 20,000 pages of material obtained from the DEA and wholesale distributors, participated in numerous briefings

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<sup>130</sup> See *Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives: Hearing Before the H. Comm. on Energy and Commerce*, 115th Cong. (2017) available at <https://docs.house.gov/meetings/IF/IF00/20171025/106533/HHRG-115-IF00-Transcript-20171025.pdf>.

<sup>131</sup> *Id.* at 6.

<sup>132</sup> See *Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives: Hearing Before the H. Comm. on Energy and Commerce*, 115th Cong. (2017) available at <https://docs.house.gov/meetings/IF/IF00/20171025/106533/HHRG-115-IF00-Transcript-20171025.pdf>.

<sup>133</sup> See Press Release, H. Comm. on Energy and Commerce, Bipartisan E&C Leaders Call on DEA to “Stop Playing Games” (Feb. 6, 2018) available at <https://energycommerce.house.gov/news/press-release/bipartisan-ec-leaders-call-dea-stop-playing-games/>.

<sup>134</sup> See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.



with the DEA and wholesale distributors, and held two hearings. Using a case study method, the Committee's investigation into the practices of wholesale distributors and the DEA's oversight thereof was primarily limited to the state of West Virginia, with a specific focus on the southwestern part of the state hardest hit by the opioid epidemic. The findings derived from the Committee's investigation are staggering and provide ample reason to question the efforts of the wholesale distributors that were subject to the Committee's investigation, as well as the efforts of the DEA, to prevent diversion in other areas of the country that have been impacted by the opioid epidemic.

## V. The Role of the Drug Enforcement Administration

The DEA is tasked with providing oversight of more than 1.73 million registrants allowed to manufacture, distribute and prescribe controlled substances in the United States.<sup>135</sup> As the number of opioid overdose deaths has increased dramatically since 1999,<sup>136</sup> the DEA has had to rethink its strategy to combat prescription drug diversion. To provide effective oversight of registrants amid the opioid epidemic, DEA must not only have the necessary tools, but also wield them effectively.

To better understand the DEA's past approach to addressing pharmaceutical diversion, how the agency's approach shifted amid the opioid epidemic, and the degree to which it has been effective, the Committee requested a variety of documents and information from the agency.<sup>137</sup> The Committee reviewed DEA ARCOS data regarding the amount of hydrocodone and oxycodone shipped between 2005 and 2016 to eleven three-digit ZIP codes in West Virginia, other information including e-mail communications regarding pharmaceutical diversion enforcement activities and strategies, and received briefings from DEA staff.

As detailed in the section below, the Committee's investigation identified weaknesses in the DEA's enforcement posture in West Virginia as well as policy approaches that appear to have limited the agency's ability to take enforcement action against registrants suspected of diversion. The Committee found evidence to support claims that the Office of Chief Counsel adopted a new approach to administrative cases during this timeframe that led to greater scrutiny regarding the strength of cases. The DEA's then-Chief Counsel confirmed that a series of cases regarding Florida pill mills led to new case precedent that required adjustment on the part of DEA lawyers. Emails obtained by the Committee also showed that DEA lawyers, in some cases, asked field agents to collect additional evidence, such as medical expert testimony, before they would approve cases. Disagreements between employees within the Office of Diversion Control and the Chief Counsel's Office over policy interpretations led to tension within the agency that degraded working relationships. Collectively, these actions may have slowed the agency's enforcement mechanisms, including the ability to issue ISOs.

Another issue complicating DEA's use of ISOs was its prioritization of criminal case investigations over administrative enforcement activity, the latter being an important tool for DEA to suspend or revoke a distributor's DEA registration. DEA seemingly made it a practice to postpone administrative actions at the request of U.S. Attorney's Offices, so evidence could continue to be collected in criminal cases. The Committee identified one instance in West Virginia in which administrative actions were put on hold for a parallel criminal case and ultimately allowed a target pharmacy to remain in operation for an additional two years.

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<sup>135</sup> 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 Dec. 6, 2018).

<sup>136</sup> 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](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4).

<sup>137</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Chuck Rosenberg, Acting Adm'r, U.S. Drug Enforcement Admin., May 8, 2017, available at <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508DEA.pdf>.

Also identified through the Committee’s investigation was a lack of DEA resources devoted to diversion issues in West Virginia. DEA was put on notice by the Department of Justice’s (DOJ) Office of Inspector General (OIG) in 2002 that it had not dedicated the requisite level of resources to address the growing problem of controlled substance diversion in West Virginia.<sup>138</sup> Yet years later, in 2006, the DEA had only two diversion investigations dedicated to West Virginia and activity in the state was overseen by the DEA’s Washington, D.C. Field Division.<sup>139</sup>

While the Committee utilized DEA ARCOS data to pinpoint massive quantities of opioids distributed to West Virginia pharmacies, the DEA has not always used this information in a similar proactive manner. Until recently, DEA used ARCOS data reactively to strengthen the case for an ISO or other enforcement action after a target was identified by other means.<sup>140</sup> Only within the last few years has the agency begun to use the data proactively to generate leads and create “targeting” packages that could be utilized by the field.

These matters contributed to failures on the part of DEA to adequately use its enforcement tools as the opioid crisis worsened in West Virginia.

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<sup>138</sup> See U.S. DEP’T OF JUSTICE OFFICE OF INSPECTOR GEN., REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION’S INVESTIGATIONS OF THE DIVERSION OF CONTROLLED PHARMACEUTICALS (Sept. 2002) *available at* <https://oig.justice.gov/reports/DEA/e0210/final.pdf>.

<sup>139</sup> Briefing from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018. See also *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).

<sup>140</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

## A. DEA's Response to the Opioid Crisis in West Virginia

### 1. DEA Appears to Have Missed Warnings Signs of the Growing Crisis

The DEA has taken steps in recent years to increase its presence in West Virginia and reorganize its assets in the Appalachian region to combat opioid trafficking and prescription drug diversion. These actions are not unexpected given that West Virginia leads the country in the number of overdose deaths per capita.<sup>141</sup> In 2017, approximately 86 percent of the overdose deaths in the state involved at least one opioid.<sup>142</sup>

Despite these recent steps, warning signs of the impending opioid crisis were apparent in West Virginia nearly two decades ago, as use of oxycodone surged and was then followed by dependence on methadone. In 2001, the West Virginia Attorney General sued drug maker Purdue Pharma over its marketing of OxyContin, alleging that the drug manufacturer used coercive tactics to sell the drug and mislead state residents about its safety.<sup>143</sup> Meanwhile from 1999 to 2004, the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent.<sup>144</sup>

By the mid-2000s, news reports from across Appalachia were highlighting the growing concern regarding opioid addiction. A 2006 article from rural West Virginia detailed the rise in deaths related to methadone in the state, which was increasingly being prescribed to treat pain in addition to being used to curb opioid withdrawal symptoms.<sup>145</sup> A year later, another article highlighted a new prescription drug of choice for West Virginians – hydrocodone, which grew in popularity after doctors became wary of prescribing OxyContin.<sup>146</sup>

More than fifteen years ago, in 2002, the DOJ OIG made DEA aware that it was not devoting the requisite level of resources to address the growing problem of controlled substance

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<sup>141</sup> Centers for Disease Control and Prevention, *Drug Overdose Mortality by State*, [https://www.cdc.gov/nchs/pressroom/sosmap/drug\\_poisoning\\_mortality/drug\\_poisoning.htm](https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm) (last updated Jan. 10, 2018).

<sup>142</sup> Caity Coyne, *Fatal drug overdoses in West Virginia surpassed 1,000 in 2017*, HERALD-DISPATCH, Sept. 1, 2018, [http://www.herald-dispatch.com/news/fatal-drug-overdoses-in-west-virginia-surpassed-in/article\\_f8786ade-ad99-11e8-9c54-a3f4895de6e3.html](http://www.herald-dispatch.com/news/fatal-drug-overdoses-in-west-virginia-surpassed-in/article_f8786ade-ad99-11e8-9c54-a3f4895de6e3.html).

<sup>143</sup> Landon Thomas Jr., *Maker of OxyContin Reaches Settlement With West Virginia*, N.Y. TIMES, Nov. 6, 2004, <https://www.nytimes.com/2004/11/06/business/maker-of-oxycotin-reaches-settlement-with-west-virginia.html?mtrref=www.google.com>.

<sup>144</sup> Memorandum from Aron J. Hall, DVM, Epidemic Intelligence Service Officer, W. Va. Dep't of Health & Human Res. et al. to Douglas H. Hamilton, M.D., PhD, Dir., Epidemic Intelligence Service, Centers for Disease Control and Prevention, at 2 (Oct. 12, 2007) (On file with Committee).

<sup>145</sup> Scott Finn and Tara Tuckwiller, *The Killer Cure: Deaths tied to methadone escalate across state, nation*, CHARLESTON GAZETTE-MAIL, June 4, 2006, [https://www.wvgazette.com/news/special\\_reports/deaths-tied-to-methadone-escalate-across-state-nation/article\\_9a021a7d-b1f8-5f50-9711-17a5c9b182f7.html](https://www.wvgazette.com/news/special_reports/deaths-tied-to-methadone-escalate-across-state-nation/article_9a021a7d-b1f8-5f50-9711-17a5c9b182f7.html).

<sup>146</sup> Tom Breen, *Hydrocodone Abuse on the Rise in Appalachia*, ASSOCIATED PRESS reprinted in WASH. POST, Aug. 21, 2007, <http://www.washingtonpost.com/wp-dyn/content/article/2007/08/21/AR2007082100146.html>.

diversion.<sup>147</sup> Overall the OIG found that, at the time, “DEA’s enforcement efforts [had] not adequately addressed the problem of controlled pharmaceutical diversion” which, in the OIG’s estimation, was largely attributable to DEA’s failure to devote sufficient resources to address the issue.<sup>148</sup> Central to OIG’s finding was the relative few number of diversion investigators employed by the agency when compared to other field positions, stating “[d]espite the widespread misuse of controlled pharmaceuticals, field diversion investigators, whose goal is to prevent the diversion of controlled pharmaceuticals, constitute only 10 percent of the DEA’s total field investigator positions.”<sup>149</sup>

The OIG report noted the increased OxyContin abuse seen in West Virginia, as well as other areas, stating it was “important for the DEA to recognize emerging trends and patterns of controlled pharmaceutical diversion and to respond quickly where significant problems are developing.”<sup>150</sup>

The OIG found that, at the time, diversion investigations constituted only a fraction of the DEA’s overall casework. Investigations related to illicit drug trafficking garnered the vast majority of the time DEA devoted to its field work, with diversion investigations constituting only 7.7 percent of DEA investigators’ time in FY 2001.<sup>151</sup> OIG noted that the DEA had less resources allocated for diversion investigations in FY 2001 than it did in FY 1993, despite significant increases in the utilization and abuse of controlled substances that occurred during this period.<sup>152</sup> In order to more effectively address controlled substance diversion, the OIG recommended, among other things, that the DEA increase the resources devoted to controlled substance diversion. The DEA concurred with the OIG’s recommendation.<sup>153</sup>

**FINDING: In 2002, DOJ OIG found that “DEA’s enforcement efforts [had] not adequately addressed the problem of controlled pharmaceutical diversion” and that diversion investigators accounted for only 10 percent of the agency’s total field investigator positions.**

Five years later, in 2007, the DEA indicated in a fact sheet that diversion was a significant problem in the state at that time, stating:

Current investigations indicate that diversion of hydrocodone products and diazepam continues to be a problem in West Virginia. Primary methods of diversion being reported are illegal sale and distribution by health care professionals and workers, “doctor shopping” (going to a number of doctors to obtain prescriptions for a controlled pharmaceutical), employee theft,

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<sup>147</sup> See U.S. DEP’T OF JUSTICE OFFICE OF INSPECTOR GEN., REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION’S INVESTIGATIONS OF THE DIVERSION OF CONTROLLED PHARMACEUTICALS (Sept. 2002) *available at* <https://oig.justice.gov/reports/DEA/e0210/final.pdf>.

<sup>148</sup> *Id.* at ii.

<sup>149</sup> *Id.* at 11.

<sup>150</sup> *Id.* at 1.

<sup>151</sup> *Id.* at 13.

<sup>152</sup> *Id.* at 12.

<sup>153</sup> *Id.*

forged prescriptions, and the Internet. Alprazolam, Vicodin, and methadone were also identified as being among the most commonly abused and diverted pharmaceuticals in West Virginia. West Virginia leads the nation in methadone-related deaths per capita, and has the fastest-growing rate of methadone overdoses.<sup>154</sup>

Methadone is a synthetic opioid frequently used as part of a treatment for an addiction to prescription opioids or heroin.<sup>155</sup>

**FINDING: In 2007, a DEA fact sheet indicated that diversion was a significant problem in West Virginia, which led the nation in methadone-related deaths per capita, and had the fastest-growing rate of methadone overdoses.**

Nearly five years after that, in 2011, an internal DEA report noted that OxyContin was heavily marketed in West Virginia due to the high rate of work-related injuries, and that once addicted, many patients were cut off from their supply by their doctors and then turned to street dealers or doctor shopping to acquire pharmaceuticals.<sup>156</sup> In a message appended to the report, the DEA Special Agent in Charge of the Washington Division at the time summarized the growing problem:

Abuse and distribution of illicit pharmaceuticals continues to increase in West Virginia, driven by independent drug trafficking organizations and diversion by some doctors and pharmacists. Although law enforcement agencies in West Virginia have been focusing on the problem of prescription drug trafficking, and cooperating with the medical community on creating prevention programs and initiatives, the upward trend of pharmaceutical diversion and abuse is proving to be a difficult problem to address.<sup>157</sup>

According to the report, the sources of controlled substance diversion in West Virginia were varied. The report stated:

West Virginia has a growing problem with controlled pharmaceuticals being diverted by health care providers and by the friends and relatives of pharmaceutical drug users, and sold by independent drug trafficking organizations (DTO) operating in the surrounding region. Diversion of pharmaceutical controlled substances by doctors and pharmacists has resulted in these individuals becoming sources of supply (SOS) for pharmaceutical DTOs. Pharmacy employee theft and robbery by addicts

<sup>154</sup> U.S. Drug Enforcement Admin., *West Virginia 2007* (On file with Committee).

<sup>155</sup> *What is Methadone?* WebMD, available at <https://www.webmd.com/mental-health/addiction/what-is-methadone#1> (last accessed Dec. 7, 2018).

<sup>156</sup> Special Agent in Charge, Washington Div., U.S. Drug Enforcement Admin., *Pharmaceutical Trafficking and Abuse Situation in West Virginia*, Jan. 2011 (On file with Committee).

<sup>157</sup> *Id.*

and traffickers has also helped to place more drugs in the hands of addicts. Pharmaceutical DTOs are particularly active in West Virginia, drawn by the high demand and potential for profit – pharmaceuticals are often sold illicitly at prices two to three times higher than in other states.<sup>158</sup>

Independent drug trafficking organizations were “particularly drawn to the rural southern counties that have a long history of alcohol and illicit drug abuse” and much of the diverted controlled substances sold in West Virginia at that time were believed to have originated from out-of-state sources, including Florida pill mills.<sup>159</sup> The report also stated that West Virginia physicians were another source of diversion, with some doctors unknowingly contributing to the problem, while others knowingly sought to profit and wrote prescriptions in exchange for cash or knowingly prescribed to “doctor shoppers.”<sup>160</sup> The report stated:

Many cases of diversion by doctors stem from neglect or a lack of knowledge on the part of the physician. Most doctors are not pain specialists, and when a patient comes with a real or faked chronic pain, some doctors are quick to prescribe often excessive amounts of painkillers such as oxycodone without understanding and warning patients of the addictive qualities of the drug. These patients often develop addictions, and if the doctor cuts them off they must turn to independent drug trafficking organizations for their supply. In some cases, doctors may fail to recognize the addiction, or only medically examine the patient a few times and simply continue prescribing powerful narcotic drugs.

Other West Virginia doctors divert pharmaceuticals for a variety of reasons and in some instances with numerous methods of creating fraudulent prescriptions. In return for money, or a portion of the drugs, doctors may sell prescriptions to known distributors, becoming themselves part of the DTOs. Other cases suggest that doctors may knowingly prescribe to “doctor shoppers.” Often these doctors will require that patients pay for visits in cash and will issue ‘no refill’ prescriptions. The patient must return repeatedly to the doctor to get a new prescription and pay for each visit, in cash, or a portion of the drugs prescribed being provided back to the doctor. Some unscrupulous doctors have solicited sexual acts in return for giving their patient a prescription.<sup>161</sup>

The report also cited pharmacies in West Virginia as being a potential source of diversion, with some working in tandem with suspect clinics or doctors. The report stated:

Some pharmacies in West Virginia are also places where diversion of controlled substances occur. These pharmacies often fill ‘suspicious’ prescriptions without verifying the prescription with the clinic of origin

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<sup>158</sup> *Id.* at 2.

<sup>159</sup> *Id.* at 2-3.

<sup>160</sup> *Id.* at 4.

<sup>161</sup> *Id.*

reporting their suspicions. Some pharmacies have taken this a step further and are linked with the clinic or doctor that issues the suspect prescriptions, and may be located close to the clinic for patients to fill their prescriptions. Through falsification of records, fraudulently filling ‘call-in’ prescriptions, and adding refills to ‘no-refill’ prescriptions, pharmacies can contribute to diversion with or without the aid of a prescribing physician. These pharmacies are often linked to cases involving insurance fraud, and exist both in West Virginia and out of the state, and can act as a source of supply for DTOs bringing controlled substances into West Virginia.<sup>162</sup>

**FINDING: In 2011, DEA was aware that distribution of diverted controlled substances was on the rise in West Virginia and that drug trafficking organizations selling the diverted drugs were “particularly active” in the state.**

In 2006, four years after the OIG warned DEA that it was not devoting enough resources to address controlled substance diversion nationwide, including in West Virginia, the agency only had two diversion investigators assigned to the state.<sup>163</sup> That year, West Virginia, along with New Mexico, had the highest overdose death rate in the United States.<sup>164</sup> DEA has maintained that in the 2006 timeframe the agency was concentrating most of its resources to combatting illicit pill mill doctors and pharmacies in Florida and indicated that it didn’t start to devote significant resources to West Virginia until 2015.<sup>165</sup> According to the West Virginia Department of Health and Human Services, between 2001 and 2015, 6,001 lives were lost in West Virginia to an overdose involving at least one opioid.<sup>166</sup>

**FINDING: In 2006, the DEA had two diversion investigators assigned to West Virginia. That year, West Virginia, along with New Mexico, had the highest overdose death rate in the United States.**

In recent years, the DEA has placed greater emphasis and devoted additional resources to addressing controlled substance diversion in West Virginia. For example, as of 2018 there are six diversion investigators assigned to West Virginia, according to the DEA.<sup>167</sup>

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<sup>162</sup> *Id.* at 5.

<sup>163</sup> Briefing from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018. See also *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).

<sup>164</sup> Centers for Disease Control and Prevention, *Unintentional Drug Poisoning in the United States*, available at [https://www.cdc.gov/medicationsafety/pdfs/cdc\\_5538\\_ds1.pdf](https://www.cdc.gov/medicationsafety/pdfs/cdc_5538_ds1.pdf).

<sup>165</sup> Briefing from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

<sup>166</sup> W. Va. Dep’t of Health and Human Res., *West Virginia Drug Overdose Deaths Historical Overview 2001-2015*, 7, Aug. 17, 2017 available at [https://dhhr.wv.gov/oeeps/disease/ob/documents/opioid/wv-drug-overdoses-2001\\_2015.pdf](https://dhhr.wv.gov/oeeps/disease/ob/documents/opioid/wv-drug-overdoses-2001_2015.pdf).

<sup>167</sup> See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).



In addition, the DEA's efforts to combat controlled substance diversion are now overseen by an Assistant Special Agent in Charge who is based in Charleston, West Virginia instead of Washington, D.C.<sup>168</sup> In 2016, the DEA also established a second Tactical Diversion Squad (TDS) in the state, bringing additional resources to coordinate and enhance multi-jurisdiction investigations into controlled substance diversion.<sup>169</sup> A "mobile" TDS was dispatched to the state the following year.<sup>170</sup> On November 29, 2017, then-Attorney General Sessions and then-Acting Administrator Patterson announced DEA's plan to establish a new field division, based in Louisville, Kentucky, to better enhance and consolidate DEA enforcement efforts in the Appalachian region.<sup>171</sup> The new field division became operational on January 1, 2018 and has jurisdiction over DEA's efforts in Kentucky, Tennessee, and West Virginia.<sup>172</sup>

Most recently, in October 2018, the DOJ announced the formation of the Appalachian Regional Prescription Opioid Strike Force (ARPO Strike Force) which is a joint law enforcement effort involving a number of federal entities, including the DOJ's Health Care Fraud Unit, U.S. Attorney's Offices in nine federal districts, the FBI, DEA, and the Department of Health and Human Services Office of Inspector General.<sup>173</sup> According to the DOJ, "[t]he mission of the ARPO Strike Force is to identify and investigate health care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids."<sup>174</sup>

Notwithstanding recent actions, DEA officials told Committee staff that in hindsight it is clear more could and should have been done in West Virginia, particularly in the 2006-2009 timeframe.<sup>175</sup> DEA has not indicated in detail to the Committee what lessons were learned, however, and how DEA could have acted sooner.

## **2. DEA Did Not Effectively Use ARCOS Data in West Virginia or Elsewhere**

One way the DEA is able to review and detect possible diversion trends is through use of registrant-submitted data regarding controlled substance usage. The Committee found, however,

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<sup>168</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 5 (2018) (statement of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Wstate-PattersonR-20180320.pdf>.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* "Mobile" TDSs are units that DEA can deploy quickly to "hot spots" around the country in furtherance of the agency's efforts to combat controlled substance diversion.

<sup>171</sup> See Press Release, U.S. Dep't of Justice, Attorney General Sessions and Acting DEA Administrator Patterson Announce New Tools to Address Opioid Crisis (Nov. 29, 2017), <https://www.justice.gov/opa/pr/attorney-general-sessions-and-acting-dea-administrator-patterson-announce-new-tools-address>.

<sup>172</sup> *Id.*

<sup>173</sup> See Press Release, U.S. Dep't of Justice, Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force for Focus on Illegal Opioid Prescriptions (Oct. 25, 2018), <https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid>.

<sup>174</sup> *Id.*

<sup>175</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

that the DEA did not utilize these data in a proactive manner to combat controlled substance diversion at the time the opioid epidemic was worsening in West Virginia. When the Committee reviewed the historical registrant-submitted data, it was able to identify large increases in hydrocodone and oxycodone shipments to West Virginia pharmacies that should have merited closer inspection by DEA at the time.

Pharmaceutical manufacturers and distributors are required to report their controlled substance transactions to the DEA under the CSA.<sup>176</sup> The bulk of these reported transactions include manufacturers' sales to distributors, and distributors' sales to pharmacies, hospitals and doctors, but can also include other types of transactions such as loss through theft. With approximately 90 million transactions reported to the DEA every year,<sup>177</sup> the agency relies on an automated reporting system to record and track these transactions. The system developed by the DEA for this purpose is known as the Automation of Reports and Consolidated Orders System (ARCOS). This system enables the DEA to keep a current and historical record of controlled substance inventories and allows the agency to track controlled substances from the time they are manufactured until they are dispensed to consumers through pharmacies, doctors or other means.

The information recorded and tracked through ARCOS includes all manufacturer and distributor transactions involving all schedule I and schedule II controlled substances, as well as narcotic substances in schedule III and other select substances. Manufacturers are also required to report the manufacture of certain schedule III and schedule IV psychotropic controlled substances.<sup>178</sup> Entities required to report transactions through ARCOS are required to report on a quarterly basis, at a minimum.<sup>179</sup> Regulations allow entities to report their transactions to the DEA more frequently, but not more frequently than once a month.<sup>180</sup> Though the majority of registrants submit reports electronically, the DEA estimates that approximately 50 registrants still report by paper submission.<sup>181</sup>

The ARCOS data provide DEA with a unique investigative tool that can be used to detect drug diversion or to build a case against a registrant. Enforcement actions such as an OTSC or ISO brought against a pharmacy or distributor could, for example, cite ARCOS data to demonstrate the amount of controlled substances dispensed by a registrant.<sup>182</sup> However, according to the DEA, the way the agency has used ARCOS data as part of its anti-diversion efforts has evolved over time.

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<sup>176</sup> See 21 U.S.C. §827(d)(1). The CSA requires reports be made to the Attorney General, who has delegated this authority to the DEA. See also 28 C.F.R. § 0.100.

<sup>177</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, June 25, 2018.

<sup>178</sup> U.S. Drug Enforcement Administration, ARCOS Registrant Handbook, <https://www.deadiversion.usdoj.gov/arcos/handbook/section1.htm> (last visited Sept. 14, 2018).

<sup>179</sup> 21 C.F.R. § 1304.33.

<sup>180</sup> *Id.*

<sup>181</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, June 25, 2018.

<sup>182</sup> See e.g., U.S. Drug Enforcement Admin., *In re Masters Pharmaceutical, Inc.*, Order to Show Cause, Aug. 9, 2013 (On file with Committee). In the Order to Show Cause brought against Masters Pharmaceutical, Inc., the DEA wrote that ARCOS data showed the distributor's oxycodone sales in Florida exceeded 52 million dosage units between April 1, 2009 and March 31, 2011.

a. *DEA's Historical Use of ARCOS Data*

Prior to 2010, the ARCOS system was “an extremely manual process” and therefore difficult to use proactively in investigations.<sup>183</sup> This was due both to the posture of the program at the time as well as technical limitations that made it difficult to verify and use the data submitted.<sup>184</sup> In the early to mid-2000s, the DEA relied on registrants to submit suspicious orders—something DEA officials said many registrants did not do—to detect possible diversion.<sup>185</sup> Officials from DEA Diversion Control’s Pharmaceutical Investigations Section told Committee staff that proactive analysis of ARCOS data was difficult because the reports submitted by registrants often contained errors and it took time to verify the data.<sup>186</sup> At that time, registrants were not required to fix errors in an ARCOS report until they submitted the next report, meaning that if a registrant submitted reports on a quarterly basis, several months could pass before they addressed errors in the last submission. As a result, the employees who reviewed ARCOS reports spent more time correcting the data than proactively analyzing it for use in investigations.<sup>187</sup>

Instead, ARCOS data were used reactively to build and strengthen enforcement action cases. The Diversion Control unit that analyzed ARCOS data would provide relevant data to investigators after they had identified a target and were working to build a case.<sup>188</sup> Those targets were often identified by other means, such as through a tip or undercover work.<sup>189</sup> However, the fact that ARCOS data were utilized in enforcement actions and cited in orders from the DEA Administrator demonstrates that the agency possessed the capacity to overcome the data quality issues it cited as a deterrent to proactive use.<sup>190</sup> In addition, documents produced to the Committee suggest that the DEA did use ARCOS data on a proactive basis in at least some cases. For example, in a December 2005 memorandum, the then-Chief of DEA’s E-Commerce Section wrote:

On November 28, 2005, [redacted], Legal Counsel, representing the McKesson Corporation, contacted, [redacted] and [redacted] responding to questions about sales of controlled substances by the McKesson Corporation to six Internet Pharmacies located in the Miami Field Division.

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<sup>183</sup> See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 32 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>184</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

<sup>185</sup> *Id.*

<sup>186</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, June 25, 2018.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> See, e.g. 72 Fed. Reg. 36,487, July 3, 2007. In the July 3, 2007 final order issued by the DEA’s Deputy Administrator that revoked the DEA registration of Southwood Pharmaceuticals Inc., the Deputy Administrator cited ARCOS data to demonstrate the volume of hydrocodone doses Southwood sold to various customers.

Questions to the McKesson Corporation were based upon the October ARCOS reports.<sup>191</sup>

In a January 2006 memorandum, and reproduced in relevant part below, the DEA specifically cited ARCOS data from October 2005 as one of the items it discussed during a January 2006 meeting with McKesson.<sup>192</sup>

- The E-Commerce Section retrieved ARCOS data which revealed that between October 10 and October 21, 2005, the following alleged Internet pharmacies received the identified quantities of hydrocodone:
  - United Prescription Services – 252,100 d.u.
  - Universal RX – 254,700 d.u.
  - Bi-Wise Pharmacy – 158,400 d.u.
  - Avee Pharmacy – 520,200 d.u.
  - Medipharm RX – 500,900 d.u.
  - Accumed Pharmacy – 404,400 d.u.

DEA began to refine its strategy related to using ARCOS data around 2010, as diversion investigators' focus turned to tackling the massive problem that pill mill pharmacies posed in Florida. The DEA launched the ARCOS Electronic Data Interchange Program in November 2009 to provide registrants access to a secure internet portal system to speed up the processing of transaction and error reports.<sup>193</sup> DEA's Diversion Control's Pharmaceutical Investigations Section also started developing better querying tools around that time and began to analyze ARCOS data in new ways to identify diversion targets.<sup>194</sup> Specifically, DEA officials said the data analysis unit began reviewing ARCOS data to identify information on top purchasers of controlled substances.<sup>195</sup>

**FINDING: Prior to 2010, DEA primarily used ARCOS data reactively in enforcement cases. According to DEA, technical limitations and data errors made it difficult for the DEA to utilize ARCOS data to identify investigative leads.**

*b. DEA's Failure to Use ARCOS Data Proactively*

The Committee saw firsthand what a powerful tool ARCOS data can be in the course of this investigation. The DEA provided the Committee with ARCOS data that detailed

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<sup>191</sup> Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee).

<sup>192</sup> Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee). All the pharmacies referenced in the screen shot above were cited by the DEA in its 2007 final order revoking the registration of Southwood Pharmaceuticals. Southwood's sales to each of the pharmacies were among the predicates for the revocation of its DEA registration in 2007. See 72 Fed. Reg. 36,487, July 3, 2007.

<sup>193</sup> U.S. Drug Enforcement Admin, Automated Reports and Consolidated Orders System (ARCOS), Nov. 10, 2009, available at <https://www.deadiversion.usdoj.gov/arcos/index.html#edi>.

<sup>194</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

<sup>195</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, June 25, 2018.

hydrocodone and oxycodone shipments to pharmacies in rural regions of West Virginia. The data were presented by ZIP code prefix and included the number of dosage units each distributor shipped annually to individual pharmacies.

The data highlighted numerous problems, including suspicious spikes in controlled substance purchases that merited investigation, such as the nearly five million hydrocodone and oxycodone dosage units McKesson shipped in two years to a pharmacy in a 406-person town.<sup>196</sup> That pharmacy, Sav-Rite Pharmacy No. 1, received approximately 13 million doses of hydrocodone and oxycodone from all distributors between 2006 and 2012 and eventually closed and its owner served time in prison for charges related to the operation of a pill mill.<sup>197</sup> Analysis of ARCOS data would have allowed for comparisons with other independent or chain pharmacies in the region, where hydrocodone and oxycodone purchases remained fairly level. For example, four Rite Aid pharmacies in the same zip code prefix area each received between 1.48 and 2.66 million doses of hydrocodone and oxycodone in total between 2006 and 2016.<sup>198</sup>

**FINDING: Had DEA more proactively used ARCOS data, it could have discovered that between 2006 and 2012, distributors shipped more than 13 million doses of hydrocodone and oxycodone to Sav-Rite Pharmacy No. 1. By contrast, four Rite Aid pharmacies in the same zip code prefix area each received between 1.48 and 2.66 million doses of hydrocodone and oxycodone between 2006 and 2016.**

Despite the limitations DEA officials have described regarding their ability to proactively analyze ARCOS data and detect outliers and potential bad actors, the information the DEA collected should have been enough to trigger closer scrutiny as some pharmacies continued to receive high numbers of opioids for years. During the Subcommittee's March 20, 2018 hearing Mr. Patterson testified that, based on raw data alone, the DEA should have been able to identify the significant amount of controlled substances that distributors sent to Sav-Rite Pharmacy No. 1 in Kermit, West Virginia. Mr. Patterson testified:

Q. Thank you so much, Mr. Chairman, and I agree that we - - Mr. Patterson, that we do need to look forward how we can improve things. But I don't think we can do it without examining the past, and this ARCOS system is the perfect example. I want to spend a few minutes following up on what the chairman was asking you, because you said - - my understanding is ARCOS was in place during this whole time period, 2006 to 2016, correct?

A. That's correct, ma'am.

Q. And but - - and so what was happening the data was just being reported in but nothing was being done with it. Isn't that correct?

<sup>196</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>197</sup> See *infra*, Section V(B)(3).

<sup>198</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

- A. I would say it was used in a very reactive way.
- Q. Right. So – so you said that a lot of times you wouldn’t have been able to tell this from ARCOS. I am going to assume, though, if we had been analyzing this data we would have found the 184,000 pills per month that McKesson was selling to Kermit if some had looked at it. Wouldn’t you think so?
- A. I do agree with that.
- Q. Yes. And wouldn’t you - - wouldn’t you agree that in Kermit - - I think you said yes when the chairman said this - - it was 2.2 million pills in a year in Kermit. All you’d have to do is look at that raw data and see that, wouldn’t you?
- A. That’s correct.<sup>199</sup>

The DEA also told the Committee, that based on its analysis, the ARCOS data from distributors who sold controlled substances in southern West Virginia between 2006 and 2016 “demonstrates similar patterns that DEA observed in Florida in 2011 and 2012.”<sup>200</sup>

**FINDING: According to DEA, an analysis of ARCOS data from distributors who sold controlled substances to West Virginia pharmacies “demonstrates similar patterns that DEA observed in Florida in 2011 and 2012.”**

The DEA had long-standing knowledge that controlled substance diversion was an issue that plagued West Virginia. Had the DEA better used ARCOS data to identify potentially problematic pharmacies, it could have better leveraged its resources to combat diversion in West Virginia.

*c. Improvements to ARCOS Analysis*

As stated previously, DEA began to refine its approach to using ARCOS data beginning in 2010. Since then, the DEA has implemented a number of initiatives that make it easier to utilize the ARCOS data for investigative purposes. In 2015, the DEA created a new online reporting system for ARCOS that was meant to simplify the ARCOS reporting process and immediately flag any errors in registrants’ reports.<sup>201</sup> As of April 2016, the online system

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<sup>199</sup> *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 35-36 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.*

<sup>200</sup> Letter from Section Chief, Cong. Affairs Section, U.S. Drug Enforcement Admin. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Nov. 8, 2017 (On file with Committee).

<sup>201</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

flagged errors which the registrants were required to fix before the reports could be submitted.<sup>202</sup> In his written testimony for the Subcommittee’s March 20, 2018 hearing, then-Acting Administrator Patterson stated that this effort “will help the ARCOS system to capture more accurate data and provide a more real time snapshot of the flow of controlled substances within the drug supply chain.”<sup>203</sup> More recently in 2017, the DEA began sending targeted “packages” to field divisions that included analysis of ARCOS data, including drug sales trends within the division and top pharmacy purchasers.<sup>204</sup> Field agents can also log into ARCOS to run reports themselves, for example, to identify the top purchasers or distributors of a certain controlled substance within their state or region.<sup>205</sup>

Since the Committee began its investigation and highlighted the importance and use of ARCOS data, DEA appears to have increased its use of ARCOS data as well. For example, in August 2017 then-Attorney General Jeff Sessions announced the formation of a “new data analytics program”—the Opioid Fraud and Abuse Detection Unit—that will run data analytics to identify opioid-related use trends, such as physicians who write opioid prescriptions at rates that far exceed their peers and pharmacies that dispense disproportionately large amounts of opioids.<sup>206</sup>

On December 5, 2017, DEA announced “Operation Faux Pharmacy,” in which DEA investigations targeted 26 pharmacies “identified as potential violators of the Controlled Substances Act as a result of investigations triggered by data that was exhaustively compared and analyzed with previous administrative or criminal violations from previous, similar cases” including data that manufacturers and distributors report to the DEA.<sup>207</sup>

Similarly, on April 2, 2018, DEA announced that, during a surge period in February and March, DEA analyzed “80 million transaction reports from DEA-registered manufacturers and distributors” among other reports, which resulted in the development of 366 leads to DEA field offices, 188 of which resulted in active investigations.<sup>208</sup> When then-Attorney General Sessions

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*See also*, Letter from Chief, Registration & Program Support Section, U.S. Drug Enforcement Admin. to Registrants, Oct. 21, 2015, *available at* [https://www.deadiversion.usdoj.gov/arcos/arcos\\_letter.pdf](https://www.deadiversion.usdoj.gov/arcos/arcos_letter.pdf).

<sup>202</sup> Letter from Chief, Registration & Program Support Section, U.S. Drug Enforcement Admin., to Registrants, [undated], *available at* [https://www.deadiversion.usdoj.gov/arcos/arcos\\_enhancement.pdf](https://www.deadiversion.usdoj.gov/arcos/arcos_enhancement.pdf).

<sup>203</sup> *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 9 (2018) (statement of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) *available at* <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Wstate-PattersonR-20180320.pdf> (internal quotations omitted).

<sup>204</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, June 25, 2018.

<sup>205</sup> *Id.*

<sup>206</sup> Press Release, Dep’t of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017) *available at* <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>.

<sup>207</sup> Press Release, U.S. Drug Enforcement Admin., DEA Large-scale Operation Targets 26 Pharmacies In Three States In Attack Against Illicit Opioid Abuse And Trafficking, (Dec. 5, 2017) *available at* <https://www.dea.gov/press-releases/2017/12/05/dea-large-scale-operation-targets-26-pharmacies-three-states-attack>.

<sup>208</sup> Press Release, U.S. Drug Enforcement Admin., DEA Surge In Drug Diversion Investigators Leads To 28 Arrests And 147 Revoked Registrations, (April, 2, 2018) *available at* <https://www.dea.gov/press-releases/2018/04/02/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked>.

announced this surge on January 30, 2018, he stated that “DEA will aggregate these numbers to find patterns, trends, statistical outliers—and put them into targeting packages.”<sup>209</sup>

The DEA also told the Committee that, between January 2016 and June 2018, it identified 160 distributors that shipped “potentially excessive amounts of opioids” and 7,680 pharmacies that “purchased potentially excessive amounts of opioids” through proactive analyses of ARCOS data.<sup>210</sup>

*d. Increasing ARCOS Transparency*

The DEA currently makes only a summary of ARCOS data publicly available.<sup>211</sup> That information includes a breakdown of the number of controlled substances distributed to each state and three-digit ZIP code prefix but does not identify any of the companies that ship or receive the controlled substances. Amid the opioid crisis, some have called for greater transparency of ARCOS data. For example, the Healthcare Distribution Alliance, an association representing major wholesale drug distributors, has said it would be helpful for distributors to have access to “aggregated and blinded purchasing data from the ARCOS database” in order to compare their own customers’ orders against the total amount of controlled substances the customer receives from all distributors.<sup>212</sup>

The DEA announced some steps this year to provide greater access to ARCOS data. In February 2018, the DEA presented a new ARCOS feature that would enable distributors and manufacturers to view the number of businesses that had sold a particular controlled substance to a prospective customer during the prior six months.<sup>213</sup> The DEA said this tool would help distributors and manufacturers evaluate whether a new customer posed a risk for diversion.<sup>214</sup> In April 2018, the DEA announced an agreement between the agency and 48 attorneys general that would allow ARCOS data to be shared with local prosecutors in exchange for states granting the

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<sup>209</sup> Remarks by Attorney General Sessions on Efforts to Reduce Violent Crime and Fight the Opioid Crisis, U.S. Dep’t of Justice (Jan. 30, 2018) *available at* <https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-efforts-reduce-violent-crime-and-fight-opioid>.

<sup>210</sup> See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).

<sup>211</sup> See ARCOS Retail Drug Summary Reports, U.S. Drug Enforcement Admin, *available at* [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary/index.html](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html) (last accessed Dec. 7, 2018).

<sup>212</sup> Press Release, Healthcare Distribution Alliance, HDA Statement on Enhanced Information Sharing Between DEA and Attorneys General (Apr. 18, 2018) *available at* <https://www.healthcaredistribution.org/news/2018-04-18-hda-statement-on-enhanced-information-sharing-between-dea-and-attorneys-general>. As discussed in greater detail in section VI(A)(1), distributors can request and obtain dispensing data from their pharmacy customers, which would also provide the aggregated volume of controlled substances the pharmacy dispenses in a given period of time.

<sup>213</sup> Press Release, U.S. Drug Enforcement Admin., DEA Creates New Resource to Help Distributors Avoid Oversupplying Opioids (Feb. 14, 2018) *available at* <https://www.dea.gov/press-releases/2018/02/14/dea-creates-new-resource-help-distributors-avoid-oversupplying-opioids>.

<sup>214</sup> *Id.*



DEA access to prescription drug information, often from prescription drug monitoring programs.<sup>215</sup>

In October 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act).<sup>216</sup> Section 3273 of the SUPPORT for Patients and Communities Act amends the CSA and provides distributors with additional data through ARCOS by requiring the DEA to make available to distributors, among other things, the total number of distributors that provide controlled substances to a pharmacy or practitioner as well as the total number and type of opioids that are distributed to a pharmacy or a practitioner during a given period, but not less frequent than quarterly.<sup>217</sup>

### **3. DEA's Efforts to Follow Up on Red Flags Identified by Distributors in West Virginia**

#### **a. DEA's Response to Suspicious Orders Submitted by Distributors**

In addition to ARCOS data submitted by pharmaceutical manufacturers and distributors, the DEA receives other information that could warrant investigation of unusually high opioid shipments. The Committee's investigation found many instances in which distributors sent suspicious order reports to the DEA or otherwise apprised the agency of concerning activity by doctors or pharmacies, but what action the DEA took in response, if any, was not clear. For example, information obtained by the Committee shows that AmerisourceBergen flagged Tug Valley Pharmacy in more than half of the suspicious order reports it submitted to the DEA in 2009.<sup>218</sup> Similarly, during a two-month period in 2008, H.D. Smith reported 67 of Tug Valley's orders to the DEA as suspicious.<sup>219</sup> H.D. Smith also warned the DEA about two doctors whose prescriptions were filled at Tug Valley, Drs. Katherine Hoover and Diane Shafer.<sup>220</sup> On April 25, 2008, H.D. Smith notified the DEA "that Tug Valley was ordering a significant amount of hydrocodone and that approximate 87% of the prescriptions for hydrocodone were collectively written by Dr. Katherine Hoover and Dr. Diane Shafer."<sup>221</sup>

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<sup>215</sup> Press Release, Dep't of Justice, DEA to Share Painkiller Prescription Information with 48 Attorneys General (Apr. 17, 2018) available at <https://www.justice.gov/opa/pr/dea-share-painkiller-prescription-information-48-attorneys-general>.

<sup>216</sup> See SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

<sup>217</sup> SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

<sup>218</sup> AmerisourceBergen began submitting suspicious orders regarding West Virginia customers to the DEA in 2007. In 2009, it sent 60 such reports to the DEA and 36 of the reports submitted that year flagged purchases made by Tug Valley Pharmacy. See AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

<sup>219</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>220</sup> More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i). More information regarding Dr. Shafer can be found at *infra* fn. 751.

<sup>221</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

The DEA registrations of both doctors were eventually either revoked or surrendered voluntarily,<sup>222</sup> but the Committee did not receive any documentation suggesting that the DEA took action to investigate Tug Valley Pharmacy itself. For example, the Committee saw no indication that the DEA issued either an ISO or OTSC against Tug Valley. The pharmacy's activities were, however, of interest to the DEA. The DEA did consider the pharmacy's practices concerning enough to cite them as a basis for an administrative action against a distributor that supplied the pharmacy. Years later when the DEA filed an OTSC against Miami-Luken in 2015, it cited the company's high controlled substance shipments to several West Virginia pharmacies, including Tug Valley. Yet if the controlled substance shipments to Tug Valley Pharmacy were of great a concern to the DEA, the agency had been in possession of information about the pharmacy's suspect dispensing practices since 2008.

**FINDING: DEA received suspicious order reports regarding sales to Tug Valley Pharmacy as early as 2008 and cited controlled substance sales to the pharmacy in an OTSC against a distributor in 2015, yet never issued an ISO or OTSC against the pharmacy.**

In addition, while distributors did not always submit suspicious order reports, the Committee's investigation found that thousands have been submitted to the DEA in recent years regarding West Virginia pharmacies alone. For example, according to data submitted by the distributors:

- McKesson reported more than 10,000 suspicious orders regarding West Virginia customers between 2013 and 2017.<sup>223</sup>
- Cardinal Health reported more than 2,000 suspicious orders regarding West Virginia customers between 2012 and 2017.<sup>224</sup>
- AmerisourceBergen reported more than 2,000 suspicious orders regarding West Virginia customers between 2007 and 2017.<sup>225</sup>

Many of the suspicious orders involve the same customers, meaning the DEA was alerted that some pharmacies were repeatedly being denied controlled substance orders because distributors were concerned about possible diversion.

For example, AmerisourceBergen submitted approximately 400 suspicious orders for a single pharmacy, Beckley Pharmacy between 2012 and 2015.<sup>226</sup> While the Committee does not

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<sup>222</sup> See E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Nov. 3, 2017 5:56 pm) (On file with Committee).

<sup>223</sup> McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

<sup>224</sup> Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2012 – 2017 (On file with Committee).

<sup>225</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

<sup>226</sup> *Id.*

know whether the DEA took any investigative action regarding the suspicious orders reported, when AmerisourceBergen investigated the pharmacy in 2015 it found numerous red flags of diversion and opted to stop doing business with Beckley.<sup>227</sup> An investigative report prepared for AmerisourceBergen by the Pharma Compliance Group states that the pharmacist at Beckley said 50 percent of prescriptions filled there were for controlled substances and that other pharmacies refused to fill prescriptions for some of Beckley’s customers.<sup>228</sup> Additionally, the report said some of the pharmacy’s top controlled substance prescribers were among the top hydrocodone prescribers in West Virginia, and the investigators noted, “[i]t appears that the pharmacy is filling excessive and unusual amounts of controlled substances.”<sup>229</sup> Investigators also interviewed the pharmacy’s security guard who referred to some of the pharmacy’s customers as “drug addicts” and “drug dealers,” adding that he witnessed numerous drug deals in the pharmacy’s parking lot.<sup>230</sup>

One possible reason for the DEA’s inconsistent responses to suspicious orders could be the irregular way they are reported. Some suspicious order reports are sent to DEA field divisions while others are sent to diversion staff at DEA headquarters. According to DEA officials, only distributors with which the DEA has a memorandum of agreement are required to report suspicious orders to headquarters.<sup>231</sup> All other distributors report suspicious orders to field divisions. Because the reporting is decentralized, it leaves open the possibility that the DEA’s 23 field divisions might review or investigate suspicious orders in inconsistent manners. Based on the Committee’s investigation, it appears that DEA headquarters did not always communicate effectively or consistently with the agency’s field divisions to ensure that regulations were being applied in a consistent manner. At the Subcommittee’s March 20, 2018 hearing, then-Acting Administrator Patterson testified:

Q. Has DEA identified breakdowns in the way its field division processes suspicious order reports in the past and what corrections or adjustments have been made or do you anticipate being made?

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<sup>227</sup> AmerisourceBergen reinstated Beckley Pharmacy as a customer in 2016 after a subsequent review determined that several of the concerns leading to its termination had been alleviated and the risk of diversion was reduced. *See Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) (On file with Committee)

<sup>228</sup> Pharma Compliance Group, Observations and Recommendations Report – Beckley Pharmacy, Feb. 15, 2015 (On file with Committee).

<sup>229</sup> *Id.* The report also noted that, in 2012, the pharmacy filled more than 2,000 oxycodone and Oxycontin prescriptions that were written by Dr. David Morgan whose practice was located more than 2-hour round-trip drive from the pharmacy. For further discussion on Dr. Morgan *see infra* Section VI(A)(2)(d)(ii)(C). The report also noted that a local pain management physician was potentially the top oxycodone prescriber in the United States under the Medicare Part D program, with 7,810 prescriptions written and filled in 2012. The report noted, however, that the pharmacist in charge did not identify this physician as a top prescriber at Beckley.

<sup>230</sup> Pharma Compliance Group, Observations and Recommendations Report – Beckley Pharmacy, Feb. 15, 2015 (On file with Committee).

<sup>231</sup> Briefing, Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Feb. 27, 2018.

- A. So, again, I think the uniformness of how we look at these things and the accountability that we hold the people to when we get these reports is critical.<sup>232</sup>

If suspicious orders are reviewed only at the local level, the DEA could miss broader national trends. Congress recently addressed this issue through the enactment of the SUPPORT for Patients and Communities Act. Pursuant to Section 3292 of the Act, DEA registrants are required to report suspicious orders to both the DEA Administrator as well as the Special Agent in Charge of the applicable DEA field division office. In addition, Section 3292 directs the DEA, within one year of enactment, to establish a centralized data base for collecting suspicious order reports.<sup>233</sup>

***b. Communication between the DEA and Distributors***

While the DEA has pointed to its Distributor Initiative program and other outreach efforts as a means of improving communications with distributors in recent years, distributors have voiced concern that the communication has been inadequate to provide meaningful guidance. Despite reporting suspicious orders and sharing other information with the DEA, distributors indicated they got little feedback from the DEA and did not know what—if anything—DEA investigators did with the information. Distributors' critique of DEA communication was not limited to West Virginia and reflected a broader dissatisfaction.

For example, at the Subcommittee's May 8, 2018 hearing, former H.D. Smith President and CEO J. Christopher Smith was asked whether he knew what the DEA did with the suspicious orders the company submitted over the years. Mr. Smith testified:

- Q. I think you testified to this, your company reports suspicious orders. What does the DEA do with that information when you report it?
- A. I don't really know.
- Q. You've sold your company, I understand that.
- A. But I don't really know. And the DEA, as we talk about the DEA, the DEA has not been the same in their outlook, attitude, and interaction with the industry over my career. For most of my career, the interactions with the DEA were very collaborative and very purposeful, in terms of working with them to try to control controlled substance distribution. Back about 10 years ago, with the advent of this expectation of holding orders, it became very, very difficult to

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<sup>232</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 134 (2018) (testimony of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.*

<sup>233</sup> *See SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).*

interact with the DEA and to get feedback. They were, in fact, as evasive as possible in the midst of this crisis to us, in terms of giving us guidance[.]<sup>234</sup>

After the hearing, other distributors expressed similar sentiment. In response to questions for the record, Cardinal Health wrote that the company “generally does not have knowledge of what actions DEA may take in response to suspicious order reporting.”<sup>235</sup> AmerisourceBergen similarly questioned the degree to which the suspicious orders it reported were shared within the agency, noting that “pharmacies remain DEA-licensed even after suspicious orders are reported.”<sup>236</sup> AmerisourceBergen told the Committee:

ABDC does not know whether DEA shares suspicious order reports with drug manufacturers, or even with DEA’s own local field offices. ABDC does not provide its suspicious order reports to any drug manufacturer ABDC does not have visibility into DEA’s internal processes and does not know how DEA processes, analyzes and uses the suspicious order data it provides. ABDC does know that pharmacies remain DEA-licensed even after suspicious orders are reported.<sup>237</sup>

While the DEA is under no obligation to tell distributors what it does with the data they provide and would likely refrain from sharing any information that might jeopardize an ongoing investigation, distributors’ confusion over the matter underscores a key concern of the Committee—whether the DEA acts on the information it requires distributors to report.

**FINDING: Distributors have expressed concern about the lack of guidance or feedback provided by the DEA, including on how it utilizes information provided by distributors, such as suspicious order reports.**

Several distributors also appear to have had the impression that if they submitted sales information to the DEA, the agency would flag concerning sales transactions for them. Cardinal Health indicated a preference for this arrangement in 2012 when it took the DEA to court to challenge an ISO which sought to revoke the DEA registration for the company’s distribution center in Lakeland, Florida. In a complaint filed in the case, Cardinal Health said it previously asked the DEA to “inform it of the identify of any Cardinal Health customer that the agency has

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<sup>234</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 88-89 (2018) (testimony of J. Christopher Smith, Former President and CEO, H.D. Smith Wholesale Drug Co.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>235</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by Cardinal Health, Inc.) (On file with Committee).

<sup>236</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the S. Comm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, Steven H. Collis, Chairman, President, and CEO, AmerisourceBergen Corp.) (On file with Committee).

<sup>237</sup> *Id.*

determined is engaged in the diversion of controlled substances,” and that the company would “immediately cease distribution of controlled substances to any customer that DEA so identifies.”<sup>238</sup> The DEA declined to provide customer names, according to Cardinal.<sup>239</sup>

Miami-Luken’s Board Chairman, Dr. Mastandrea, similarly testified that the company’s former management believed “that since Miami-Luken regularly provided the DEA with sales data for all its customers, the government would have advised them if they had concerns with sales to specific parties.”<sup>240</sup> But he also conceded that waiting for such communication from the DEA was not an acceptable substitute for maintaining a satisfactory suspicious order monitoring program.<sup>241</sup>

The DEA told the Committee that informing distributors about potentially problematic pharmacy customers without taking any enforcement action on its own would likely raise due process concerns. The agency stated:

For due process reasons, DEA does not inform distributors or other DEA registrants which of their commercial counterparties may have engaged in improper behavior. Were DEA to intercede in such a manner, constitutional issues would likely arise, as the entity DEA identified as a wrongdoer would have no forum in which to seek redress or otherwise confront the assertions made against it.<sup>242</sup>

**FINDING: For due process reasons, it is current DEA practice not to inform distributors or other registrants about customers that “may have engaged in improper behavior.”**

Irrespective of any limitation on its ability to communicate any concerns to distributors, it is imperative the DEA devotes the resources necessary to adequately review information it requires distributors to report, and takes action when deemed necessary. As the country continues to feel the effects of the opioid crisis, neither distributors nor the DEA can shirk their oversight responsibilities.

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<sup>238</sup> *Cardinal Health v. Holder* No. 12-cv-00185-RBW (D.D.C.) (Feb. 3, 2012) (Complaint and Prayer for Declaratory and Injunctive Relief) (On file with Committee) (internal quotation marks omitted).

<sup>239</sup> *Cardinal Health v. Holder* No. 12-cv-00185-RBW (D.D.C.) (Feb. 3, 2012) (Complaint and Prayer for Declaratory and Injunctive Relief) (On file with Committee).

<sup>240</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 27 (2018) (testimony of Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>241</sup> *Id.*

<sup>242</sup> E-Mail from Staff, U.S Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (May 21, 2018, 4:37 pm) (On file with Committee).

## **B. The Evolution of DEA’s National Strategy on Diversion Enforcement**

### **1. Decline in DEA Enforcement Actions Amid the Opioid Epidemic**

Under the CSA, the sale and manufacture of controlled substances in the United States are regulated through a closed system of drug distribution to ensure controlled substances are not diverted and used for illegitimate purposes.<sup>243</sup> Oversight of the closed system is primarily provided by the DEA, which has the authority to take civil, criminal, or administrative actions to investigate and prevent diversion.<sup>244</sup> The CSA requires all legitimate handlers of controlled substances to obtain a registration and, as a condition of maintaining such registration, take reasonable steps to ensure their registration is not being used as a source of diversion.<sup>245</sup> In situations where a registrant may be engaging in or facilitating diversion of controlled substances, the DEA has the authority to take administrative action to revoke or suspend a registration.<sup>246</sup> To effectuate this enforcement authority, the DEA may utilize OTSCs or ISOs.

An OTSC triggers an administrative process through which an entity’s DEA registration can be revoked or suspended, while an ISO immediately suspends the DEA registration while the underlying administrative case is adjudicated. An OTSC summarizes and outlines the allegations against a registrant and requires the registrant to appear at a hearing before an Administrative Law Judge (ALJ) to present evidence as to why their DEA registration should not be revoked or suspended.<sup>247</sup> Once the proceedings conclude, the ALJ prepares a report for the DEA Administrator, which includes a recommended disposition for the case.<sup>248</sup> The DEA Administrator has final say over whether the registration should be suspended or revoked and issues a ruling on the matter which is published in the Federal Register.<sup>249</sup>

If the DEA believes a registrant’s activities constitute an imminent danger to the public health or safety, the DEA Administrator may issue an ISO in conjunction with the OTSC.<sup>250</sup> This requires the immediate surrender of the registrant’s DEA registration pending the final resolution of an accompanying OTSC.<sup>251</sup> ISOs are the primary way the DEA can immediately halt controlled substance shipments when investigators suspect registrants are engaged in or facilitating diversion.

Yet, in recent years, even as the opioid epidemic has worsened, the number of ISOs issued by the DEA dramatically dropped. For example, the DEA issued 58 ISOs against all

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<sup>243</sup> 21 U.S.C. § 801 *et seq.*

<sup>244</sup> Pursuant to 21 U.S.C. § 871(a), the Attorney General has delegated administration and enforcement of the CSA to the Administrator of the Drug Enforcement Administration. *See* 28 C.F.R. § 0.100.

<sup>245</sup> 21 U.S.C. § 822 and 21 U.S.C. § 823.

<sup>246</sup> 21 U.S.C. § 824.

<sup>247</sup> 21 U.S.C. § 824(c) and 21 C.F.R. § 1301.37.

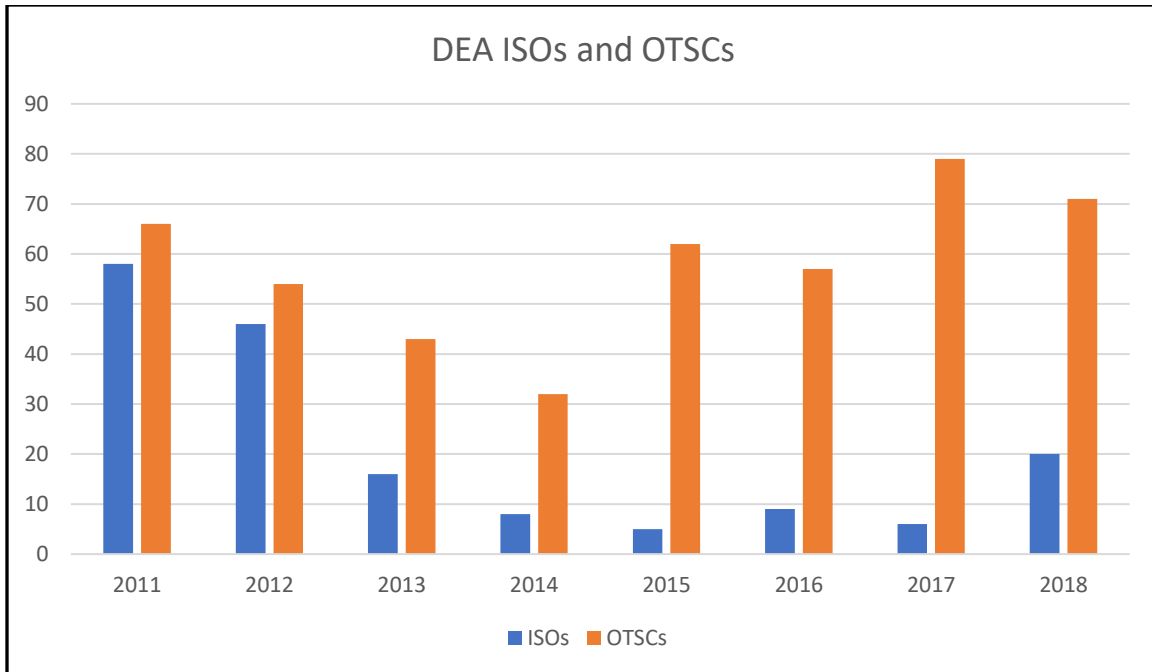
<sup>248</sup> 21 C.F.R. § 1316.52 and 21 C.F.R. § 1316.65.

<sup>249</sup> 21 C.F.R. § 1316.67.

<sup>250</sup> 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e).

<sup>251</sup> *Id.*

registrants in Fiscal Year (FY) 2011 and issued 46 ISOs the following year.<sup>252</sup> Since then, however, the number of ISOs issued by the DEA dropped precipitously – 16 ISOs in FY 2013; 8 ISOs in FY 2014; 5 ISOs in FY 2015; 9 ISOs in FY 2016; 6 ISOs in FY 2017, and 20 ISOs in FY 2018.<sup>253</sup>



Source: U.S. Drug Enforcement Administration

**FINDING:** The number of ISOs issued by DEA declined from a high of 58 in FY 2011 to a low of five in FY 2015. In FY 2018, DEA issued the same number of ISOs as it had in all of 2015, 2016 and 2017 combined.

The reason for decline in ISOs has been a source of contention for the DEA. Agency officials have said that when the administrative enforcement trend line is viewed as a whole, the ISO peak in the 2011-2012 timeframe is attributable to action the DEA took to shut down numerous rogue “pill mill” pharmacies and practitioners in Florida.<sup>254</sup> But former DEA officials

<sup>252</sup> The DEA revised previously provided data regarding the number of ISOs and OTSCs issued in recent years. See E-Mail from Staff, U.S. Drug Enforcement Admin., to Staff, H. Comm. on Energy and Commerce (May 15, 2018, 8:52 am) (On file with Committee).

<sup>253</sup> E-Mail from Staff, U.S. Drug Enforcement Admin., to Staff, H. Comm. on Energy and Commerce (May 15, 2018, 8:52 am) (On file with Committee); see also *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).

<sup>254</sup> See *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before S. Comm. on the Judiciary*, 115th Cong., 7 (2017) (statement of Demetra Ashley, Acting Assistant Adm’r, Diversion Control Div., U.S. Drug Enforcement Admin.) available at <https://www.judiciary.senate.gov/imo/media/doc/12-12-17%20Ashley%20Testimony.pdf>. In her written testimony, then-Acting Assistant Administrator Ashley stated, “DEA issued 104 ISOs between FY2011 and FY 2012, with all but four being issued against practitioners . . . and



have publicly come forward with serious concerns about delays of proposed enforcement actions. The former officials have alleged that lawyers in the DEA Office of the Chief Counsel instituted new policies in 2013, requiring a higher standard of proof before their cases could move forward, which in turn slowed enforcement action.<sup>255</sup> The former officials further alleged that these actions resulted in DEA pursuing fewer enforcement actions against entities suspected of violating the CSA and contributed to prescription opioid diversion.

As part of its investigation into potential breakdowns in the CSA's statutory and regulatory framework, the Committee endeavored to determine whether the allegations regarding a change in enforcement strategy were accurate. As part of its investigation, the Committee obtained DEA e-mails sent to and from four employees in the Office of Chief Counsel and the Office of Diversion Control. The e-mails were limited to discussions during the 2011 to 2013 timeframe about changes in diversion enforcement strategy as well as communications regarding ISOs and OTSCs. While the e-mails do not provide a full accounting of DEA's discussions regarding diversion enforcement at the time, the communications have informed the Committee's understanding of both problems affecting DEA enforcement and changes in strategy. The Committee's investigation found evidence which suggested that some new requirements were imposed, whether through formal or informal guidance, which altered the way DEA lawyers vetted and approved ISOs. Whether or not the DEA had adequate evidence to issue any particular ISO or OTSC is not for the Committee to decide. Moreover, documents reviewed by the Committee also revealed a tension between diversion investigators and DEA lawyers that potentially inhibited DEA's ability to prevent controlled substance diversion.

a. *Enforcement Decline Documented in ALJ Memoranda*

The decline in enforcement action was highlighted in a series of quarterly reports authored by the DEA's Chief Administrative Law Judge, John J. Mulrooney II. The Committee obtained copies of some of the quarterly reports and reviewed others *in camera*. The reports, in part, document case load and progress, as well as the length of time it takes to adjudicate each case, and are part of the Office of Administrative Law Judges' oversight and reporting responsibilities.<sup>256</sup> The first mention of the decline in enforcement actions is in a June 2013 quarterly report, in which Judge Mulrooney wrote that OTSCs had been on the decline despite

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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."

<sup>255</sup> See 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=.01bcab95a85f](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=.01bcab95a85f). See also Bill Whitaker, *Ex-DEA agent: Opioid crisis fueled by drug industry and Congress*, CBS NEWS 60 Minutes, Oct. 15, 2017, available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress> and Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, [https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.0f96c25e5f99](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.0f96c25e5f99).

<sup>256</sup> U.S. Drug Enforcement Admin., Office of the Administrative Law Judges, <https://admin.dea.gov/administrative-law-judges> (last visited Sept. 14, 2018).

estimates that such enforcement actions would increase.<sup>257</sup> Hypothesizing the reason for the drop, he indicated that the DEA’s Chief Counsel had instituted a new vetting and quality assurance initiative that appeared to have slowed the movement of some cases forwarded by the field.<sup>258</sup>

**FINDING: DEA’s Chief Administrative Law Judge, first highlighted the decline of DEA enforcement actions in a quarterly report issued in June 2013. He hypothesized that the reason for the decline was a new vetting and quality assurance initiative instituted by DEA’s Office of Chief Counsel.**

Of the cases that the DEA did pursue, Judge Mulrooney noted “a steadily rising trajectory” in the percentage of “no state authority cases,” in which the DEA subsequently seeks the surrender of a registrant’s DEA registration after a state entity revokes a registrant’s medical license or ability to handle controlled substances.<sup>259</sup> Judge Mulrooney also described the relative ease by which the Chief Counsel’s Office could process no state authority cases, saying, “[i]nasmuch as the Agency has taken the position that no-state-authority cases are decided as a matter of law without a hearing, these charging documents could arguably have been prepared and filed by non-attorney investigators or paralegals.”<sup>260</sup> In FY 2014, for instance, administrative hearings were possible in only 17 of the 34 OTSCs brought by the DEA because half of the cases were no state authority cases resolved through summary dispositions.<sup>261</sup> With such a low number of DEA diversion cases handled administratively, DEA administrative law judges began to take on cases from other agencies including the Bureau of Alcohol, Tobacco, Firearms and Explosives and the Bureau of Prisons.<sup>262</sup>

In a June 2014 quarterly report to the DEA Deputy Administrator, Judge Mulrooney highlighted the “extremely low numbers of orders to show cause” for the third quarter of Fiscal Year 2014 and remarked that the level of administrative diversion enforcement remained “stunningly low for a national program.”<sup>263</sup> He also indicated that he had raised his concerns regarding the low enforcement numbers directly with the DEA Office of Diversion Control and the Chief Counsel’s Office, stating:

I have shared my concerns about the low enforcement numbers separately with Wendy G. and Joe R. Wendy G. indicated that internal CC [Chief Counsel] data she has reviewed does not show an increase in declined prosecutions or tougher standards being applied to the review of the cases

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<sup>257</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to [Name Redacted] (June 24, 2013). This memorandum was viewed *in camera*.

<sup>258</sup> *Id.*

<sup>259</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to Chuck Rosenberg, Acting Adm’r, U.S. Drug Enforcement Admin. (Jan. 27, 2016) (On file with Committee).

<sup>260</sup> *Id.*

<sup>261</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to [Name Redacted] Deputy Adm’r, U.S. Drug Enforcement Admin. (Sept. 23, 2014) (On file with Committee).

<sup>262</sup> *Id.*

<sup>263</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to [Name Redacted] Deputy Adm’r, U.S. Drug Enforcement Admin. (June 24, 2014) (On file with Committee).

by CCD [Chief Counsel, Diversion and Regulatory Litigation Section] attorneys, while Joe R. indicated that CCD is declining cases from the field orally and in writing in record numbers, and that the field components have indicated to him that they cannot get administrative prosecution decisions on many cases that have been forwarded to CCD for review. Naturally, I have no means to know the quality of cases being rejected by CCD or the number of cases being referred by the field (nor should I), but the raw data does reflect a dramatic downward departure from past trends commencing at the approximate timeframe of a leadership transition at CCD (I have also shared this concern with Wendy G.).<sup>264</sup>

In a September 23, 2014 report summarizing the DEA's administrative enforcement efforts for FY 2014, Judge Mulrooney noted:

This is an unprecedented year in the Agency for lack of administrative enforcement actions filed by the Office of Chief Counsel Diversion & Regulatory Litigation Section (CCD). Notwithstanding the most current Center for Disease Control data which reflects that controlled-drug overdose deaths are at record levels and still on the increase, FY 2013 saw the filing of only 34 orders to show cause (OSCs) and 9 immediate suspension cases, for a total of 43 filed enforcement actions – and this is for the entire country.<sup>265</sup>

In a final status report sent to Administrator Leonhart before her retirement in 2015, Judge Mulrooney opined on the drop in administrative cases, noting that the decline did not appear to be the product of more complicated investigations or even better work product.<sup>266</sup> He wrote that CCD was not bringing cases that were larger or more complicated in scope, rather there were simply fewer cases being brought to trial before the ALJs.<sup>267</sup> Judge Mulrooney also remarked that he had not seen any increase in the quality of attorney preparation or representation on the part of DEA lawyers.<sup>268</sup> In the same memorandum, Judge Mulrooney also highlighted his concern over the decrease in cases, which he believed was the product of a shifting approach in the way cases were handled by the Chief Counsel's office.<sup>269</sup>

**FINDING: In April 2015, DEA's Chief Administrative Law Judge noted that the decline in administrative cases did not appear to be the product of the DEA bringing larger or more complicated cases, rather there were simply fewer cases being brought to trial before the DEA ALJs.**

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<sup>264</sup> *Id.*

<sup>265</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to [Name Redacted] Deputy Adm'r, U.S. Drug Enforcement Admin. (Sept. 23, 2014) (On file with Committee).

<sup>266</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to Hon. Michelle Leonhart, Adm'r, U.S. Drug Enforcement Admin. (Apr. 15, 2015) (On file with Committee). Portions of this memorandum were viewed *in camera*.

<sup>267</sup> *Id.*

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

In a July 2015 status report addressed to DEA Acting Administrator Chuck Rosenberg, the first since his appointment, Judge Mulrooney brought up the low number of diversion enforcement actions, noting that the decline was dramatic enough to warrant examination by agency leadership.<sup>270</sup> Subsequent memoranda indicate a continued reliance on no-state authority cases. According to a January 2016 memorandum, the percentage of no-state authority cases increased from 50 percent of the DEA cases brought in FY 2014 to 64 percent in FY 2015, and in the first quarter of FY 2016 represented 75 percent of the caseload.<sup>271</sup> This increase led Judge Mulrooney to deduce in January 2016 that “states have reacted to the reduction in the DEA enforcement actions since FY2012 by attempting to pick up the slack with their own administrative enforcement actions.”<sup>272</sup>

**FINDING: Memoranda drafted by DEA’s Chief Administrative Law Judge documents an increased reliance by the DEA on no-state authority cases. This led the judge to deduce in January 2016 that “states have reacted to the reduction in the DEA enforcement actions since FY2012 by attempting to pick up the slack with their own administrative enforcement actions.”**

## 2. Evolving Legal Positions and Internal Discord at the DEA

A comparison of public statements made by the DEA to documents obtained by the Committee reveals contrasting interpretations regarding the decline in diversion enforcement actions. Former DEA officials and Judge Mulrooney have surmised that the drop in DEA enforcement action was the result of a change in enforcement strategy within the DEA.<sup>273</sup> Other agency officials have disagreed with this characterization,<sup>274</sup> although former DEA Chief Counsel Wendy Goggin acknowledged to the Committee that the surge of DEA enforcement

<sup>270</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to Chuck Rosenberg, Acting Adm’r, U.S. Drug Enforcement Admin. (July 7, 2015) (On file with Committee).

<sup>271</sup> Memorandum from Hon. John J. Mulrooney II, Chief A.L.J., U.S. Drug Enforcement Admin., to Chuck Rosenberg, Acting Adm’r, U.S. Drug Enforcement Admin. (Jan. 27, 2016) (On file with Committee).

<sup>272</sup> *Id.*

<sup>273</sup> See 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=.c0f6093f50a0](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=.c0f6093f50a0).

<sup>274</sup> At the Subcommittee’s March 20, 2018 hearing, then-Acting Administrator Patterson resisted characterizing the change as a quality assurance initiative, as it had been described by Judge Mulrooney, suggesting it may have been guidance. See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 95-96 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>. During an October 25, 2017 full Committee hearing, Neil Doherty, DEA Deputy Assistant Administrator for the Office of Diversion Control, was asked whether there had been a change in the evidentiary standard required to bring an enforcement action. He said no such change had taken place. See *Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives: Hearing Before the H. Comm. on Energy and Commerce*, 115th Cong., 142 (2017) (testimony of Neil Doherty, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF00/20171025/106533/HHRG-115-IF00-Transcript-20171025.pdf>.

action associated with the agency's activities in Florida led to new case precedent that required some adjustment on the part of DEA lawyers.<sup>275</sup>

As stated earlier, DEA has said the drop in ISOs since 2011 should not be viewed as a steep decline, but rather the 2011 figures should be viewed as an uncharacteristic surge in enforcement.<sup>276</sup> According to the DEA, while a comparison of the 2011 statistics and data from more recent years may give the appearance of a drop in enforcement action, the agency is instead relying on other enforcement mechanisms. For example, in his March 20, 2018 testimony before the Subcommittee, then-DEA Acting Administrator Patterson indicated that the DEA now puts more of an emphasis on "trying to expedite the surrender of registrations."<sup>277</sup> For comparison's sake, Mr. Patterson testified that when done "in an efficient manner," an ISO case could be built in 45 to 90 days. But if the agency pursues a voluntary surrender of a DEA registration, he said the agency could more quickly cut off registrants' access to controlled substances.<sup>278</sup> Mr. Patterson testified:

Q. So the ISO – how long are we talking about to build that case?

A. I think probably, in an efficient manner, 45 to 90 days.

Q. So during that period, they can continue to dispense these drugs?

A. The same way an illicit person would be out on the street as we gather the evidence we need to present the charge. That's why, sir, I go back to my point on surrender for cause, or voluntary surrender. If I can walk in and lay out to that person why they need to surrender that and I can do it in a day and that's the method that we have actually been using much more aggressively than the ISO process, then we are going to do that.<sup>279</sup>

In the opinion of some former DEA officials, however, the downturn in ISOs was a result of new standards imposed by DEA Associate Chief Counsel and head of the Diversion and Regulatory Litigation Section, Clifford Lee Reeves II, a career Justice Department attorney who

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<sup>275</sup> Briefing, Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Mar. 23, 2018.

<sup>276</sup> See *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before S. Comm. on the Judiciary*, 115th Cong., 7 (2017) (statement of Demetra Ashley, Acting Assistant Adm'r, Diversion Control Div., U.S. Drug Enforcement Admin.) available at <https://www.judiciary.senate.gov/imo/media/doc/12-12-17%20Ashley%20Testimony.pdf>. See also *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 95 (2018) (testimony of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>277</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 95 (2018) (testimony of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>278</sup> *Id.* at 45-46.

<sup>279</sup> *Id.*

joined the DEA in December 2012. For example, former DEA attorney Jonathan Novak told *CBS News* that, beginning in 2013, cases with “crystal clear” evidence of wrongdoing, which his supervisors once would have previously approved, suddenly required additional evidence.<sup>280</sup> Jim Geldhof, a former diversion program manager in DEA’s Detroit field office, blamed Mr. Reeves for putting up roadblocks that left cases languishing.<sup>281</sup> Similarly, Mr. Geldhof has maintained that DEA lawyers were the reason why an OTSC he requested against Miami-Luken in 2013 wasn’t issued until November 2015.<sup>282</sup>

Mr. Geldhof also told the *Washington Post* that under Mr. Reeves’ leadership, DEA lawyers began requiring that investigators meet criminal evidentiary standards, which require the establishment of proof beyond a reasonable doubt, before enforcement actions were allowed to proceed.<sup>283</sup> Previously, according to Mr. Geldhof, enforcement actions were allowed to proceed so as long as the DEA was able to establish its case by a preponderance of the evidence.<sup>284</sup>

***a. DEA Chief Counsel’s Office Provides Updated Guidance on ISOs***

The Committee’s investigation uncovered evidence which seems to substantiate some claims that the Office of Chief Counsel instituted new requirements that may have had an impact on the number of diversion cases advanced by the agency.

The Committee received documents which show that shortly after Mr. Reeves’ arrival at DEA, he drafted guidance on the use of ISOs that was distributed to DEA attorneys. In January 2013, approximately one month after joining DEA, Mr. Reeves distributed a 14-page memorandum to all Diversion and Regulatory Litigation Section attorneys entitled

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<sup>280</sup> Bill Whitaker, *Ex-DEA agent: Opioid crisis fueled by drug industry and Congress*, CBS NEWS 60 Minutes, Oct. 15, 2017, available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress>

<sup>281</sup> Lenny Bernstein, David Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: ‘No one was doing their job.’* WASH. POST, Oct. 22, 2016, available at [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\\_story.html?utm\\_term=.abe834ac4993](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.abe834ac4993).

<sup>282</sup> *Id.*

<sup>283</sup> 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=.01bcab95a85f](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=.01bcab95a85f).

<sup>284</sup> *Id.* See also 21 U.S.C. § 824(c)(4) (stating, “[p]roceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5”); and *Sea Island Broad Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980) (“The use of the ‘preponderance of evidence’ standard is the traditional standard in civil and administrative proceedings. It is the one contemplated by the [Administrative Procedure Act], 5 U.S.C. § 566(d).”). On appellate review, the DEA’s factfinding will be deemed conclusive, if supported by substantial evidence. 21 U.S.C. § 877. Appellate courts will apply the Administrative Procedure Act’s arbitrary and capricious standard of review when examining the DEA Administrator’s decision on an enforcement action. *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005); and 5 U.S.C. § 706(2).

“Pharmacy/Distributor Immediate Suspension Order Guidelines.”<sup>285</sup> In a later e-mail, Mr. Reeves described the memo to an associate as “guidelines that I hope will prove helpful when we (CCD) are evaluating a request for an ISO, and when we are drafting the ISO itself.”<sup>286</sup>

E-mails provided to the Committee indicate that as early as February 2013, the Chief of the Office of Diversion Control’s Pharmaceutical Investigations Section said he had seen a change in the way diversion cases were being handled.<sup>287</sup>

On February 13, 2013 Mr. Reeves sent an e-mail to the Pharmaceutical Investigations Section Chief, communicating the need for the Office of Diversion to prioritize cases sent to the Chief Counsel’s office because the workload in two major cases was requiring extra resources.<sup>288</sup> The Pharmaceutical Investigations Section Chief forwarded this e-mail to a DEA Associate Deputy Assistant Administrator and questioned whether the workload issues fully explained recent changes, observed by his office, regarding the way the Chief Counsel’s Office was handling cases.<sup>289</sup> The e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Thursday, February 14, 2013 02:05 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** FW: case assignments

For your information [REDACTED] We have been noticing a trend of declinations, attempts at MoAs (not talking about Masters), and downgrading of ISOs to OTSC. Since you and Joe have firsthand knowledge that the ALJs aren't overly busy, this may come to a head at some point. Walgreens certainly is taxing their resources but I'm not sure that this fully explains what we are noticing in the way of their handling of cases. I have a meeting with Lee this afternoon and plan to discuss.

[REDACTED]  
**Chief – Pharmaceutical Investigations Section (ODP)**  
**Office of Diversion Control**  
**DEA HQS – Operations Division**  
(202) [REDACTED] (office) | (571) [REDACTED] (cell)  
[REDACTED]@usdoj.gov

<sup>285</sup> Memorandum from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to Attorneys, U.S. Drug Enforcement Admin. Office of Chief Counsel, Diversion and Regulatory Litigation Section (Jan. 2, 2013) (On file with Committee).

<sup>286</sup> E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to [Name Redacted] (Feb. 28, 2013, 9:52 am) (On file with Committee).

<sup>287</sup> E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to [Name Redacted], Chief of Office of Diversion Control’s Pharmaceutical Investigations Section (Feb. 13, 2013 2:06 pm) (On file with Committee).

<sup>288</sup> See E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to [Name Redacted], Chief of Office of Diversion Control’s Pharmaceutical Investigations Section (Feb. 13, 2013 2:06 pm) (On file with Committee).

<sup>289</sup> E-Mail from [Name Redacted], Chief of Pharmaceutical Investigations Section, U.S. Drug Enforcement Admin., to [Name Redacted] Associate Deputy Assistant Administrator, U.S. Drug Enforcement Admin. to (Feb. 14, 2013 2:05 pm) (On file with Committee).

**FINDING: In February 2013, the Chief of DEA’s Office of Diversion Control’s Pharmaceutical Investigations Section noticed a change in the way the Chief Counsel’s Office handled administrative cases, including downgrades of ISOs to OTSCs and a trend of declinations.**

Committee staff requested to be briefed by Mr. Reeves regarding the DEA’s administration of the CSA. The DOJ and DEA declined this request but made Mr. Reeves’ superior, Wendy Goggin, available.

According to Ms. Goggin, at the time of Mr. Reeves’ hiring, the diversion process needed to adapt to rulings in cases brought during the Operation Pill Nation investigations in Florida that resulted in additional evidence being required in enforcement cases. Specifically, the DEA Chief Counsel’s Office interpreted a series of DEA Administrator decisions from the 2011 to 2013-time period as indicating that the volume of controlled substances alone would be insufficient evidence to support an enforcement action against a registrant, meaning that the number of prescriptions written by a doctor, filled by a pharmacy, or dispensed by a distributor in-and-of-itself was not sufficient to bring an enforcement action. Two cases cited by the DEA in support are *In re Carlos Gonzalez, M.D.*<sup>290</sup> and *In re Sigrid Sanchez, M.D.*<sup>291</sup>

In *Gonzalez*, the DEA Administrator revoked a physician’s DEA registration.<sup>292</sup> Dicta in the decision discussed the probative value of the volume of prescriptions written by a doctor in considering whether to revoke a DEA registration.<sup>293</sup> The Administrator noted that, as applied to this case, evidence related to the volume of prescriptions on its own was insufficient.<sup>294</sup> Specifically, the ALJ stated:

This is not to say that statistical data could not support substantial evidence to revoke a registrant’s [Certificates of Registration] in all cases. There was simply insufficient contextual evidence adduced at the hearing to utilize the statistics that were offered. In the absence of testimony or other evidence that could provide some context to the data, and why the numbers [DEA Senior Diversion Investigator] provided demonstrated whether or to what extent the Respondent was exercising due care regarding his responsibilities as a registrant, there is no use that the impressive array of statistical information he provided can be put to. Beyond doubt, there are a host of factors that could account for why the Respondent’s level of controlled substance prescribing should have been lower, higher, or was just right . . . The [volume] data was presented in something of a contextual vacuum, and as such, cannot be used to reach a determination as to whether the continuation of the Respondent’s [Certificates of Registration] is in the public interest.<sup>295</sup>

<sup>290</sup> 77 Fed. Reg. 63,118, Oct. 11, 2011.

<sup>291</sup> 78 Fed. Reg. 39,331, July 1, 2013.

<sup>292</sup> 77 Fed. Reg. 63,118, Oct. 11, 2011.

<sup>293</sup> *Id.* at 63,138.

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*



In the corresponding footnote, the ALJ stated:

The Government's argument that these raw numbers demonstrate the impact of the Respondent's poor prescribing practices is not persuasive on this record. The numbers here reflect only volume; not high volume or low volume . . . Put another way, volume of total prescriptions issued does not reveal anything meaningful (or even usable) about community impact.<sup>296</sup>

In *Sanchez*, the DEA Administrator issued an order denying the physician's registration application.<sup>297</sup> In the case, the volume of prescriptions was not specifically cited to justify the application denial, but was mentioned in a footnote, with the Administration seeming to suggest that relying on volume alone would be insufficient to meet the requisite evidentiary standard to support the denial of a DEA registration application.<sup>298</sup> The Administrator stated:

Hanging over this matter is the dark cloud of evidence that Mercy was a pain clinic and that Respondent was seeing some 60 to 65 patients a day to whom she was prescribing such drugs as oxycodone 30 mg and 15 mg, muscle relaxants such as carisoprodol, and Xanax (alprazolam). However, evidence which creates only a suspicion of wrongdoing does not constitute substantial evidence.<sup>299</sup>

In effect, the changing landscape of ALJ opinions and precedents required, in the opinion of the Office of Chief Counsel, that the DEA obtain more evidence prior to bringing an enforcement action. Ms. Goggin thought Mr. Reeves could help lead the effort to educate field agents about the perceived heightened requirements.<sup>300</sup>

***b. DEA Requirements For Medical Expert Testimony***

One area in which the impact of the DEA Chief Counsel office's interpretation of the Operation Pill Nation investigation precedents as requiring additional evidence may have been felt was in the use of medical expert testimony in ISO case. The DEA did not provide clear guidance on which cases would require medical expert testimony, which created confusion in the Office of Diversion Control.

Ms. Goggin told Committee staff there was no policy requiring a medical expert's opinion in all cases, but that there would be instances in which it was necessary.<sup>301</sup> She

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<sup>296</sup> 77 *Id.* at fn. 88.

<sup>297</sup> 78 Fed. Reg. 39,332, July 1, 2013.

<sup>298</sup> See 78 Fed. Reg. 39,336 fn. 10, July 1, 2013 (citing *NLRB v. Columbian Enameling & Stamping Co., Inc.*, 306 U.S. 292, 299-300 (1939)).

<sup>299</sup> 78 Fed. Reg. 39,336 fn. 10, July 1, 2013 (citing *NLRB v. Columbian Enameling & Stamping Co., Inc.*, 306 U.S. 292, 299-300 (1939)).

<sup>300</sup> Briefing, Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Mar. 23, 2018.

<sup>301</sup> *Id.*

explained that the DEA had lost cases in the past when defendants used expert witnesses and the DEA had not lined up its own expert witnesses for rebuttal.<sup>302</sup>

It is unclear how frequently the Chief Counsel's Office required investigators to obtain expert medical testimony before approving ISOs, but the office's requests for medical experts may have been part of a larger pattern in which DEA lawyers asked field agents to collect more evidence before filing an ISO.<sup>303</sup> The requests raised concern for some within the agency who worried it could delay, and in turn jeopardize, ISO requests.<sup>304</sup> For example, in an April 2013 e-mail responding to an ISO request, a Senior Attorney within DEA's Office of Chief Counsel wrote that the Office of Diversion would need to hire and pay for a medical expert witness in a proposed ISO case.<sup>305</sup> The senior attorney also wrote that Diversion Investigators were not qualified to testify regarding the issuance of controlled substance prescriptions without a legitimate medical reason outside the usual course of professional practice.<sup>306</sup>

In response, a DEA employee whose name was redacted asked whether there was now a requirement to obtain a medical expert before submitting an ISO. The employee also questioned the feasibility of the decision, expressing concerns both over the cost of obtaining a medical expert, and the potential that the delay of time to secure an expert could undermine the DEA's ability to meet the imminent danger requirement.<sup>307</sup> The e-mail stated:

In the past, I was party to numerous ISO's (during the internet era) directed against physicians and pharmacies that did not require medical expert opinion. The facts of the case, along with the testimony provided by field investigators and other witnesses, were deemed sufficient. Is it now the requirement of CC that a medical expert be obtained *in advance* of the submission of *any* ISO? It would be helpful to the field to know this due to the expense associated with securing such an expert and the time it would take to [sic] for the expert to review the documents which, if not obtained in advance of a submission, would call into question the reason for the issuance of an ISO based on immediacy. The immediacy issue comes into play with your request for us to secure a medical expert since this will take

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<sup>302</sup> *Id.*

<sup>303</sup> See 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=.01bcab95a85f](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=.01bcab95a85f). See also Bill Whitaker, *Ex-DEA agent: Opioid crisis fueled by drug industry and Congress*, CBS NEWS 60 Minutes, Oct. 15, 2017, available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress>; Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, [https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.0f96c25e5f99](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.0f96c25e5f99).

<sup>304</sup> See E-Mail from [Name Redacted] to [Name(s) Redacted] (Apr. 23, 2013 11:28 am) (On file with Committee).

<sup>305</sup> E-Mail from [Name Redacted] to [Name(s) Redacted] (Apr. 23, 2013 10:01 am) (On file with Committee).

<sup>306</sup> *Id.*

<sup>307</sup> E-Mail from [Name Redacted] to [Name(s) Redacted] (Apr. 23, 2013 11:28 am) (On file with Committee).

time, possibly weeks to obtain a written opinion. Also, we may have an issue securing funding within our division due to sequestration.<sup>308</sup>

Approximately four months later, in August 2013, Mr. Reeves received an e-mail from a Diversion Program Manager in DEA’s Houston Division with the subject line “CCD Interpretation of Policy.”<sup>309</sup> In this e-mail, the Diversion Program Manager asked whether an expert witness report was required prior to submitting a request for an ISO or an OTSC, noting “given the current fiscal climate we all face, as the Diversion Program Manager, it will be difficult if not impossible for me to justify and authorize expenditures for expert witness review on a case(s) which has not been at least tentatively accepted by your office[.]”<sup>310</sup> The e-mail stated:

**From:** [Redacted]  
**Sent:** Monday, August 19, 2013 5:24 PM  
**To:** Reeves, Lee  
**Cc:** [Redacted]  
**Subject:** CCD Interpretation of Policy

Good Afternoon!

I was in DEA HQ last week and met with a number of OD Section Chiefs. Several of them advised me that on a number of recent occasions, CCD has required them to submit an “expert witness” report and review of documents (e.g., prescription monitoring programs data, patient files, etc.), prior to submitting either (or both) requests for Immediate Suspension Orders and Orders to Show Cause.

I informed my colleagues that we (in the Houston Division) had not encountered this issue in the past, but given that we have a case we plan on sending up to you shortly, [Redacted] I thought I should write to ask you whether that is a requirement and/or CCD policy?

As you might guess, if the “expert witness” review process is now a mandatory requirement and practice, given the current fiscal climate we all face, as the Diversion Program Manager, it will be difficult if not impossible for me to justify and authorize expenditures for expert witness review on a case(s) which has not been at least tentatively accepted by your office, so...I thought it prudent to touch base with you on this ahead of time (prior to our sending up the case I referred to above) and seek any guidance or other suggestions you might have.

If it would be more productive/efficient, perhaps we can discuss this by telephone, at your convenience.

Thank you.

[Redacted]  
Diversion Program Manager  
Drug Enforcement Administration  
Houston Division

In response to this e-mail, Mr. Reeves wrote, “[t]hank you for your email regarding the use of and need for medical experts. I appreciate the opportunity to clear up what I believe may be some misconceptions on the nature and origin of the need for medical experts in diversion cases involving improper prescribing.”<sup>311</sup> He then provided additional information on the Chief Counsel’s Office’s approach to requiring expert witnesses, stating that, while there was no policy or requirement to have expert testimony, but cases where the DEA won without an expert were “the exception rather than the rule.” Mr. Reeves wrote, in part:

Establishing that a practitioner’s conduct exceeded the bounds of any legitimate medical practice necessarily requires an understanding of what conduct would, or arguably would, constitute legitimate medical practice. Because such determinations require specialized knowledge, training,

<sup>308</sup> *Id.* (Emphasis in the original),

<sup>309</sup> See E-Mail from Diversion Program Manager, Houston Div., U.S. Drug Enforcement Admin., to Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. (Aug. 19, 2013, 5:24 pm) (On file with Committee) (Internal Quotation Marks Omitted).

<sup>310</sup> *Id.*

<sup>311</sup> E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to [Name Redacted] (Aug. 20, 2013, 11:48 am) (On file with Committee).

and/or judgment, **expert testimony is generally necessary to sustain allegations of improper prescribing.**

**To be clear, this is not a Chief Counsel's Office requirement/policy. This is the requirement of the Administrator and the courts, as evidenced by decisions they have issued on this subject, including the Administrator's very recent decision in *Ruben* (in which the Administrator rejected evidence related to undercover buys which were not supported by expert testimony).<sup>312</sup> I cannot tell you in advance, without knowing the facts of a case, whether expert testimony will be needed to support a particular allegation (whether in an ISO or an OTSC). However, we are and remain willing to assist you in determining whether an expert is required in a given case, and urge you to please contact us so that we can discuss the merits of proceeding without or with an expert. **To reiterate, there is no Chief Counsel/CCD requirement or policy that there needs to be a medical expert in every case. It depends on the nature of the allegations as well as the facts underlying that case.****

**It is important to note that Chief Counsel has brought cases and prevailed without expert testimony where the evidence that the practitioner knew he was engaged in a blatant drug deal. As a general matter, however, these cases are the exception rather than the rule.**

I understand and appreciate the cost concern that you have raised, and I have raised this issue with OD here. Given that diversion-related activities (including the retention of experts) are fee-funded, that fact of sequestration is not relevant. It is my understanding from OD that obtaining funds for an

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<sup>312</sup> In the case referenced by Mr. Reeves, the DEA issued an OTSC to an Arizona doctor, notifying the doctor that the agency was taking action to revoke his DEA registration and deny any pending applications to renew or modify an existing registration. Following a hearing, the ALJ instead recommended that the doctor's registration be continued and that any pending applications be renewed, subject to certain conditions. The DEA Administrator, however, rejected the ALJ's recommendation, finding that "the ALJ failed to consider both the egregiousness of the violations and the Agency's interest in deterring similar misconduct by Respondent in the future as well as on the part of others." 78 Fed. Reg. 38,379, June 26, 2013. The DEA Administrator ultimately suspended the doctor's DEA registration for a period of one year, citing various factors for this decision. However, in reaching this decision, the Administrator rejected the DEA's contention that the doctor operated outside the scope of the usual course of professional practice and prescribed controlled substances to two undercover confidential sources without a legitimate medical purpose. To support its assertion, the DEA, through testimony of a special agent, offered hearsay statements from the confidential sources alleging the doctor did not perform a physical examination prior to issuing them prescriptions for controlled substances. However, transcripts of the undercover visits suggest that the confidential sources were examined before they were prescribed controlled substances. Specifically, the Administrator stated, "[a]s for the hearsay statements of the confidential sources, the Government offered no evidence to support a finding that each statement is sufficiently reliable to constitute substantial evidence . . . expert testimony was required to show that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the two [confidential sources]." 78 Fed. Reg. 38,384, June 26, 2013.

expert should be not [sic] a significant hardship. I encourage your office to submit a request to OD for expert witness funding when appropriate.<sup>313</sup>

**FINDING: In 2013 the DEA’s Office of Chief Counsel’s policy toward requiring expert witnesses in ISO or OTSC cases was circumstance dependent. While experts were not required in every case, cases where DEA prevailed without medical expert testimony were “the exception rather than the rule.”**

Mr. Patterson told the Subcommittee at the March 20, 2018 hearing that it was not a DEA policy to require medical expert testimony to bring an ISO case.<sup>314</sup> But in response to questions posed at the hearing, Mr. Patterson agreed that in cases in which a medical expert was sought, it would take a considerable amount of time to identify and secure an expert, which could delay the DEA’s work to issue an ISO. Mr. Patterson testified:

Q. Let’s discuss this policy of requiring experts, and I know that you’re trying to shift from some of that but let’s discuss it. It would take some time for the DEA field to find a medical expert, wouldn’t you agree?

A. I would.

Q. And to obtain the services of a medical expert the DEA would have to issue a sole source contract and the agency and the expert would have to figure out and reach an agreement on fee and deliverables. Isn’t that true?

A. I don’t necessarily know about the contract but it would require some type of compensation.

Q. And after all of that, the medical expert would need to review prescription monitoring program, data patient files, and other information. It’s going to take some time for the medical expert to review and render an opinion, isn’t it?

A. It would.

Q. Yes. After the medical expert completes the review then the chief counsel’s office would need additional time to review the field submissions of the request for an immediate suspension order. Isn’t that true?

A. Yes.

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<sup>313</sup> E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to [Name Redacted] (Aug. 20, 2013, 11:48 am) (internal citations omitted) (emphasis added) (On file with Committee).

<sup>314</sup> See *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

Q. Realistically -- this scenario assumes no delays along the way, and realistically this process, in many ISO cases, will take weeks, won't it?

A. I would believe so.

Q. And that's where you get your 45 to 90 days. If the DEA registrant sought a restraining order against the ISO, the delay in timing getting the medical expert and going through all the steps we just went through would in fact weaken the DEA's case in court for immediacy, wouldn't it?

A. I would believe so.

Q. Yes, it would. And so in fact, insisting on an expert medical testimony for the ISO -- I get the trial in [chief], the merits. But to protect the public, insistent on a medical expert in advance is endangering the public and endangering your case on the ISO because it takes away the immediacy factor. Wouldn't you agree?

A. Yes[.]<sup>315</sup>

As highlighted in the above exchange, one of the concerns about the length of time it takes to issue an ISO is that evidence gathered as part of an investigation potentially undermines DEA's argument that a registrant's conduct represents an imminent danger to the public health and safety.<sup>316</sup> Mr. Reeves described these concerns when assessing the DEA's investigation of McKesson in March 2013. In an e-mail, Mr. Reeves wrote that with administrative inspection warrants served on McKesson's distribution center, the DEA was on the clock with respect to serving an ISO.<sup>317</sup> He wrote that the longer the DEA took to prepare an ISO, the greater the chance that the agency's argument of imminent danger could be undermined.<sup>318</sup>

**FINDING: In May 2013, the DEA's Associate Chief Counsel was of the legal opinion that a delay in the issuance of an ISO may weaken DEA's ability to successfully argue that a registrant's conduct constituted an imminent danger to the public health or safety.**

Some of the DEA's actions may have slowed investigations or downgraded the level of enforcement action pursued against registrants, including wholesale distributors. The documents reviewed by the Committee indicates that this was due to more cautious—perhaps excessively

<sup>315</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 67-69 (2018) (testimony of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>316</sup> See 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36. See also *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822 (5th Cir. 1976).

<sup>317</sup> E-Mail from Clifford Lee Reeves II, Assoc. Chief Counsel, U.S. Drug Enforcement Admin. to David A. Schiller, Assistant Special Agent in Charge, U.S. Drug Enforcement Admin., et al. (Mar. 14, 2013, 9:48 am) (On file with Committee) (Redacted portions viewed *in camera*).

<sup>318</sup> *Id.*

cautious—lawyering as opposed to improper influence. At the March 20, 2018 hearing, Mr. Patterson was asked whether the actions taken by Mr. Reeves and the DEA’s Chief Counsel’s Office amounted to stonewalling investigations against wholesale distributors and pharmacies. Mr. Patterson testified:

Q. Okay. Are you familiar with the Washington Post articles that have been running the last three to four months? One of them talks about the tension between the field enforcement offices and the Washington administrative officials?

A. I have.

Q. Okay. Do you agree or disagree with the basic thrust of those - - of those articles - - that the enforcement people were very enthusiastic and willing to really go after the distribution centers and the drug manufacturers and the pharmacists - - pharmacies and the Washington staff, for lack of a better term, stonewalled them or town them down?

A. So I believe that’s an overstatement. I think you have a number of issues that, quite frankly, play out in this space, some of which have to do with personalities. But I don’t find that the folks in the field, for the most part, had this belief that they were shut down. I do think there were people that felt that way at headquarters but not necessarily in the field.

Q. Are you familiar with a gentleman named Clifford Lee Reeves, II?

A. I am.

Q. You don’t think he stonewalled them or turn them down - - toned them down?

A. Sir, as I’ve talked about with everybody I’ve met on this situation, I will simply explain this. I could put three people in a room and talk about probable cause and they could all have different opinions on [it.]<sup>319</sup>

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<sup>319</sup> *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 53-54 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.*

c. *Tensions Between the DEA's Chief Counsel and Diversion Control Offices*

In addition to the evolving legal interpretations documented in e-mails obtained by the Committee, documents also lay bare the long-simmering tensions between the DEA's Office of Diversion Control and the Office of Chief Counsel over the handling of enforcement actions. The strained working relationship on display in these e-mails gives the Committee the impression that diversion enforcement efforts may have been negatively affected. Moreover, it does not appear that anyone above these two offices—namely, previous DEA Administrators—intervened in the dispute.

In a January 2012 e-mail to Ms. Goggin, the then-head of DEA's Office of Diversion Control, Joseph Rannazzisi, expressed frustration with the time it took the Chief Counsel's Office to complete a series of ISOs, writing, among other things, “[e]very day that goes by increases the chance of someone overdosing because of our inaction or slow response in stopping the flow of these drugs to drug seekers.”<sup>320</sup> The January 2012 e-mail sent by Mr. Rannazzisi to Ms. Goggin is reproduced in its entirety below:

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<sup>320</sup> E-Mail from Joseph Rannazzisi, Deputy Assistant Adm'r, U.S. Drug Enforcement Admin. to Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. (Jan. 25, 2012 10:41 pm) (On file with Committee).



**From:** Rannazzisi, Joseph T.  
**To:** Goggin, Wendy H.; [REDACTED]; [REDACTED]  
**Sent:** 1/25/2012 10:41:40 PM  
**Subject:** Cardinal/CVS

Wendy,

I had a telephone conversation with [REDACTED] this evening concerning the investigation of 2 CVS stores in Sanford, Florida and the Cardinal wholesale distribution facility in Lakeland, Florida. [REDACTED] advised that your attorneys are completing the CVS ISOs and should have them ready in about a week. He also said that you are not sure if Cardinal meets the [REDACTED] requirement for the ISO and that you have decided to schedule a meeting with [REDACTED], Cardinal's Counsel, to listen to what I assume is their argument to save themselves from revocation of their registration in Lakeland. This would potentially be followed by the service of an OTSC. This is unacceptable.

First, we have been patiently waiting for your attorneys to complete these ISOs for several weeks. Every day that goes by increases the chance of someone overdosing because of our inaction or slow response in stopping the flow of these drugs to drug seekers. This is not a difficult legal exercise. I would expect that there would be some sense of urgency to get these orders out to save a life or two, but it appears that your attorneys do not understand the gravity of the situation. The CVS pharmacies and the Cardinal distribution center did not comply with their legal obligations under the act resulting in the illegal distribution of millions of doses of oxycodone and other controlled substances. They worked hand in hand, CVS pharmacists filling all prescriptions and Cardinal supplying the pharmacies with the drugs to do so. In fact, Cardinal is under an MOA because of their previous failure to comply with the act resulting in the diversion of millions of dosage units of controlled substances. Obviously, they did not learn from their previous violations and at the Lakeland facility they did not comply with their agreement with the government. So, instead of putting an end to the hemorrhaging immediately, we are going to listen to what Cardinal has to say, and then possibly issue an OTSC to show that we really, really, really mean business...this time. How many chances do we have to give Cardinal? Cardinal is putting the public at risk of imminent danger and the only way to stop it is through the ISO. The OTSC will give us no leverage because they will continue to operate pending the hearing, will maintain their controlled substance distribution privileges and will attempt to work out a deal. As I have said before, without the ISO, We are putting ourselves in the untenable position of allowing a defendant company to dictate settlement through procedural maneuvering. We have seen this before. Their financial bottom line is much more important than say, the approximately nine people that die every day in Florida from prescription drug overdose. There is no requirement that we meet with these people prior to taking an administrative action. If you want to meet, do so after we have served the ISO...at least we would have something to discuss. If I recall correctly, we issued ISOs to 2 smaller distributors in South Florida in 2010 for similar distribution schemes, and they were not afforded the same courtesy. What makes Cardinal different?

My other issue is that you and your attorneys continue to make unilateral decisions concerning a determination of whether an order should be an ISO or OTSC without consulting this office or the field SACs. If I am not mistaken, your job is to recommend, advise and counsel on legal issues...period. You serve as a support function to the decision-maker in providing legal advice and client support in the decision process. You are not an investigator nor are you a decision/policy maker. Those responsibilities are vested in this office. So, I am surprised to learn that the ISO/OTSC documents were sent to your office a few days ago for review and a determination of whether they should proceed as an ISO or OTSC. I now understand that you are out of the office, further delaying the issuance of the ISO and holding my investigators hostage waiting for your decision. Once again, I am perplexed as to what your role is in this matter. The determination of whether there is an imminent threat to public health and safety is to be made by the Administrator or, in her absence, OD. I am concerned that you are now inserting yourself in this role, further delaying the process.

So, once again, we disagree. I am trying to avoid another confrontation with you before the Administrator, but it appears that we are heading down that path once again. Therefore, I suggest we meet with OC to discuss this matter and see if we can get it resolved quickly. If not, I will schedule a meeting with the Administrator to discuss early next week. Your attorneys are now becoming a detriment to my program, and my next step is to request that diversion litigation attorneys be directly assigned to this office for proper oversight and supervision.

Joe

Joseph Rannazzisi  
Deputy Assistant Administrator  
Operations Division/Office of Diversion Control  
Drug Enforcement Administration  
[REDACTED] (office) [REDACTED] (cell)

Ms. Goggin forwarded the e-mail to a senior official in the Office of Chief Counsel, who responded, writing, “Nice. Time for the showdown with the Administrator to clarify, once and for all, our role in the process and OD’s role.”<sup>321</sup> The Committee was unable to verify whether then-DEA Administrator Michele Leonhart interceded.

In a follow-up message, sent a few hours later and reproduced below, the same senior official wrote that his reaction to Mr. Rannazzisi’s e-mail “really illustrates the heart of the problem in our relationship with [Office of Diversion Control.]”<sup>322</sup> This e-mail is reproduced below:

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<sup>321</sup> E-Mail from [Name Redacted], Deputy Chief Counsel, U.S. Drug Enforcement Admin. to Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. (Jan. 26, 2012 6:43 am) (On file with Committee).

<sup>322</sup> E-Mail from [Name Redacted], Deputy Chief Counsel, U.S. Drug Enforcement Admin. to Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. (Jan. 26, 2012 8:40 am) (On file with Committee).

**From:** [REDACTED]  
**Sent:** Thursday, January 26, 2012 08:40 AM  
**To:** Goggin, Wendy H.  
**Subject:** RE: Cardinal/CVS

This e-mail really illustrates the heart of the problem in our relationship with OD. It is not possible to have a substantive discussion on the merits of any particular situation. If Joe doesn't get what he wants, his reaction is an ad hominem attack, saying we are at best incompetent and apathetic, if not actively hostile to the accomplishment of the mission. This is not the first time he has accused us of being a detriment to his program. He seems to do so every time we disagree with him on something (which is, in truth, not all that often, yet he paints it as if we're a constant annoyance, always being a roadblock to effective diversion control).

I don't need to recount all of his allegations in this e-mail for you, but he accuses us of everything from unnecessary delay ("we've been patiently waiting for several weeks") to being unable to provide "proper oversight and supervision" to the Diversion litigators, to not caring whether people die! We can disagree on the substance of things, and we can work out those disagreements, but the Administrator cannot permit him to accuse us of not having the best interests of his agency and the public safety at heart.

His attitude, which he freely shares with anyone who will listen (except face-to-face with us, of course), now permeates all of OD. The result is his "lawyers" feel free to second guess anything we say and ignore us whenever they feel like it. Forget about the substance of Cardinal – the conversation that needs to be had with the Administrator is about his lack of professionalism and the impact it is having. We've tried talking to Joe, and we've tried talking to [REDACTED] without improvement.

A previous e-mail exchange between Mr. Rannazzisi and Ms. Goggin from 2011 further demonstrates the acrimonious relationship. In a 2011 discussion about an attempted ISO against a pharmacy, Ms. Goggin wrote to Mr. Rannazzisi asking why the Office of Diversion Control had "made a unilateral decision" to end settlement discussions in the case and questioned why diversion control was in communication with the U.S. Attorney's Office about the case but had failed to return e-mails from Office of Chief Counsel attorneys.<sup>323</sup> This e-mail is reproduced below:

-----Original Message-----  
From: Goggin, Wendy H.  
Sent: Friday, August 12, 2011 4:36 PM  
To: Rannazzisi, Joseph T.

Joe,

Technically, the ISO is still in place. The District Judge issued a TRO prohibiting DEA from enforcing the ISO until a final order is issued by the A. The ISO was not dissolved.

I would prefer to have this discussion in person and not through email, but let me tell you my concerns. They are really more about process than how we proceed on this particular case. My concern is not the merits of the decision to walk away from settlement, but the fact that OD made a unilateral decision in a case we are litigating and communicated it to the USAO without consulting with CC or even telling us. In fact, we found out that the decision had been made and communicated to the USAO only because the Division forwarded us a copy of [REDACTED] e-mail to the USAO. We still do not know the specific facts that led to the decision to abandon settlement discussions.

<sup>323</sup> E-Mail from Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. to Joseph Rannazzisi, Deputy Assistant Adm'r, U.S. Drug Enforcement Admin. (Aug. 12, 2011 4:36 pm) (On file with Committee).

██████ attempted without success on multiple times to get information about the decision. He did have a conversation, finally, with ██████. However, I am told that the discussion had to do with ██████ frustration at OD 's repeated failure to respond to requests to discuss the matter. ██████ did tell him that OD did not want to pursue settlement, but as of my email to you today, no one from OD (including ██████) has provided any justification for walking away from settlement. Frankly, we may agree. However, as stated, this is not about OD's position on this case, it is about OD communicating the Agency's position to the USAO on a case in litigation without consulting with our office. Plus, we can't participate in a call with the USAO without first understanding the position of OD and Seattle (as well as the A, of course, when they are looking for the official position of the Agency, since she has the official position)

It is quite possible that at the end of the day we agree with OD's and Seattle's recommendation. But we cannot reach any conclusion without sitting down and discussing the matter internally. I do not want to air our dirty laundry on a phone call with the USAO, nor do I want to give the USAO a mixed response. We should speak with one voice, after resolving what that position is, and when it is litigation, that communication should be through the Agency's lawyers - CC.

Thanks,  
Wendy

In response, Mr. Rannazzisi, among other things, criticized the Office of the Chief Counsel's desire to settle cases instead of pursuing more punitive remedies, writing "[w]e are too quick to dispose of our cases in a manner that is beneficial to the defendant, but not the government. This ultimately weakens the administrative authority of this agency."<sup>324</sup>

The discord between the Chief Counsel and Diversion Control offices also impacted DEA's interactions with DOJ. In October 2012, an Assistant U.S. Attorney from the Eastern District of Michigan wrote in an e-mail that was forwarded to Ms. Goggin that an "ongoing lack of communication" with DEA headquarters was hindering prosecutors' discussions with a pharmaceutical manufacturer regarding a potential settlement over its alleged failure to report suspicious orders.<sup>325</sup>

Less than an hour later, Ms. Goggin forwarded this e-mail to Mr. Rannazzisi and wrote that the issues highlighted in the e-mail were "about to become a major problem and hurt relationships with partners."<sup>326</sup> This e-mail is reproduced below:

**From:** Goggin, Wendy H.  
**Sent:** Friday, October 05, 2012 4:18 PM  
**To:** Rannazzisi, Joseph T.; ██████  
**Cc:** ██████  
**Subject:** Fw: ██████

Joe and ██████

<sup>324</sup> E-Mail from Joseph Rannazzisi, Deputy Assistant Adm'r., U.S. Drug Enforcement Admin. to Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. (Aug. 12, 2011 7:39 pm) (On file with Committee).

<sup>325</sup> E-Mail from [Name Redacted], Asst. U.S. Attorney, U.S. Dept. of Justice. to [Name Redacted] (Oct. 5, 2012 3:21 pm) (On file with Committee).

<sup>326</sup> E-Mail from Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. to Joseph Rannazzisi, Deputy Assistant Adm'r, U.S. Drug Enforcement Admin. (Oct. 5, 2012) (On file with Committee).

I'm not aware of the agency policy that [redacted] and [redacted] cited to the USAO in Detroit, nor do I understand all the dynamics of this case since my office has not really been involved to any extent. However, it is clear that this is about to become a major problem and hurt relationships with partners. I am advised that the complaints about DEA headquarters will go higher at DOJ. Whether or not that happens, I can't say. I will leave it to you to advise AD/A as you see fit.  
Wendy

The tension between the two offices also appears to have impacted DEA field offices. In a May 2013 e-mail, a DEA Diversion Group Supervisor in the Cincinnati field office expressed frustration regarding a perceived delay in the agency's ability to move forward with enforcement actions, stating:

The continued lack of any action regarding [redacted] and their registration(s) is unacceptable...**It is respectfully requested that [Chief Counsel, Diversion and Regulatory Litigation Section] and/or [Office of Diversion Control] come to some agreement regarding [redacted] and the Pending OTSC request so the field is not held captive and in limbo.**<sup>327</sup>

Considering the clear tension between the Office of the Chief Counsel and the Office of Diversion Control regarding enforcement actions, the Committee asked the DEA which division ultimately makes the final recommendation to the Administrator on what type of enforcement action to pursue. The DEA responded:

Each DEA Field Division is responsible for determining which recommendation to provide to the Administrator with regards to a particular administrative action (e.g. OTSC or ISO) that will be taken against a registrant within their own division. That recommendation is then reviewed by the Office of Chief Counsel prior to obtaining concurrence or nonconcurrence from the Assistant Administrator of the Diversion Control Division. Under regulation, OTSCs may only require concurrence at the Diversion Control Division level. ISOs require concurrence or nonconcurrence from the Administrator.<sup>328</sup>

**FINDING: E-mails between the DEA's Office of Chief Counsel and the Office of Diversion Control demonstrate an acrimonious relationship over the proper handling of enforcement actions, which impacted relationships within the agency as well as dealings with the Department of Justice.**

Whether attributable to some DEA attorneys' reactions to federal courts' temporary enjoinder of ISOs, attorneys' reading of agency precedent to require the use of expert witnesses

<sup>327</sup> E-Mail from [Name Redacted], Diversion Group Supervisor, DEA Cincinnati Resident Office to [Names Redacted] (May 21, 2013 11:30 am) (emphasis added) (On file with Committee).

<sup>328</sup> See *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record, submitted by U.S. Drug Enforcement Admin.) (On file with Committee).

more frequently, ineffective communication between the agency's Office of Chief Counsel and its field divisions, or another reason not uncovered by the Committee's investigation, the number of enforcement actions began to drastically decline around 2013, while the number of opioid-related deaths has continued to grow. While the agency may now rely more heavily on criminal diversion cases or pursue voluntary surrender of registrants' authorities, ISOs remain a key tool of diversion enforcement. If the DEA does not utilize this tool effectively, it does not have a means to immediately shut down registrants who misuse or allow the diversion of controlled substances.

*d. Ensuring Patient Access and Effective Drug Enforcement Act of 2016*

Media reports have raised concerns that the enactment of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 made it more difficult for the DEA to initiate ISOs against drug distributors.<sup>329</sup> The legislation, among other things, amended the CSA and defined the term "imminent danger to the public health or safety," the necessary predicate for the DEA to initiate an ISO. The act defined the imminent danger requirement:

The phrase 'imminent danger to the public health or safety' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.<sup>330</sup>

At the Committee's October 25, 2017 hearing, DEA Office of Diversion Control Deputy Assistant Administrator Neil Doherty was asked about the enactment of the Ensuring Patient Access to Effective Drug Enforcement Act and its implementation. Mr. Doherty testified:

Q. So but I want to start with Mr. Doherty, if that is okay. The law has been written again about the Ensuring Patient Access and Effective Drug Enforcement Act. [sic] I want to take the opportunity to ask you a couple of questions. Yes or no, please, because of time. Was DEA part of the negotiation for the final language of this particular bill?

A. Yes, sir.

Q. Okay. Did DEA recommend that President Obama veto the bill?

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<sup>329</sup> See Bill Whitaker, *Ex-DEA agent: Opioid crisis fueled by drug industry and Congress*, CBS NEWS 60 MINUTES, Oct. 15, 2017, <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress>; see also Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, [https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.0f96c25e5f99](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.0f96c25e5f99).

<sup>330</sup> Ensuring Patient Access and Effective Drug Enforcement Act, Pub. L. No. 114-145 (2016) *codified at* 21 U.S.C. § 824(d)(2).

- A. No, sir.
- Q. Okay. Has DEA made any communication to this committee, this particular committee, Energy and Commerce Committee, about the need to change [the] statute?
- A. Not to my knowledge, sir, no.
- Q. Did DEA include any requests for statutory changes in their budget submission this year, dealing with this particular law?
- A. Not to my knowledge, sir.
- Q. Okay. Has DEA's ability to enforce our Nation's drug laws been compromised because of the passage of this particular bill?
- A. This changes the way we look at the ISO, sir, but we use an array of other tools.<sup>331</sup>

The DOJ has since indicated that it would support amending the statute. Justice Department Assistant Attorney General for Legislative Affairs Stephen E. Boyd outlined suggested amendments to the law in a letter to the Committee in February 2018, writing:

We recommend that the Immediate Suspension Order "substantial likelihood" standard be amended to a "probable cause" standard. We believe that "probable cause" is the appropriate standard for two reasons. First, the meaning of "probable cause" is firmly established in case law and thus relatively immune from varying court interpretations. Second, using "probable cause" should confine the focus to the agency's determination of whether an imminent danger to the public health and safety exists, and eliminate the possibility that a reviewing court would include a subjective element in its analysis. We believe this would be more in line with the original intent of Congress when it enacted the ISO provision in 1970 – and commensurate with the aim of the provision to give DEA a rapid means of protecting the public from imminent danger resulting from the diversion of controlled substances. We believe that this standard is consistent with the current intent of Congress to clearly define the ISO standard going forward.<sup>332</sup>

As discussed in this section, DEA's use of ISOs had already begun to decline more than three years before the Ensuring Patient Access and Effective Drug Enforcement Act was enacted. The Committee's investigation also found evidence to suggest that the Office of the Chief

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<sup>331</sup> *Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives: Hearing Before the H. Comm. on Energy and Commerce*, 115th Cong., 147-148 (2017) (testimony of Neil Doherty, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.) *available at* <https://docs.house.gov/meetings/IF/IF00/20171025/106533/HHRG-115-IF00-Transcript-20171025.pdf>.

<sup>332</sup> Letter from Stephen E. Boyd, Asst. Attorney Gen. for Legislative Affairs, U.S. Dep't of Justice, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 28, 2018 (On file with Committee).

Counsel imposed new requirements that affected the way ISO cases were vetted and approved. Additional evidence showed DEA lawyers were, in some cases, also requiring the medical experts to testify in order to approve ISOs. As will be subsequently discussed, ISOs were also being delayed by DEA at the request of federal prosecutors so evidence could be gathered in criminal cases.

In May 2017, the DOJ OIG announced it was undertaking an examination of the DEA's controlled substance enforcement efforts.<sup>333</sup> According to the DOJ OIG, the examination will assess "whether DEA's regulatory activities and enforcement efforts effectively prevent the diversion of controlled substances, particularly opioids, to unauthorized users. Specifically, this review will examine (1) DEA's enforcement regulations, policies, and procedures; (2) DEA's use of enforcement actions involving manufacturers, distributors, physicians, and pharmacists who violate these policies and procedures; and (3) DEA's coordination with state and local partners to combat the opioid epidemic."<sup>334</sup>

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<sup>333</sup> See Letter from Section Chief, Cong. Affairs Section, U.S. Drug Enforcement Admin., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, July 11, 2017 (On file with Committee).

<sup>334</sup> U.S. Dep't of Justice, Office of the Inspector Gen., *Drug Enforcement Administration Ongoing Work*, <https://oig.justice.gov/ongoing/dea.htm> (last updated Oct. 2018).



### **3. Prioritization of Criminal Investigations Over Administrative Enforcement**

In addition to requiring additional evidence, at times, for ISOs, the Committee’s investigation also found that the DEA was in some instances prioritizing evidence gathering for criminal investigations over an administrative enforcement action. Such prioritization of criminal investigations could delay DEA from taking an enforcement action against a registrant suspected of facilitating diversion of controlled substances for months or even years while a criminal investigation progressed. In addition, delaying action could jeopardize DEA’s ability to successfully impose an ISO against a registrant as doing so under the CSA requires the DEA’s determination that the registrant’s activities constitute an “imminent danger to the public health or safety” and a prolonged delay could hinder the agency’s ability to credibly argue the imminency requirement.<sup>335</sup>

At the Subcommittee’s March 20, 2018 hearing, then-Acting Administrator Patterson testified that it was an “ongoing theme” for federal prosecutors to request that the DEA delay issuing ISOs so prosecutors would have more time to gather evidence in criminal cases.<sup>336</sup> He indicated the requests lead to some of DEA’s delays in taking administrative action against registrants.<sup>337</sup> He testified:

- Q. And are you saying that the U.S. attorneys were asking -- as a former U.S. attorney are you saying the U.S. attorneys were asking or telling DEA not to issue ISOs?
- A. In trying to gather evidence in their criminal case.
- Q. I understand, but that can take months if not years sometimes in criminal cases. But that is what -- do you believe that's what happened prior to you coming in October of 2017 -- that delays happened?

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<sup>335</sup> See 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36. At the Subcommittee’s March 20, 2018, then-DEA Acting Administrator Robert Patterson testified that delaying the issuance of an ISO could negatively impact DEA’s ability to argue that an “imminent danger” to the public health or safety exists. *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 69 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>. See also *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822 (5th Cir. 1976) wherein the court held that a district court’s previous determination that the DEA did not satisfy the “imminent danger” requirement for issuing an ISO was not erroneous, attributable to, among other things, DEA’s decision to wait seven months before issuing the ISO. In its decision the court noted that the underlying conduct “had been known for approximately seven months. Genuine apprehension of imminent danger to the public health and safety could reasonably have been expected to cause prompt notice and an equally prompt hearing.” *Id.*

<sup>336</sup> *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 105 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>337</sup> *Id.*

- A. I think that's been an ongoing theme of what some of these delays are caused by.
- Q. And why would the DEA delay that type of administrative action in pursuit of a criminal investigation? What -- why?
- A. Because people believe that the criminal investigation is an important endeavour towards whether it's that doctor or that pharmacy.<sup>338</sup>

**FINDING: Federal prosecutors ask the DEA to postpone enforcement actions against registrants with such frequency that the requests became an “ongoing theme” behind delays in DEA enforcement actions.**

Mr. Patterson informed the Committee that he had engaged with the Attorney General’s Advisory Committee and states’ attorneys general to develop guidance on to the proper balance for the contemporaneous development of criminal cases and DEA administrative enforcement actions but noted, “[t]he concern I have, like I said, if we are using an ISO, it feels awful weird to be signing that ISO a year after we learned of that problem.”<sup>339</sup>

The Committee’s investigation identified one case in West Virginia that raises the question of whether an enforcement action was put on hold in the pursuit of a criminal investigation. The case involved two Sav-Rite pharmacies and the Justice Medical Clinic in Kermit, West Virginia. For reasons not fully clear to the Committee, after one of the pharmacies and clinic were raided by federal authorities the DEA allowed the second pharmacy to remain open—and continue dispensing opioids and other controlled substances into the community—for more than two years until its owner surrendered the pharmacy’s DEA registration as part of a plea agreement with the federal government.<sup>340</sup>

Sav-Rite Pharmacy (hereinafter “Sav-Rite No. 1”) received more than 11.28 million doses of hydrocodone and oxycodone between 2006 and 2009.<sup>341</sup> The owner of Sav-Rite No. 1, James Wooley, opened a second pharmacy in 2008 located just two miles away from the original pharmacy.<sup>342</sup> The second pharmacy, Sav-Rite Pharmacy No. 2 (hereinafter “Sav-Rite No. 2”),

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<sup>338</sup> *Id.*

<sup>339</sup> *Id.* at 107.

<sup>340</sup> See E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Nov. 15, 2017 9:22 am) (On file with Committee).

<sup>341</sup> In total, Sav-Rite No. 1 received approximately 13 million doses of hydrocodone and oxycodone between 2006 and the fall of 2011. See U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee). See also Letter from Counsel to McKesson Corp. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). It has been reported that, in 2006, Sav-Rite No. 1 was the 22nd ranked retail pharmacy in the United States in regard to the overall number of hydrocodone dosage units it received. See Curtis Johnson, *Big pill network exposed*, HERALD-DISPATCH, Apr. 1, 2009, [http://www.herald-dispatch.com/news/recent\\_news/big-pill-network-exposed/article\\_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html](http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html).

<sup>342</sup> According to U.S. Census data, the town of Kermit had a population of 406 in 2010. See American FactFinder, *Kermit town, West Virginia* (<https://factfinder.census.gov>).

was only in operation for approximately six months, however, before it and the co-located Justice Medical Clinic were raided and forced to close in March 2009.<sup>343</sup>

Despite the raid and forced closure of Sav-Rite No. 2, the DEA did not force Mr. Wooley to surrender the DEA registration for Sav-Rite No. 1 and the pharmacy was allowed to remain in operation for more than two years, until late 2011.<sup>344</sup> In the time DEA allowed Sav-Rite No. 1 to remain open, the pharmacy likely received and dispensed somewhere between one million and two million doses of hydrocodone and oxycodone.<sup>345</sup> In addition, documents suggest that Sav-Rite No. 1 had been under federal investigation as early as March 2008.<sup>346</sup>

**FINDING: DEA allowed Sav-Rite No. 1 to maintain its registration for more than two years after the 2009 raid and forced closure of the same owner's Sav-Rite No. 2, during which time the pharmacy received somewhere between one to two million doses of hydrocodone and oxycodone.**

Committee staff asked DEA why it allowed Mr. Wooley to maintain an active DEA registration for Sav-Rite No. 1 for more than two years after he was forced to surrender Sav-Rite No. 2's registration after it was raided by federal authorities.<sup>347</sup> The DEA initially offered a partial response to the Committee, stating that "typically a case involving one registrant provides

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<sup>343</sup> See Curtis Johnson, *Big Pill Network Exposed*, HERALD-DISPATCH, Apr. 1, 2009, available at [http://www.herald-dispatch.com/news/recent\\_news/big-pill-network-exposed/article\\_8e1791fc-5162-5c36-8bae-6e76bcdb3ec9.html](http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcdb3ec9.html). The article reported that both Sav-Rite locations were raided in March 2009 along with the Justice Medical Clinic. However, the Committee has not seen evidence that Sav-Rite No. 1 was raided at the same time as Sav-Rite No. 2. See also *United States v. \$65,806.86, More or Less, In United States Currency*, Verified Complaint of Forfeiture, No. 2:09-cv-0944 (S.D. W. Va. Aug. 18, 2009) (On file with Committee). The DEA represented to Committee staff that Sav-Rite No. 2 was the "prime reception location for the flood of pills that was being sent into the area." See E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Mar. 14, 2018 12:57 pm) (On file with Committee). However, as mentioned, Sav-Rite No. 2 was only in operation for approximately six months between 2008 and 2009. During this time, the pharmacy received 736,100 doses of hydrocodone and oxycodone. Conversely, between 2006 and the fall of 2011, Sav-Rite No. 1 received approximately 13 million doses of hydrocodone and oxycodone. U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>344</sup> McKesson told the Committee that Sav-Rite No. 1 was purchased in the fall of 2011 and began operating under the name "Medicine Cabinet Pharmacy" but continued to use Sav-Rite No. 1's DEA registration number until early 2012. See Letter from Counsel to McKesson Corp. to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). According to the DEA, the owner of Sav-Rite No. 1 surrendered the pharmacy's DEA registration number on February 2, 2012. See E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Nov. 3, 2017 5:56 pm) (On file with Committee).

<sup>345</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee). The data provided to the Committee show that Sav-Rite No. 1 received 924,550 doses of hydrocodone and oxycodone in 2009; 473,750 doses in 2010; and 449,520 doses in 2011. However, these figures are not broken down by month and therefore the Committee is unable to precisely ascertain the exact number of hydrocodone and oxycodone doses Sav-Rite No. 1 received from March 2009, when Sav-Rite No. 2 was raided, and the fall of 2011, when the pharmacy was reportedly sold to a new owner who utilized Sav-Rite No. 1's DEA registration number until early 2012.

<sup>346</sup> *United States v. \$65,806.86, More or Less, In United States Currency*, No. 2:09-cv-0944 (S.D. W. Va. Aug. 18, 2009) (Verified Complaint of Forfeiture) (On file with Committee).

<sup>347</sup> E-Mail from Staff, H. Comm. on Energy and Commerce to Staff, U.S. Drug Enforcement Admin. (Nov. 8, 2017 3:11 pm) (On file with Committee).

leads to others and the difference may be time required to build and move forward with the case and resultant action.”<sup>348</sup> The DEA subsequently told the Committee that Mr. Wooley was forced to surrender the DEA registration for Sav-Rite No. 1 on February 2, 2012 as part of a plea agreement with the federal government.<sup>349</sup>

The plea agreement that the government and Mr. Wooley eventually reached related to criminal conduct that took place in 2006, stemming from a distribution scheme whereby Sav-Rite No. 1 would fill fraudulent prescriptions for patients of the Justice Medical Clinic.<sup>350</sup> At the plea hearing, the judge presiding over the case expressed skepticism about the amount of time it took for the government to take action against Mr. Wooley, noting the five-year statute of limitations for the charges had already lapsed, and remarking “[c]ertainly the government knew about this long before the closure of that five-year period.”<sup>351</sup> The judge was also troubled that the government’s plea offer did not call for any prison time, stating:

I will tell you at the outset I'm very concerned about that limitation. The court has had other cases from this same area involving some of the same matters. And in the year 2006, which is the area covered by the information, the defendant's pharmacy Sav-Rite filled six million prescriptions for hydrocodone, 22nd in the United States. It seems peculiar to me that the government would not have known about that and the defendant's relationship to it in time to have filed within the five-year period and that the gravity of the matter would be such that more than a two-year probation period would be appropriate.<sup>352</sup>

Ultimately, Mr. Wooley was sentenced to six months in federal prison and one year of probation for his role in the scheme that resulted in millions of opioids being shipped to Kermit, West Virginia.<sup>353</sup> At the Subcommittee’s March 20, 2018, hearing, Mr. Patterson was asked why the DEA would allow Sav-Rite No. 1 to remain in operation for more than two years when the agency knew its owner was engaged in controlled substance diversion and endangering the public health while the agency had the ability to stop it. Mr. Patterson testified:

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<sup>348</sup> E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Nov. 9, 2017 1:45 pm) (On file with Committee).

<sup>349</sup> E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Nov. 15, 2017 9:22 am) (On file with Committee).

<sup>350</sup> *United States v. Wooley*, No. 2:12-00007 (S.D. W. Va. Feb. 2, 2012) (Transcript of Proceedings) (On file with Committee). In 2010, prior to Mr. Wooley’s guilty plea, the owner of the Justice Medical Clinic as well as two other physicians were each sentenced to prison time for their role in the controlled substance distribution scheme. See Press Release, Fed. Bureau of Investigation, Pittsburgh Div., Mingo County Pharmacist Sentenced to Prison Time for Conspiracy to Acquire Controlled Substances by Fraud (Nov. 15, 2012), <https://archives.fbi.gov/archives/pittsburgh/press-releases/2012/mino-county-pharmacist-sentenced-to-prison-time-for-conspiracy-to-acquire-controlled-substances-by-fraud>.

<sup>351</sup> *United States v. Wooley*, No. 2:12-00007 (S.D. W. Va. Feb. 2, 2012) (Transcript of Proceedings) (On file with Committee).

<sup>352</sup> *Id.*

<sup>353</sup> Press Release, Fed. Bureau of Investigation, Pittsburgh Div., Mingo County Pharmacist Sentenced to Prison Time for Conspiracy to Acquire Controlled Substances by Fraud (Nov. 15, 2012), <https://archives.fbi.gov/archives/pittsburgh/press-releases/2012/mino-county-pharmacist-sentenced-to-prison-time-for-conspiracy-to-acquire-controlled-substances-by-fraud>.

- Q. Mr. Patterson, we need to find out whether DEA is really addressing the lessons you say DEA has learned. Case in point is the one I raised, the questionable enforcement approach regarding the two Sav-Rite pharmacies in Kermit, West Virginia that I mentioned in my opening statement. Sav-rite number two was shut down in April of 2009, correct?
- A. I don't know the specific dates. I know there was two pharmacies. One was shut down and one wanted criminal - -
- Q. Yes, it was - - our data show April of 2009 Sav-Rite two was shut down. Sav-Rite one was not shut down until over two years later when the owner of the pharmacy entered a guilty plea to charges that he illegally issued prescriptions, correct?
- A. That's correct.
- Q. And in April 1st of 2009, an article in the local Herald Dispatch reported that the two Sav-Rite pharmacies and a local pain clinic were under federal investigation for operating a drug operation. The article reported an affidavit from federal investigators who stated there were two overdose deaths linked to this network. So my question is why did DEA shut down Sav-Rite number two but not Sav-Rite number one in April of 2009 if both pharmacies were part of a network linked to deaths?
- A. Sir, I would have to get back to you on that one particular issue and I will [sic] you the reason why. **It's my understanding it was - - it was part of the criminal process in that case and I don't know the answer for why that was.** But I would be happy to get that back to you.
- Q. Thank you. So why would the DEA even consider such an arrangement when it knew the owner operated the pharmacies two miles apart, one of which the DEA claimed to be the prime reception location for the flood of pills -- that's a direct quote -- being sent to the area and linked to overdose deaths? Same owner, same operator, two miles apart?
- A. I agree with you, and it's something I will get back to you on.
- Q. During the time the DEA allowed Sav-Rite number one to remain in operation, this pharmacy received somewhere between 1 and 2 million hydrocodone and oxycodone pills. Allowing Sav-Rite one to continue to dispense such a volume of opioids posed a continuing risk to public health and safety. Isn't that right?
- A. I would agree.

- Q. So, Mr. Patterson, what's the biggest priority? Protecting public safety or deferring to an ongoing criminal investigation?
- A. It should have been to protect public safety.
- Q. So in this case, the government originally entered a plea agreement with the pharmacy owner that didn't even call for any prison time. The lack of any prison time troubled the judge and eventually the defendant was sentenced to six months -- six months in prison. What kinds of evidentiary challenges would have been involved in such a case and would putting an immediate suspension order on hold really help solve these challenges?
- A. So putting an immediate suspension order on hold, like, again, I don't know the particular facts of that criminal case and I would be happy to get back to you. **I will tell you that I have a very strong opinion and this has been relayed throughout our agency that whether it's an immediate suspension or whether a surrender for cause, that if we are having harm issues that that suspension needs to occur even in lieu of a criminal prosecution.**<sup>354</sup>

The DEA did not clarify whether the decision to allow Sav-Rite No. 1 to remain in operation for more than two years was attributable to the agency's deference to an ongoing criminal investigation or whether there was another explanation for the delay. Nevertheless, DEA potential decision to forego issuing an ISO in order to allow for the further development of a criminal case was not limited to the Sav-Rite example, as Mr. Patterson also testified that he continued to see inappropriate delays in the current day. He told the Committee, "I see in too many instances on ISOs, current ones that I sign off on, where there has been a delay that I don't find appropriate."<sup>355</sup>

Former DEA Chief Counsel Wendy Goggin also told Committee staff that there have been instances in which DEA administrative actions and criminal cases have been developed contemporaneously, but noted that the DEA investigators were not always aware of the parallel criminal investigations.<sup>356</sup> In Ms. Goggin's estimation, developing administrative and criminal cases on parallel tracks has its merits, though she conceded that complications could arise with respect to evidentiary concerns.<sup>357</sup> According to Ms. Goggin, some U.S. Attorneys have been

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<sup>354</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 40-43 (2018) (emphasis added) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>355</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 44-45 (2018) (testimony of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>356</sup> Briefing, Wendy Goggin, Chief Counsel, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce, Mar. 23, 2018.

<sup>357</sup> *Id.*

generally amenable to the DEA developing an administrative case parallel to a criminal investigation while others have asked the DEA not to use certain evidence in an administrative action or have threatened to abandon criminal cases altogether if the DEA proceeded with an administrative action such as an ISO.<sup>358</sup>

At the March 20, 2018 hearing, Mr. Patterson testified that it was his belief that the DEA could advance an administrative action such as an ISO “even against the wishes of a U.S. attorney or a state's attorney” but noted that “[i]t probably doesn’t help relationships to take those kind [sic] of unilateral actions.”<sup>359</sup> On June 18, 2018, Mr. Patterson announced that he was retiring from the DEA, effective at the end of the month,<sup>360</sup> with Uttam Dhillon subsequently named as his successor.<sup>361</sup> The Committee asked DEA whether Acting Administrator Dhillon is supportive of and will continue with his predecessor’s plans to work with the Attorney General’s Advisory Committee and state’s attorneys to develop guidance on the DEA’s use of ISOs in situations where a separate criminal case is also being developed.<sup>362</sup> DEA responded that Acting Administrator Dhillon is supportive of “efforts to ensure that administrative actions . . . are conducted in parallel with an ongoing criminal investigation” and that administrative actions “are not unduly delayed while federal prosecutors seek criminal charges.”<sup>363</sup>

ISOs are a primary administrative tool the DEA can use to protect the public health and safety, allowing the DEA to immediately revoke the registration of entities the agency believes are engaged in or enabling controlled substance diversion. While there may be occasions to temporarily defer administrative action so as not to jeopardize a criminal case, these instances should not cause an undue delay in enforcement proceedings.

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DEA was well aware of the breadth of the prescription drug diversion problem in West Virginia – a 2007 factsheet published by the agency noted, among other things, that diversion of hydrocodone products was an ongoing problem in West Virginia at the time. Four years later, a 2011 internal DEA report found that abuse and distribution of illicit pharmaceuticals was continuing to increase in West Virginia and pharmaceutical drug trafficking organizations were particularly active in the state. Despite its long-standing knowledge of West Virginia’s struggle with controlled substance abuse and being warned by the DOJ OIG in 2002 that it was not devoting sufficient resources to combat controlled substance diversion, the DEA only had two

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<sup>358</sup> *Id.*

<sup>359</sup> *The Drug Enforcement Administration’s Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 111 (2018) (testimony of Robert Patterson, Acting Adm’r, U.S. Drug Enforcement Admin.) available at <https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf>.

<sup>360</sup> David Shortell and Clare Foran, *Acting DEA chief to retire at end of month*, CNN, June 18, 2018, <https://www.cnn.com/2018/06/18/politics/dea-administrator-retiring-robert-patterson/index.html>.

<sup>361</sup> Press Release, U.S. Dep’t of Justice, Attorney General Jeff Sessions Announces Uttam Dhillon as New Acting Administrator Of Drug Enforcement Administration (July 2, 2018), <https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-announces-uttam-dhillon-new-acting-administrator-drug>.

<sup>362</sup> E-Mail from Staff, H. Comm. on Energy and Commerce to Staff, U.S. Drug Enforcement Admin. (Aug. 10, 2018 4:41 pm) (On file with Committee).

<sup>363</sup> E-Mail from Staff, U.S. Drug Enforcement Admin. to Staff, H. Comm. on Energy and Commerce (Aug. 24, 2018 1:28 pm) (On file with Committee).

diversion investigators assigned to West Virginia at the time the opioid epidemic was spiraling out of control in the state. Only recently has the DEA started to devote significant, additional resources to the state. Had the DEA assigned more personnel to West Virginia sooner or more effectively utilized the tools it possessed to identify, and combat diversion, perhaps the human and economic toll of the opioid epidemic in West Virginia may have been less severe.

The Committee also identified a number of practices within DEA that hampered the agency's ability to more fully investigate and respond to the opioid epidemic in West Virginia. DEA's ability to proactively investigate cases of possible drug diversion was limited prior to 2010 because of the way the agency utilized ARCOS data. Prior to 2010, ARCOS data were used reactively to build and strengthen enforcement action cases. It was only when DEA improved its technological capabilities and adopted a more proactive posture to go after Florida pill mills that it began using the data to identify possible diversion targets. The DEA similarly appears to have underutilized suspicious order reports, which could have been analyzed proactively to identify potentially problematic pharmacies.

Nationwide, and at the height of DEA enforcement action against Florida pill mills, the agency issued 58 ISOs in FY 2011. In the following years, however, the number of ISOs issued against all registrants declined and then remained under ten per year from FY 2014 until FY 2018 when 20 were issued. Former agency officials alleged that the decline in enforcement action was attributable to new policies instituted by the DEA's Office of the Chief Counsel in 2013. DEA's Chief Counsel acknowledged that a surge of DEA enforcement action associated with the agency's activities in Florida led to new case precedent that required some changes regarding case preparation. Additionally, the Committee's investigation found evidence of at least two factors that, at times, may have delayed the DEA's issuance of ISOs: the Chief Counsel's Office request for the testimony of medical experts, and requests by prosecutors for the DEA to delay enforcement actions so as not to jeopardize potential criminal cases.



## VI. The Role of Wholesale Drug Distributors

The national opioid epidemic has surged for nearly two decades. Drug overdose deaths involving opioids rose nationally from approximately 8,000 deaths in 1999 to more than 42,000 in 2016.<sup>364</sup> The effects of the opioid epidemic have been most acutely felt in West Virginia, which had the highest overdose death rate in the country in 2016.<sup>365</sup> Reporting by the *Charleston Gazette-Mail* found that wholesale drug distributors dispersed more than 780 million doses of hydrocodone and oxycodone to West Virginia between 2007 and 2012,<sup>366</sup> with individual distributors, in some cases, sending volumes of controlled substances to small-town pharmacies that far exceeded what could be considered reasonable to meet the legitimate medical needs of area residents. In one instance, distributors sent more than 20.82 million doses of hydrocodone and oxycodone to two pharmacies located four blocks apart in a town of approximately 3,000 people.<sup>367</sup> In another instance, a single pharmacy in a town of 406 people received nearly 13 million doses of hydrocodone and oxycodone from all distributors between 2006 and 2012.<sup>368</sup> The extraordinary volume and pattern of opioid shipments, such as those sent to pharmacies in small West Virginia towns, were in the DEA's words "red flags of diversion."<sup>369</sup>

This investigation has questioned the rationale of shipping such massive quantities of opioids to small-town pharmacies and sought to understand what policies and procedures distributors had in place that allowed these kinds of shipments.

The Committee requested ARCOS data from eleven three-digit zip code prefix areas in the state of West Virginia. The total amount distributed per zip code prefix between 2006 and 2016 is staggering.

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<sup>364</sup> 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](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4)

<sup>365</sup> Centers for Disease Control and Prevention, *Drug Overdose Death Data*, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last updated Dec. 19, 2017).

<sup>366</sup> See Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, CHARLESTON GAZETTE-MAIL, Dec. 17, 2016, [https://www.wvgazettemail.com/news/cops\\_and\\_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article\\_99026dad-8ed5-5075-90fa-adb906a36214.html](https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html).

<sup>367</sup> Between 2006 and 2016, distributors sent 10.2 million doses of oxycodone and hydrocodone to Tug Valley Pharmacy and 10.5 million doses to Hurley Drug Company, located in Williamson, West Virginia. See U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee). In 2010, Williamson had a population of 3,191.

<sup>368</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>369</sup> U.S. Drug Enforcement Admin., DEA Distributor Conference Presentation, 6 (May 11, 2016) available at [https://www.deadiversion.usdoj.gov/mtgs/distributor/conf\\_2016/griffin.pdf](https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2016/griffin.pdf).

<b>Zip Code Prefix</b>	<b>Total Doses of Hydrocodone and Oxycodone Received from 2006 to 2016<sup>370</sup></b>
248-	43,366,190
250-	49,329,740
251-	50,480,060
252-	39,234,313
255-	115,162,751
256-	93,542,360
257-	80,495,623
261-	87,511,570
262-	42,955,050
265-	94,428,420
267-	22,029,450

In the areas of West Virginia for which the Committee obtained ARCOS data, there were more than 131 pharmacies that received between two million and five million doses of hydrocodone between 2006 and 2016.<sup>371</sup> Seventeen pharmacies received more than five million doses of hydrocodone and oxycodone.<sup>372</sup> Five of those pharmacies received more than 10 million doses. Four of the five pharmacies that received more than 10 million doses of hydrocodone and oxycodone were located in the same zip-code prefix area: Family Discount Pharmacy, Hurley Drug Company, Sav-Rite Pharmacy No. 1, and Tug Valley Pharmacy.<sup>373</sup>

These four pharmacies, as well as three others extensively discussed in this report, are all located within a short distance of each other in southern West Virginia. For example, the distance between the Sav-Rite No. 1 Pharmacy in Kermit, West Virginia, and Westside Pharmacy in Oceana, West Virginia is less than 65 miles.

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<sup>370</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>371</sup> *Id.*

<sup>372</sup> *Id.*

<sup>373</sup> *Id.*



The role of wholesale drug distributors in the pharmaceutical industry is to ensure controlled substances prescriptions are delivered to pharmacies in a secure and timely fashion so they can be distributed to patients. Distributors are required to obtain registrations to handle controlled substances and to take steps to ensure their registration is not being used as a source of drug diversion.<sup>374</sup> Specifically, the CSA’s implementing regulations require distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances[,]” and to report suspicious orders to the DEA “when discovered by the registrant.”<sup>375</sup>

But as explained in greater detail in this section, the extraordinary volume of shipments in West Virginia was a harbinger of possible breakdowns in distributors’ oversight of their customers, including their suspicious order monitoring systems.

At the Subcommittee’s May 8, 2018 hearing, the leaders of five wholesale drug distribution companies testified about their companies’ policies and actions in West Virginia. They included:

- George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc.;
- Steven H. Collis, Chairman, President, and CEO, AmerisourceBergen Corporation;

<sup>374</sup> See 21 U.S.C. § 823 and 21 U.S.C. § 829.

<sup>375</sup> 21 C.F.R. § 1301.74(b). In October 2018, through the enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), Congress codified the regulatory requirements related to suspicious order reporting. See SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018); *see also supra* Section IV(C) fn. 55.

- John H. Hammergren, Chairman, President, and CEO, McKesson Corporation;
- Joseph R. Mastandrea, D.O., Chairman of the Board, Miami-Luken, Inc.; and
- J. Christopher Smith, Former President and CEO, H.D. Smith Wholesale Drug Company.

Each of the witnesses were asked whether they believed their companies' actions contributed to the nation's opioid crisis. Witnesses for AmerisourceBergen, Cardinal Health, McKesson Corp., and H.D. Smith refuted that characterization. Only one witness, Dr. Mastandrea of Miami-Luken acknowledged that his company's actions were a contributing factor. The witnesses testified:

Q. First, do you believe that the actions that you or your company took contributed to the opioid epidemic? Mr. Barrett.

Mr. Barrett. Thank you, Mr. Chairman.

Q. We're really looking here, because I've got a lot of questions, yes or no. And if it is not either one –

Mr. Barrett. No. No, sir, I do not believe that we contributed to the opioid crisis.

Q. We'll come back to you then. Dr. Mastandrea.

Dr. Mastandrea. Yes.

Q. Mr. Hammergren.

Mr. Hammergren. No.

Q. Mr. Smith.

Mr. Smith. I believe H.D. Smith conducted itself responsibly and discharged its obligations.

Q. Is that a no?

Mr. Smith. That is a no.

Q. Okay. Mr. Collis.

Mr. Collis. No. I believe we -- it's a no for AmerisourceBergen.<sup>376</sup>

While denying individual responsibility, the witnesses did offer reflections on what lessons their respective companies learned through reviews of past actions. Asked at the hearing whether their companies previously failed to maintain effective controls to prevent opioid diversion, distributor witnesses acknowledged that in hindsight they could have done more. Mr. Barrett of Cardinal Health apologized to West Virginians for Cardinal's actions, testifying that if the company were presented with the same red flags today, it would have more carefully vetted some of the pharmacies in question:

To the people of West Virginia, I want to express my personal regret for judgments that we'd make differently today with regard to two pharmacies that have been a particular focus of this subcommittee. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I'm deeply sorry that we did not.<sup>377</sup>

Mr. Hammergren of McKesson expressed similar sentiments, noting that "there clearly were certain pharmacies in West Virginia that were bad actors."<sup>378</sup> While Mr. Hammergren noted that McKesson terminated business relations with some West Virginia pharmacies, he said "[i]n hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies."<sup>379</sup>

Mr. Collis of AmerisourceBergen denied that his company played a role in the opioid epidemic, and said it always fulfilled its legal obligations to combat diversion, including with respect to its shipments to West Virginia. Nevertheless, Mr. Collis conceded the massive volume of opioids that flooded small towns in West Virginia could have been a symptom of an industry-wide problem.<sup>380</sup>

During a transcribed interview with Committee staff, Dr. Mastandrea of Miami-Luken expressed regret over a news article regarding a federal investigation into the Sav-Rite pharmacies in Kermit, West Virginia, both of which were Miami-Luken customers, stating:

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<sup>376</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 49-50 (2018) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.*

<sup>377</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 35 (2018) (testimony of George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.*

<sup>378</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 31 (2018) (testimony of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.*

<sup>379</sup> *Id.*

<sup>380</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 53-54 (2018) (testimony of Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.*

If I'm not mistaken, this particular individual pleaded guilty to drug diversion and served time – that owned Sav-Rite Pharmacy. How in God's name we participated in supplying this individual product when, in hindsight, clearly this was drug diversion. A picture of this pharmacy would be next to the definition in the dictionary. No one was paying attention. It's an abomination.<sup>381</sup>

As detailed in the sections below, the Committee's investigation into these five distributors identified failings in various aspects of their compliance programs or the implementation thereof. These included inadequate new customer due diligence efforts, poor implementation—or lack thereof—of thresholds capping the distribution of controlled substances, and suspicious order reporting, which resulted in continued shipments by the distributors to certain pharmacies despite clear red flags of diversion.

The scope of the Committee's review of the distributors' conduct was limited. The investigation focused only on distributors' shipments to certain areas of West Virginia and individual pharmacies located in those rural regions. Accordingly, much of this section is comprised of case studies. While the Committee cannot draw comprehensive, nationwide conclusions from this review, the findings are astonishing and concerning. They also raise questions about the effectiveness of distributors' anti-diversion efforts outside West Virginia, as the same policies were implemented across the country.

For example, the Committee found several instances in which wholesale distributors established, or in some cases, reestablished business relationships with questionable pharmacies despite the presence of multiple red flags. The DEA has interpreted the CSA and federal regulations as requiring distributors to, among other things, conduct adequate due diligence of prospective and existing customers.<sup>382</sup> But in certain cases, the due diligence documents produced to the Committee showed little evidence that distributors met this responsibility and adequately investigated red flags that presented during the onboarding process that merited heightened scrutiny.

Another area where the Committee identified failings was related to distributors' threshold systems. Through use of threshold systems, distributors have sought to comply with federal regulations requiring them to detect and report suspicious orders to the DEA. The systems allow them to automatically flag and stop suspicious orders for review before controlled substances are shipped, providing time to evaluate possible signs of drug diversion. However, the Committee found that not all distributors use threshold systems and those that do may implement them ineffectively. For instance, when thresholds are set artificially high, they allow pharmacies to purchase controlled substance amounts outside their typical ordering pattern without triggering a threshold event and subsequent review or investigation. Likewise, if distributors assign thresholds but fail to enforce the monthly limits they are useless for the purposes of preventing drug diversion.

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<sup>381</sup> Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, 34-35 (On file with Committee).

<sup>382</sup> See 80 Fed. Reg. 55,477, Sept. 15, 2015 (citing 72 Fed. Reg. 36,498, July 3, 2007).

Distributors' suspicious order monitoring systems also varied in effectiveness. Distributors are required to report suspicious orders to DEA as part of anti-diversion efforts. The Committee found, however, that distributors did not always comply with their legal obligation to report suspicious orders. Some blocked pharmacies' orders but never reported the information to DEA. Others failed to report individual suspicious orders and instead informed DEA about suspicious customers to whom they opted to stop selling controlled substances. Over the time period examined by the Committee, the DEA brought enforcement actions against AmerisourceBergen, Cardinal, McKesson, and Miami-Luken regarding allegations that each company failed to report suspicious orders.

Finally, the Committee's investigation revealed several instances where distributors supplied West Virginia pharmacies with a volume of opioids that should have raised red flags, particularly when viewed in the context of what would be considered reasonable to support the legitimate medical needs of the local population. Distributors also at times shipped millions of opioid pills to small-town pharmacies with very little corresponding due diligence. In other instances, distributors had in their possession due diligence materials that should have prompted them to conduct independent investigations of certain pharmacy customers or required them to more frequently report suspicious orders to DEA. The Committee's investigation found, however, that distributors continued to ship opioids to these pharmacies for months and, in some cases, even years.

## **A. Prospective Customer Due Diligence Efforts by the Distributors**

### **1. The Legal Framework and Distributor Policies Regarding Prospective Customer Due Diligence**

The CSA requires that wholesale distributors “[maintain] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels[.]”<sup>383</sup> In addition, federal regulations require, “[a]ll [DEA] applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”<sup>384</sup> These statutory and regulatory requirements have been interpreted as requiring, among other things, that distributors conduct adequate due diligence of their customers to mitigate against the potential diversion of controlled substances. For example, in 2007, the DEA Deputy Administrator issued a final order revoking the registration of Southwood Pharmaceuticals, a California-based wholesale distributor, for, among other things, the company’s failure to conduct adequate due diligence of its prospective and existing customers.<sup>385</sup> In the final order the Deputy Administrator noted, “[i]n short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone.”<sup>386</sup>

In September 2006 and February 2007, the DEA sent two identical letters to “every commercial entity in the United States registered with the [DEA] to distribute controlled substances” in which the agency reiterated the statutory obligation that distributors maintain effective controls against diversion, as well as the regulatory requirement to report suspicious orders.<sup>387</sup> In each letter, the DEA wrote:

It bears emphasis that the foregoing reporting requirement<sup>388</sup> is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, 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 into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as

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<sup>383</sup> 21 U.S.C. § 823(b) and 21 U.S.C. § 823(e).

<sup>384</sup> 21 C.F.R. § 1301.71(a).

<sup>385</sup> See 72 Fed. Reg. 36,487, July 3, 2007.

<sup>386</sup> 72 Fed. Reg. 36,500, July 3, 2007.

<sup>387</sup> 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 Committee); 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 Committee).

<sup>388</sup> Here, the letters reference suspicious order reporting regulations, promulgated at 21 C.F.R. § 1301.74(b), which states, “[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”



circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances.<sup>389</sup>

In September 2015, the DEA Acting Administrator issued a final order revoking the DEA registration of Masters Pharmaceuticals, a Cincinnati, Ohio-based wholesale distributor for the company's failure to conduct adequate due diligence, and report suspicious orders to the DEA.<sup>390</sup> In the final order, the Acting Administrator also referenced and quoted the aforementioned DEA letters<sup>391</sup> in addition to reiterating a distributor's obligation to conduct due diligence on prospective and existing customers, stating:

As *Southwood* makes clear, a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels." 21 U.S.C. 823(b); *see also id.* §823(e). As for the scope of the duty to perform due diligence, *Southwood* makes clear that doing "nothing more than verifying a pharmacy's DEA registration and state license" is not enough. 72 FR 36,498. Rather, a distributor must conduct a reasonable investigation "to determine the nature of a potential customer's business before it" sells to the customer, and the distributor cannot ignore "information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices."<sup>392</sup>

The Acting Administrator also stated in the *Masters* order that "depending upon the circumstances, a distributor may need to perform site visits before it engages in any distribution of controlled substances. Moreover, the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer."<sup>393</sup> In the final order, the Acting Administrator referenced that, in certain circumstances, the company failed to seek further explanation when presented with information that conflicted with what was provided

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<sup>389</sup> 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 Committee); 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 Committee).

<sup>390</sup> *See* 80 Fed. Reg. 55,418, Sept. 15, 2015.

<sup>391</sup> 80 Fed. Reg. 55,421, Sept. 15, 2015.

<sup>392</sup> 80 Fed. Reg. 55,477, Sept. 15, 2015 (quoting 72 Fed. Reg. 36,498, July 3, 2007).

<sup>393</sup> 80 Fed. Reg. 55,477, Sept. 15, 2015.

during the due diligence process, leading the Acting Administrator to suggest the company's "purpose in asking these questions was simply to go through the motion of conducting due diligence."<sup>394</sup> The Acting Administrator also faulted the company for not performing additional due diligence when it was presented with factors suggestive of possible diversion, such as a pharmacy being co-located with a clinic,<sup>395</sup> or dispensing high percentages of controlled substances.<sup>396</sup>

In the course of this investigation, the Committee requested and received information from distributors regarding their due diligence process. These documents included prospective customer forms, policies and procedures related to onboarding customers, and due diligence files on specified pharmacies. The information reviewed by the Committee raises concerns about the adequacy of the distributors' due diligence efforts at times during the time period covered by the Committee's investigation.

While the DEA has interpreted the CSA and federal regulations as requiring distributors to, among other things, conduct adequate due diligence of prospective and existing customers, neither the agency nor federal regulations require that distributors adopt any particular approach to satisfy this legal obligation. By reviewing the material obtained during the course of its investigation, the Committee was able to gain a better understanding of how distributors conducted due diligence of prospective customers.<sup>397</sup>

Based upon the Committee's review, the majority of the distributors that were the focus of the Committee's investigation updated their policies and procedures related to prospective customer due diligence between 2007 and 2008, generally requiring, at a minimum, the completion of a prospective customer questionnaire which would be reviewed prior to onboarding a pharmacy. These distributors have, at various times, updated their policies for conducting prospective customer due diligence.

In general, distributors' prospective customer questionnaires are completed by the pharmacy and provide distributors with background information with respect to the pharmacy as well as its anticipated ordering habits. For example, in the questionnaires prospective customers are generally required to disclose:

- DEA and state board of pharmacy licensure information for the pharmacy and its staff;
- Whether the pharmacy or its staff have ever been subject to discipline by the DEA or relevant state authorities;
- Whether the pharmacy fills prescriptions that were obtained over the internet;

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<sup>394</sup> 80 Fed. Reg. 55,488, fn. 179, Sept. 15, 2015.

<sup>395</sup> 80 Fed. Reg. 55,498, Sept. 15, 2015.

<sup>396</sup> 80 Fed. Reg. 55,495, Sept. 15, 2015.

<sup>397</sup> For purposes of this discussion, the term 'prospective customer' includes both pharmacies that are requesting to do business with a wholesale distributor for the first time as well pharmacies that had a prior relationship with a distributor and are requesting to reestablish any such relationship.

- Whether the pharmacy had its ability to purchase controlled substances restricted or terminated by a distributor in the past;
- Estimates regarding what percentage of the pharmacy's prescriptions are paid for by private insurance, by Medicare/Medicaid, or in cash, among other information; and
- Estimates regarding what percentage of a pharmacy's overall sales are attributable to controlled substances.

When conducting due diligence, a distributor may obtain information about a pharmacy's prescribing physicians, such as by asking a pharmacy to disclose this on a new customer questionnaire. Receiving such information enables a distributor to conduct analysis on the top prescribing physicians and enhances a distributor's ability to identify possible red flags of diversion. For example, if a distributor is provided with a pharmacy's prescribing physicians, it can then search the internet for any concerning news articles involving these physicians, in addition to any disciplinary actions that may have been taken by state medical boards. Obtaining a pharmacy's prescribing physicians also enables a distributor to identify whether a pharmacy is filling prescriptions of any physicians who may be located substantial distances from the pharmacy, which the DEA has cited as being a red flag for diversion.<sup>398</sup>

Prospective customer questionnaires also generally require pharmacies to provide estimated dispensing figures for certain controlled substances, with some distributors requiring pharmacies to submit dispensing reports in addition to the prospective customer questionnaire. Obtaining a dispensing report provides a distributor with the ability to see the total volume of controlled substances dispensed by a pharmacy over a given period of time. The dispensing reports obtained by distributors may be de-identified, providing aggregated dispensing information but not identifying the physicians whose prescriptions were filled by the pharmacy. An example of this type of dispensing report is reproduced below:<sup>399</sup>

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<sup>398</sup> See 80 Fed. Reg. 55,491, Sept. 15, 2015.

<sup>399</sup> McKesson Corp., Family Discount Pharmacy (Mount Gay-Shamrock) Dispensing Report 2/23/12 to 8/23/12 (On file with Committee).

FAMILY DISCOUNT PHARMACY  
 Old Route 119  
 Mt. Gay, WV 25637  
 Fax: [REDACTED]

UTILIZATION  
 Period 2/23/12 to 8/23/12  
 Thu Aug 23, 2012

Page 21  
 FID: [REDACTED]  
 NPI: [REDACTED]

Rank	Drug Name	NDC	Rxs	Rfs	Qty	Total U&C	Total Price	Total Cost	Gross Margin	% Margin
881	HALOPERIDOL 1MG	0378-0257-10	1	0	90					
882	HALOPERIDOL 20 MG TABLET	68382-081-01	2	4	720					
883	HALOPERIDOL 5MG	0378-0327-10	4	5	261					
884	HALOPERIDOL DEC 100 MG/ML	10147-0922-5	2	5	7					
885	HECTOROL 1 MCG CAPSULE	58468-0124-1	1	5	210					
886	HEPARIN LOCK FLUSH 100 UN	63323-545-05	1	0	5					
887	HEPARIN LOCK FLUSH 100UNI	0409-1152-70	0	1	10					
888	HOMATROPAIRE 5% EYE DROPS	59390-0192-05	2	0	10					
889	HUGGIES SNUG & DRY STEP 5	36000-55395	3	4	1750					
890	HUGGIES SNUG & DRY STEP 6	36000-55506	1	8	1550					
891	HUMALOG	0002-7510-01	15	12	390					
892	HUMALOG 100 UNITS/ML CART	0002-7516-59	0	3	90					
893	HUMALOG KWIKPEN 15ML	0002-8799-59	30	31	945					
894	HUMALOG MIX 50/50	0002-7512-01	1	3	240					
895	HUMALOG MIX 75-25 KWIKPEN	0002-8797-59	4	6	270					
896	HUMALOG MIX 75/25 10ML	0002-7511-01	16	52	2700					
897	HUMIRA 40MG/0.8ML SYRINGE	0074-3799-02	4	10	28					
898	HUMULIN 70/30 INSULIN	0002-8715-01	9	5	370					
899	HUMULIN N PEN	0002-8730-59	9	11	390					
900	HUMULIN N U100 VIAL 10ML	0002-8315-01	15	16	640					
901	HUMULIN R U-500 VIAL 20ML	0002-8501-01	0	3	100					
902	HUMULIN R U100 VIAL 10ML	0002-8215-01	1	2	30					
903	HYALGAN 20 MG/2 ML SYRING	89122-0724-20	1	0	6					
904	HYDRALAZINE 10 MG TABLET	23155-001-01	4	3	630					
905	HYDRALAZINE 100 MG TABLET	23155-004-01	1	5	720					
906	HYDRALAZINE 25 MG TABLET	23155-002-10	17	25	3630					
907	HYDRALAZINE 50 MG TABLET	23155-003-01	5	12	1260					
908	HYDROCHLOROTHIAZIDE 12.5	23155-045-05	86	95	5918					
909	HYDROCHLOROTHIAZIDE 25 MG	0603-3856-34	132	168	9481					
910	HYDROCHLOROTHIAZIDE 50MG	0603-3857-32	7	22	1110					
911	HYDROCOD/BITART/ACETAM 10	0603-3886-28	83	60	12801					
912	HYDROCODON-APAP 10-325	0603-3887-32	138	110	25409					
913	HYDROCODON-APAP 10-500	0406-0363-05	1657	1167	211568					

Distributors also have the ability to obtain dispensing information from pharmacies that not only shows the volume of controlled substances a pharmacy dispenses over a given period of time, but also identifies the physicians associated with each prescription that is filled by a pharmacy.<sup>400</sup> This enables a distributor to identify whether any physicians are responsible for writing a disproportionate percentage of the prescriptions filled by the pharmacy, which the DEA has also identified as being a red flag for diversion,<sup>401</sup> in addition to being able to assess a pharmacy's overall dispensing volume. An example of this type of dispensing report is reproduced below:<sup>402</sup>

<sup>400</sup> The distributors' policies regarding obtaining dispensing data are discussed later in this section.

<sup>401</sup> See 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 Committee); 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 Committee).

<sup>402</sup> H.D. Smith Wholesale Drug. Co., Westside Pharmacy Dispensing Report 6/1/2010 to 6/30/2010 (On file with Committee).

Rx Register Brief-Landscape

DRUG REPORT  
WESTSIDE PHARMACY

FROM: 06/01/2010 THROUGH: 06/30/2010

RX#	DATE	PATIENT	ITEM	QTYD	PRESCRIBER	DISP COST	TOT ADJ AMT	PAT PAY	PRM CVG
N 299866	06/14/2010		OXYCODONE 15MG TAB	21.00	KOSTENKO, MICHAEL				CASH
N 301917	06/14/2010		OXYCODONE 15MG TAB	35.00	KOSTENKO, MICHAEL				CASH
N 301952	06/14/2010		OXYCODONE 15MG TAB	112.00	KOSTENKO, MICHAEL				CASH
N 302009	06/14/2010		OXYCODONE 15MG TAB	112.00	KOSTENKO, MICHAEL				CASH
N 302013	06/14/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				CASH
N 302043	06/14/2010		OXYCODONE 15MG TAB	84.00					CASH
N 302029	06/15/2010		OXYCODONE 15MG TAB	180.00	DERAKHSHAN, I MD				MEDCO
N 302132	06/15/2010		OXYCODONE 15MG TAB	45.00	KOSTENKO, MICHAEL				CASH
N 302138	06/15/2010		OXYCODONE 15MG TAB	21.00	KOSTENKO, MICHAEL				CASH
N 302278	06/15/2010		OXYCODONE 15MG TAB	120.00	KOSTENKO, MICHAEL				ADV
N 302313	06/15/2010		OXYCODONE 15MG TAB	112.00	MORGAN, DAVID MD				CASH
N 302349	06/16/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				CASH
N 302361	06/16/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				CASH
N 302363	06/16/2010		OXYCODONE 15MG TAB	28.00	KOSTENKO, MICHAEL				CASH
N 302417	06/16/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				WEST
N 302450	06/16/2010		OXYCODONE 15MG TAB	70.00	KOSTENKO, MICHAEL				CASH
N 299396	06/17/2010		OXYCODONE 15MG TAB	28.00	KOSTENKO, MICHAEL				CASH
N 302539	06/17/2010		OXYCODONE 15MG TAB	120.00	MORGAN, DAVID MD				CASH
R 302539	06/17/2010		OXYCODONE 15MG TAB	120.00	MORGAN, DAVID MD				WVIA
N 302541	06/17/2010		OXYCODONE 15MG TAB	120.00	MORGAN, DAVID MD				WVIA
R 302541	06/17/2010		OXYCODONE 15MG TAB	120.00	MORGAN, DAVID MD				CASH
N 302591	06/17/2010		OXYCODONE 15MG TAB	168.00	MORGAN, DAVID MD				CCCRX
N 302636	06/17/2010		OXYCODONE 15MG TAB	90.00	KOSTENKO, MICHAEL				CASH
N 302637	06/17/2010		OXYCODONE 15MG TAB	58.00	KOSTENKO, MICHAEL				CASH
N 302836	06/19/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				ADV
N 302907	06/20/2010		OXYCODONE 15MG TAB	56.00	KOSTENKO, MICHAEL				MISC
N 302835	06/21/2010		OXYCODONE 15MG TAB	35.00	KOSTENKO, MICHAEL				CASH
N 303119	06/22/2010		OXYCODONE 15MG TAB	21.00	KOSTENKO, MICHAEL				CASH
N 303243	06/22/2010		OXYCODONE 15MG TAB	112.00	KOSTENKO, MICHAEL				CASH
N 303246	06/22/2010		OXYCODONE 15MG TAB	90.00	KOSTENKO, MICHAEL				ANT
N 303299	06/22/2010		OXYCODONE 15MG TAB	84.00	KOSTENKO, MICHAEL				CASH
N 303340	06/23/2010		OXYCODONE 15MG TAB	28.00	KOSTENKO, MICHAEL				CASH
N 303359	06/23/2010		OXYCODONE 15MG TAB	60.00	GEORGESCU, VICTOR				CCCRX
N 303452	06/23/2010		OXYCODONE 15MG TAB	180.00	GEORGESCU, VICTOR				EXP
N 303559	06/23/2010		OXYCODONE 15MG TAB	150.00	MORGAN, DAVID MD				CASH
N 303474	06/24/2010		OXYCODONE 15MG TAB	21.00	KOSTENKO, MICHAEL				CASH

Obtaining dispensing information that identifies prescribing physicians also ensures that a distributor is not solely relying on a pharmacy to self-disclose its top prescribing physicians and methods of payment on a new customer questionnaire.

**FINDING:** Distributors can obtain dispensing data from pharmacies that shows the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription.

Distributors may also conduct on-site pharmacy visits as part of their prospective customer due diligence efforts, where the information provided on the prospective customer questionnaire may be reviewed. Conducting an onsite visit also provides a distributor with the ability to make general observations about a pharmacy as well as its surrounding area, including

the presence of any other pharmacies that may be located in close proximity to the prospective customer which is especially relevant if a prospective customer dispenses, or estimates to dispense, a large volume of controlled substances.

*a. AmerisourceBergen's Approach to Prospective Customer Due Diligence*

AmerisourceBergen developed its process for evaluating prospective customers in 2007.<sup>403</sup> That year, AmerisourceBergen entered into a settlement agreement with the DEA to resolve allegations brought by the agency, in which the company agreed, among other things, “to maintain a compliance program designed to detect and prevent diversion of controlled substances[.]”<sup>404</sup> With respect to the company’s approach to prospective customer due diligence, Mr. Collis testified:

AmerisourceBergen Drug Corporation’s diversion control team performs due diligence to determine whether prospective new customers are suitable purchasers of controlled substances. The procedure to review prospective customers has varied over time but since 2007 has generally included the following elements: the completion of a Retail Customer Questionnaire; site visits; verification of the pharmacy’s DEA registration and state licensure; review of the pharmacy-provided information; and online investigation (including internet licensing and disciplinary searches) for the identified pharmacy, owner, and pharmacist-in-charge. The questions on the questionnaire are based on guidance from the DEA.<sup>405</sup>

Regarding the prospective customer questionnaire, the company told the Committee:

The information contained on the questionnaire is the basis for ABDC’s due diligence investigation and provides a baseline to measure the pharmacy’s ordering habits and to determine any deviation from expected purchasing practices. The questionnaire provides information to ABDC regarding anticipated ordering practices, including, among other things, the amount of controlled substances ordered, the anticipated ratio of controlled vs. non-controlled substances purchased, key prescribing doctors in the area utilizing the pharmacy, the purchasing practices of the pharmacy’s customers (*i.e.* cash, credit, insurance, etc.), and whether another supplier is known to have suspended or ceased controlled substance sales to the

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<sup>403</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 7 (2018) (testimony of Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf>.

<sup>404</sup> *In re AmerisourceBergen*, Settlement and Release Agreement, 2 (June 22, 2007) (On file with Committee).

<sup>405</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 7 (2018) (testimony of Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf>.

customer. The questionnaire also includes inquiries on topics such as high-risk drugs and high-prescribing physicians.<sup>406</sup>

Based on information provided to the Committee, AmerisourceBergen does not appear to require prospective customers to provide dispensing data as part of their application, unless specifically requested to do so by the company. In response to a question posed after the Subcommittee's May 8, 2018 hearing regarding whether the company requests dispensing data from its prospective and existing customers, AmerisourceBergen told the Committee, "ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers."<sup>407</sup>

AmerisourceBergen later told the Committee, "ABDC collects patient de-identified dispensing reports on an as-needed basis to allow it to investigate and mitigate concerns about possible suspicious behavior by its customers[,] and that "[c]ustomers may also be asked to provide full dispensing reports as part of new customer due diligence, again to mitigate red flags discovered during onboarding or to properly size the pharmacy as part of the company's Ordering Monitoring Program."<sup>408</sup> The company also added:

Collecting dispensing data on a routine basis from all pharmacies is not a requirement that is imposed upon the distributor by the governing federal laws and implementing regulations. The main purpose of collecting and reviewing dispensing data is to identify potential inappropriate patient dispensing at the pharmacy. It is well established that the "corresponding responsibility" to ensure the clinical appropriateness of a prescription falls on the practitioner who supplied the prescription as well as the pharmacist who fills the prescription. Requiring distributors, like ABDC, to collect dispensing data from all DEA registrants without cause effectively transfers [the] pharmacist's responsibilities for diversion control onto the distributor, a role the distributor should not have.<sup>409</sup>

AmerisourceBergen did say, however, "[w]hen dispensing data is requested, ABDC does generally request that its customers provide the data in a manner that allows for the identification of prescribing physicians."<sup>410</sup>

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<sup>406</sup> Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>407</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).

<sup>408</sup> E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

<sup>409</sup> *Id.*

<sup>410</sup> *Id.*

**b. Cardinal Health's Approach to Prospective Customer Due Diligence**

Cardinal Health told the Committee that after it received the DEA's February 7, 2007 letter, the company "worked to ensure its systems complied with DEA's new statements with respect to suspicious order monitoring and reporting."<sup>411</sup> In its response to the Committee, the company also added:

In 2007, Cardinal Health began requiring completion of a New Pharmacy Questionnaire as part of the account approval process for all new retail independent pharmacies. The questionnaire collected general information about the pharmacy, its owner, and the pharmacist in charge; general information about the pharmacy's other suppliers; information about the pharmacy's customers and their primary method of payment for controlled and non-controlled substances; and the pharmacy's expected controlled substance ordering, among other information. Cardinal Health employees vetted these questionnaires, and conducted additional investigation where appropriate.<sup>412</sup>

Thereafter, in December 2008, Cardinal implemented formal anti-diversion Standard Operating Procedures (SOPs), which included SOPs for conducting prospective customer due diligence.<sup>413</sup> That same year, Cardinal entered into a settlement agreement with the DEA to resolve allegations brought by the agency, agreeing, among other things, "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations."<sup>414</sup> Since 2008, the SOPs have undergone a number of revisions, including in 2017.<sup>415</sup>

Pursuant to the 2017 SOPs, upon receiving a prospective customer questionnaire, Cardinal's Corporate Anti-Diversion New Account Set-up team validates "that the customer is eligible to be reviewed for purchasing controlled substances from Cardinal Health."<sup>416</sup> The Corporate Anti-Diversion New Account Set-up team will then review the information the pharmacy provided on the prospective customer questionnaire, requesting additional information or further review, if necessary.<sup>417</sup>

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<sup>411</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).

<sup>412</sup> *Id.*

<sup>413</sup> See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee); See also Cardinal Health, Inc., Standard Operating Procedures – New Account Approval (initial release of new procedure Dec. 22, 2008) (On file with Committee).

<sup>414</sup> *In re Cardinal Health*, Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008, 3 (On file with Committee).

<sup>415</sup> See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).

<sup>416</sup> Cardinal Health, Inc., Standard Operating Procedure – New Account Approval (Effective Date – Jan. 6, 2017) (On file with Committee).

<sup>417</sup> *Id.*



Based on information provided to the Committee, Cardinal Health does not appear to require prospective customers to provide dispensing data as part of their application, unless specifically requested to do so by the company. In response to a question posed after the Subcommittee's May 8, 2018 hearing regarding whether the company requests dispensing data from its prospective and existing customers, Cardinal told the Committee:

As part of its comprehensive anti-diversion program, Cardinal Health periodically requests and receives aggregate dispensing data and total number of prescriptions filled for both controlled and non-controlled substances from prospective and existing pharmacy customers. Cardinal Health requests total number of prescriptions filled for certain controlled substances from prospective customers as part of its initial Know Your Customer account set up process.<sup>418</sup>

Cardinal added that it will not distribute opioids to a pharmacy if it refuses to provide the company with dispensing data upon request.<sup>419</sup>

*c. McKesson's Approach to Prospective Customer Due Diligence*

McKesson administers prospective customer due diligence as part of its larger Controlled Substances Monitoring Program (CSMP).<sup>420</sup> According to McKesson, the CSMP was developed during the period the company was engaged in negotiations with the DEA, ultimately leading to the settlement that was finalized on May 2, 2008.<sup>421</sup> Documents produced to the Committee indicate the company began its development of the CSMP in September 2007, following a meeting with the DEA, and that the program was launched the following April, in 2008.<sup>422</sup> Regarding the 2008 CSMP, and with respect to prospective customer due diligence, McKesson told the Committee:

McKesson's CSMP established standardized procedures for customer diligence. For example, new pharmacy customers were required to submit a questionnaire that called for information about the pharmacy's purchase history, background, and business. The CSMP also provided for customer site visits, which could include on-site interviews. During

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<sup>418</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Cardinal Health, Inc.).

<sup>419</sup> *See Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Cardinal Health, Inc.).

<sup>420</sup> *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>421</sup> *Id.*

<sup>422</sup> McKesson Corp., McKesson Pharmaceutical Controlled Substance Monitoring Program (CSMP) – DEA Discussion Document, July 31, 2008, 5 (On file with Committee).

a site visit, McKesson personnel were expected to observe, among other things, whether customer traffic appeared to be consistent with the pharmacy's business type and overall volume. Directors of Regulatory Affairs were responsible for analyzing the questionnaires and supporting documentation and making determinations about whether new customers were eligible to purchase controlled substances.<sup>423</sup>

Under the 2008 CSMP, and no later than January 2010, McKesson required prospective customers to provide the company with six months of dispensing data if the prospective customer estimated on the pharmacy questionnaire that its dispensing levels for certain controlled substances, including hydrocodone and oxycodone, exceeded 5,000 doses a month.<sup>424</sup> In an undated pharmacy questionnaire, McKesson required prospective customers to provide "information to support purchase levels" if the prospective customer estimated that its dispensing levels exceeded 5,000 doses a month.<sup>425</sup> This questionnaire, which likely predates January 2010, did not state what information the prospective customer was required to provide to support its estimated purchase levels, but did provide space for the prospective customer to draft a narrative explanation.<sup>426</sup>

McKesson told the Committee, "[i]n 2013 McKesson devoted substantial resources to enhance and revise its CSMP."<sup>427</sup> Documents produced to the Committee indicate that McKesson updated its pharmacy questionnaire in August 2013 and required pharmacies to provide three months of dispensing data, if requested by the company.<sup>428</sup> Since McKesson utilized the same pharmacy questionnaire to review its prospective and existing customers, and based on the policies and procedures produced to the Committee, it is unclear whether the production of three months of dispensing data was at the company's discretion for both prospective and existing customers or whether prospective customers were required to produce this data in all cases.

In June 2015, McKesson updated its policies, making clear that prospective customers are required to produce "[t]hree (3) months script & dose data unless the pharmacy is a Start-up

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<sup>423</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>424</sup> See e.g. McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).

<sup>425</sup> See McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Stollings) (On file with Committee).

<sup>426</sup> *Id.*

<sup>427</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>428</sup> See e.g. McKesson Corp., Pharmacy Questionnaire – Hurley Drug Company, May 6, 2014 (On file with Committee); See also McKesson Corp., McKesson Operations Manual for Pharma Distribution – Controlled Substance Monitoring Program, 32 (Document created Feb. 11, 2008 and last revised Sept. 24, 2013) (On file with Committee).

Pharmacy or the prospective customer has been in business less than three months.”<sup>429</sup> This dispensing data do not, however, identify a pharmacy’s prescribing physicians as McKesson told the Committee, “McKesson does not require the dispensing data provided by the customer to identify prescribing physicians[,]” though noting “McKesson, may, depending on the circumstances, request that the customer provide additional information on prescribers.”<sup>430</sup>

*d. H.D. Smith's Approach to Prospective Customer Due Diligence*

According to H.D. Smith, in September 2007 the company’s Vice-President of Corporate Compliance and Security attended a DEA industry conference addressing suspicious order monitoring.<sup>431</sup> Thereafter, the company stated it engaged in ongoing discussions with the DEA throughout the fall of 2007 as the company continued to develop its controlled substance order monitoring program (CSOMP), which was implemented company-wide throughout 2008.<sup>432</sup> With respect to prospective customer due diligence, the company told the Committee:

Throughout 2007, the development of CSOMP was not the only enhancement made to H.D. Smith’s compliance program. In December 2007, H.D. Smith implemented a more robust “know your customer” approach to customer monitoring. To that end, H.D. Smith directed its sales representatives to obtain in-person detailed Customer Profiles from all current customers. The Customer Profile form collected a variety of information to allow H.D. Smith to understand the pharmacy, its business model, the patients it services and the physicians treating those patients. Moving forward, all new customers were required to submit a completed Customer Profile for approval by [Corporate Compliance and Security Department] before they were permitted to order.<sup>433</sup>

Based on documents produced to the Committee, the Customer Profile form H.D. Smith utilized during 2007 and 2008 was three-pages in length and required prospective customers to provide, among other things, estimates regarding the percentage of its purchases that would be for controlled substances, as well as a narrative explanation if the pharmacy anticipated ordering a large volume of controlled substance.<sup>434</sup>

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<sup>429</sup> McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, 10 (Effective Date June 1, 2015 and last revised May 17, 2017) (On file with Committee).

<sup>430</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>431</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>432</sup> *Id.*

<sup>433</sup> *Id.*

<sup>434</sup> See H.D. Smith Wholesale Drug Co., Customer Profile – Family Discount Pharmacy, Dec. 18, 2007 (On file with Committee); see also H.D. Smith Wholesale Drug Co., Customer Profile – Hurley Drug Company, Feb. 27, 2008 (On file with Committee).

With respect to the methods it utilized in 2007 to ascertain whether a prospective customer presented any diversion concerns, the company told the Committee, “[s]pecifically, H.D. Smith (1) required the in-person completion of a detailed Customer Profile Form by the customer; (2) conducted site visits as needed; (3) analyzed dispensing information if provided by the customer, and (4) was continuing to develop CSOMP.”<sup>435</sup>

The company told the Committee that it has continued to refine its Customer Profile over time, adding, “[c]urrent and prospective customers are required to disclose their top prescribing doctors, identify the percentage of cash payments, and identify the location of prescribers and patients. For new customers, this information is independently reviewed and, to the extent possible, verified before a new account is approved to be opened.”<sup>436</sup>

Based on information provided to the Committee, H.D. Smith does not appear to require prospective customers to provide dispensing data as part of their application, unless specifically requested to do so by the company. In response to a question posed after the Subcommittee’s May 8, 2018 hearing regarding whether the company requests dispensing data from its prospective and existing customers, H.D. Smith referred the Committee to the answer provided by AmerisourceBergen to the same question in which AmerisourceBergen responded, “ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers.”<sup>437</sup> H.D. Smith did note, however, “[h]istorically, H.D. Smith did periodically request dispensing data from current or prospective customers, which was analyzed to identify patterns or trends indicative of possible diversion.”<sup>438</sup> H.D. Smith later told the Committee that it engaged with a third-party vendor in 2010 to gather dispensing data from customers on an as-needed basis, and that the company “did require dispensing data to be provided so as to identify prescribing physicians.”<sup>439</sup>

*e. Miami-Luken’s Approach to Prospective Customer Due Diligence*

The Committee could not precisely determine when Miami-Luken initially established, or substantially revised, its policies and procedures for conducting prospective customer due

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<sup>435</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>436</sup> *Id.*

<sup>437</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.). H.D. Smith was acquired by AmerisourceBergen in January 2018. See Press Release, AmerisourceBergen Corp., 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>.

<sup>438</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).

<sup>439</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

diligence. A review of the documents produced to the Committee regarding the due diligence the company performed on a prospective customer in 2008, Sav-Rite No. 2, indicates that, at that time, the company did verify the pharmacy's registrations with the DEA,<sup>440</sup> the state board of pharmacy,<sup>441</sup> and completed a one-page profile of the pharmacy.<sup>442</sup> The one-page profile for Sav-Rite Pharmacy #2 is reproduced in its entirety below.

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<sup>440</sup> Miami-Luken, Inc., Due Diligence File – Sav-Rite Pharmacy #2 (On-file with Committee).

<sup>441</sup> *Id.*

<sup>442</sup> Miami-Luken, Inc., DEA-Pharmacy Physical Location Profile – Sav-Rite Pharmacy #2 (On file with Committee). A similar document, dated August 19, 2008, was included in the due diligence file Miami-Luken maintained for Tug Valley Pharmacy. *See* Miami-Luken, Inc., DEA-Pharmacy Physical Location Profile – Tug Valley Pharmacy (On file with Committee).

**DEA – Pharmacy Physical Location Profile**

Store Name: SAV Rite Pharmacy #2

Address: US52  
Kermit, W. Va.

Store Owner: Jim Wooley

Years In Business: just opened (October 2008)

Type Store:  Rx Only  Rx & OTC  
*(a little)*

Describe Store: Stand-alone building, strip center, inside clinic or grocery, apothecary, large front end, etc.

stand alone bldg with physical therapy  
company next door. very little OTC -

Store Sales Volume: \_\_\_\_\_ Low  Medium \_\_\_\_\_ High

Neighborhood Income: \_\_\_\_\_  Low to \_\_\_\_\_  Medium \_\_\_\_\_ Upper

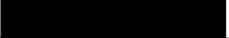
Script Sources:  Local Physicians \_\_\_\_\_ Nursing Homes  
\_\_\_\_\_ Clinics in Area  
\_\_\_\_\_ Hospitals \_\_\_\_\_ Number of Nursing  
 Pain Clinics Near by \_\_\_\_\_ Homes Sold to if Any  
\_\_\_\_\_ Other: \_\_\_\_\_

Mail Order Sales: \_\_\_\_\_ Yes  No

Internet Script Sales : \_\_\_\_\_ Yes  No

Does this pharmacy appear to be a legitimately operating facility as required by State and Federal laws:  Yes \_\_\_\_\_ No

If no describe your concerns or suspicions: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Form Completed By: 

Date Store Was Visited: \_\_\_\_\_

By 2010, the company appears to have adopted a variation of this pharmacy profile form which required pharmacies to disclose, among other things, the names and addresses of doctors whose prescriptions are filled at the pharmacy.<sup>443</sup> Documents produced to the Committee indicate the questionnaires Miami-Luken utilized to evaluate customers continued to evolve and became more detailed in later years.<sup>444</sup> While these questionnaires were submitted by pharmacies that were existing customers of Miami-Luken at the time, the Committee infers that such questionnaires were likely also provided to Miami-Luken's prospective customers as well.

In April 2015, Miami-Luken implemented a new compliance program and has since made "significant investments in analytical tools to assist with due diligence reviews of current and prospective pharmacy customers."<sup>445</sup> The company "also enhanced the controlled substances profile that its pharmacy customers must complete during the onboarding process."<sup>446</sup>

In October 2015, Miami-Luken promulgated a manual entitled, "Miami-Luken's Standard Operating Procedures for DEA Compliance."<sup>447</sup> The manual, which Miami-Luken told the Committee was implemented on October 16, 2015, provides Miami-Luken's policies and procedures for DEA compliance.<sup>448</sup>

The portion of the manual that addresses prospective customer due diligence is reproduced below.<sup>449</sup> At the time, Miami-Luken required its prospective customers to supply, among other things, 90-days of prescribing data that would identify the prescribing physician. This portion of the manual also suggests that conducting prospective customer due diligence is not a requirement under the CSA, stating "[a]lthough not specifically required by the CSA or DEA's regulations, Miami-Luken, Inc. conducts due diligence on all new customers prior to distributing controlled substances to the customers."<sup>450</sup>

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<sup>443</sup> See Miami-Luken, Inc., DEA-Detailed Pharmacy Profile – Tug Valley Pharmacy (On file with Committee).

<sup>444</sup> See Miami-Luken, Inc., M-L Pharmacy Controlled Substance Profile – Tug Valley Pharmacy, May 29, 2013 (On file with Committee); Miami-Luken, Inc., M-L Pharmacy Controlled Substance Profile – Colony Drug, May 28, 2013 (On file with Committee); and Miami-Luken, Controlled Substances Profile Questionnaire -Westside Pharmacy, May 22, 2015 (On file with Committee).

<sup>445</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 16, 2017 (On file with Committee).

<sup>446</sup> *Id.*

<sup>447</sup> See U.S. Drug Enforcement Admin., *In re Miami-Luken*, No. 2016-13 (Respondent's Exhibit #2) (On file with Committee).

<sup>448</sup> See E-Mail from Counsel to Miami-Luken, Inc., to Staff, H. Comm. on Energy and Commerce (Oct. 25, 2018 1:44 pm) (On file with Committee). Miami-Luken indicated to the Committee that policies implemented in October 2015 were revised two years later, in October 2017.

<sup>449</sup> Miami-Luken, Inc., Standard Operating Procedures for DEA Compliance, 23 -24 (On file with Committee).

<sup>450</sup> *Id.*

## Customer Reviews

Although not specifically required by the CSA or DEA's regulations, Miami-Luken, Inc. conducts due diligence on all new customers prior to distributing controlled substances to the customers. In addition, Miami-Luken, Inc. will conduct periodic reviews of current customers based on a number of factors.

### Onboarding a New Customer

Miami-Luken requires the following materials from all new customers:

1. Copy of their current DEA Registration
2. Copy of their current State License.
3. Completed Controlled Substance Profile Questionnaire.
4. In certain circumstances, a document request form may be sent to the customer requesting certain documents be provided to Miami-Luken
5. Electronic copy of 90-Day Dispensing Data for all prescriptions dispensed. The Data should include:
  - Prescription Number
  - Date Prescription was dispensed
  - Drug Name and Dose Form
  - Prescription Quantity
  - Prescriber Name
  - Prescriber Zip Code

*Note: The 90-Day Dispensing Data is not required for a start-up pharmacy.*

The compliance department will review the above documents to determine the following:

1. Total monthly order limits for all controlled substances, (CII-CV) and list 1 chemicals.
2. Any unusual dispensing history.
3. Any legal action or sanctions against the customer or their prescribers.
4. Discuss with the customer identified outliers within the information they provided to get additional information.
5. If Miami-Luken is going to do business with the prospective customer

Following the Subcommittee's May 8, 2018 hearing, Miami-Luken informed the Committee that it "no longer sells any controlled substances to retail customers."<sup>451</sup> Later, on October 8, 2018, the company told that Committee it had discontinued operations altogether, saying, "as a result of the ongoing DEA administrative proceeding and multiple lawsuits that

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<sup>451</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong. (2018)* (Responses to Questions for the Record submitted by Counsel to Miami-Luken, Inc.).



have been filed against the Company, the Company has been forced to shut its doors and go out of business.”<sup>452</sup>

## **2. Case Studies from the Committee’s Investigation**

Despite these processes and procedures, documents obtained during the Committee’s investigation showed, by and large, a cursory due diligence process.

The documents also showed little evidence that distributors considered, or requested additional explanation, when provided with information during the diligence process that should have raised a red flag. The Committee found instances where wholesale distributors established, or in some cases, reestablished business relationships with questionable pharmacies despite the presence of multiple red flags. Examples highlighted by the below case studies include that:

- AmerisourceBergen apparently failed to investigate why one of a prospective pharmacy’s top prescribing physicians was located an approximate 11-hour roundtrip drive away;
- McKesson decided to do business with a pharmacy it knew was named in a civil lawsuit related to opioid distribution yet failed to question the pharmacy’s owner about the lawsuit when it was considering the pharmacy’s application in 2015. But months later, after the pharmacy became the subject of negative national media coverage, McKesson cut off the pharmacy, citing the previously-acknowledged lawsuit as the primary reason for its decision; and
- H.D. Smith seemingly failed to fully consider the company’s prior engagement with a pharmacy when it agreed to onboard the pharmacy for a second time in 2015, despite the pharmacy’s recent termination by two other wholesale distributors.

Most striking, however, was the overall lack of due diligence documents on many pharmacies specifically requested by the Committee. The Committee was told by one distributor that the lack of documents today does not necessarily mean that there were no documents at the time. However, that distributor also could not explain why it did not retain, or why it was unable to locate, due diligence files for one of its former customers.

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<sup>452</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

a. *Case Study on McKesson: Creating and Maintaining Robust Due Diligence Files*

Distributors have a legal obligation to conduct robust due diligence on their prospective and current customers. Concomitant to this obligation is the need to create and maintain complete due diligence files on an ongoing basis. Doing so better informs prospective customer evaluations and assists distributors in conducting meaningful ongoing evaluations of their existing customers.

McKesson began its business relationship with Sav-Rite Pharmacy (hereinafter “Sav-Rite No. 1”) in February 2006, at the latest.<sup>453</sup> Sav-Rite No. 1 was located in Kermit, West Virginia, which had a population of 406 in the 2010 census.<sup>454</sup> According to data provided by McKesson, and as illustrated in the chart below, between February 2006 and November 2007, McKesson supplied Sav-Rite No. 1 with more than 5.66 million doses of hydrocodone and oxycodone.<sup>455</sup> The volume of drugs sent to the pharmacy during that two-year period alone made it McKesson’s third highest overall hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.<sup>456</sup>

<b>McKesson Distribution to Sav-Rite No. 1<sup>457</sup></b>	
<b>2006</b>	
<b>Drug</b>	<b>Dosage Units</b>
Hydrocodone	2,477,841
Oxycodone	78,500
<b>2007</b>	
Hydrocodone	3,068,805
Oxycodone	40,960
<b>Total</b>	<b>5,666,106</b>

**FINDING: McKesson supplied Sav-Rite No. 1 pharmacy with more than 5.66 million doses of hydrocodone and oxycodone in 2006 and 2007. Based on these two years alone, Sav-Rite No. 1 was McKesson’s third largest hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.**

Despite this volume, McKesson was only able to produce a single due diligence document to the Committee related to this pharmacy—a November 2007 written declaration from Sav-Rite No. 1’s owner—representing that the pharmacy fills only legitimate

<sup>453</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). In its letter to the Committee, McKesson stated that February 2006 was the most recent sales data that was available to the company and that McKesson assumed Sav-Rite No. 1 as a customer after McKesson acquired D&K Healthcare Resources, a regional wholesale distributor, in late 2005.

<sup>454</sup> American FactFinder, *Kermit (town), West Virginia* (<https://factfinder.census.gov>).

<sup>455</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).

<sup>456</sup> *Id.*

<sup>457</sup> *Id.*


prescriptions.<sup>458</sup> The November 2007 written declaration from Sav-Rite No. 1's owner is reproduced in its entirety below:

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<sup>458</sup> James P. Wooley, Declaration of Controlled Substances, Nov. 1, 2007 (On file with Committee). McKesson also produced to the Committee a May 2007 e-mail that mentions Sav-Rite No. 1 as well as Family Discount Pharmacy. *See* E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 4:14 pm) (On file with Committee). This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Sav-Rite No. 1. *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018. Rather, McKesson's production of the May 2007 e-mail was in response to a supplemental question posed by the Committee on July 31, 2018 regarding a representation McKesson made to the Committee on June 11, 2018. *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).



**DECLARATION OF  
CONTROLLED SUBSTANCES PURCHASES**

1. <sup>Strosrieder-Drug</sup> ~~by Saw-Rite Pharmacy~~ [pharmacy name] (hereinafter "Pharmacy") located at  
US HWY 57 Kermit, WV [address, city and state] is registered  
with the Drug Enforcement Administration (DEA),  [DEA  
registration #].

2. Pharmacy declares and attests that it fully complies with all federal and state laws and regulations on the dispensing of controlled substances including but not limited to dispensing to patients only pursuant to a legitimate prescription issued in the course of an established doctor-patient relationship (e.g., pursuant to a physical examination) and only for a legitimate medical purpose.

3. Pharmacy will not knowingly dispense controlled substances for prescriptions that have been received via the internet, mail-order, or other non-walk-in customer where it has reason to believe that the prescription was issued without a legitimate medical purpose.

4. Pharmacy states that its requirements for purchases of Lifestyle Drugs (e.g., hydrocodone, phentermine, alprazolam, oxycodone) from McKesson are necessary for the following reasons: [please describe the reason for purchasing these drugs in the quantities requested including information about the prescriber and the general purposes for which the drugs are being prescribed.]

Saw-Rite Pharmacy fills only controlled drugs from legitimate physicians (Licensed) for only patients that the pharmacy has a patient-Pharmacy relationship - We do not do computer-internet prescription filling -

Jim Woolly, Manager  
Saw-Rite Pharmacy

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. Pharmacy certifies that it has made sufficient inquiry to be able to make this declaration truthfully, accurately and without material omissions. Pharmacy affirms by signing this declaration that the above is true and correct to the best of its knowledge and belief.



James P. Woolley  
Printed Name of Signer

Pharmacist - owner

11-1-07

**FINDING: McKesson's due diligence file for Sav-Rite No. 1 contained only one document, a November 2007 written declaration from the pharmacy's owner representing that the pharmacy sells only legitimate prescriptions.**

At the Subcommittee's May 8, 2018 hearing, McKesson President, CEO, and Board Chairman, John Hambergren was unable to say whether McKesson had any due diligence documentation beyond this written declaration with respect to the company's engagement with Sav-Rite No. 1:

Q. Now, in your written testimony, Mr. Hambergren, you put a lot of thought into using population statistics and other arguments to justify your shipments to Sav-Rite and other pharmacies. We just heard Mr. Barrett talking about that, too. But when the committee asked you to provide McKesson's due diligence file for Sav-Rite,

you gave us a single document from 2007. Do you recognize this document, sir?

A. No, I don't.

Q. Okay. It's exhibit 3 in the binder. Do you recognize that document now? You don't.

A. This is the first time I've seen this document.

Q. Okay. Well, I will tell you for the record that this document, which says declaration of controlled substances purchases, which is a two-page document, is the only documentation that McKesson gave to this committee when we asked for the due diligence file for Sav-Rite. Do you think this fulfills the requirements of the DEA that your company do due diligence for distribution of opioids to this city?

A. I believe our relationship with Sav-Rite should have been terminated immediately.

Q. Yes or no, do you think this is sufficient documentation to show compliance with the rules of the DEA?

A. We continue to evolve our diligence - -

Q. Yes or no will work, sir.

A. I've not reviewed the document. I can't provide an answer to that.<sup>459</sup>

McKesson told the Committee that it assumed Sav-Rite No. 1 as a customer following McKesson's acquisition of D&K Healthcare Resources in late 2005.<sup>460</sup> The Committee asked McKesson whether it performed new customer due diligence for the pharmacies that it assumed through this acquisition, including Sav-Rite No. 1.<sup>461</sup> In response, McKesson told the

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<sup>459</sup> See *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 58 – 59(2018) (testimony of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>460</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>461</sup> Briefing, Staff, McKesson Corp., to Staff, H. Comm. on Energy and Commerce, May 4, 2018 and E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

Committee, “[o]ur present understanding is that at the time of the acquisition specific customer evaluations were not performed.”<sup>462</sup>

When McKesson acquired Sav-Rite No. 1 as a customer and for nearly two years thereafter, the lack of documents produced to the Committee suggest it failed to conduct and document necessary new or existing customer due diligence on the pharmacy. Had McKesson done so, the company presumably would have been made aware of potential red flags associated with the pharmacy, allowing the company to terminate the pharmacy in a timelier manner, possibly preventing millions of doses of opioids from being sent to a pharmacy that was engaged in diversion.

***b. Case Study on McKesson: Reengaging with a Customer After Termination***

The need to maintain complete, robust due diligence files is also demonstrated in situations where a distributor may receive a new customer application from a pharmacy that it had a business relationship with previously, or from a pharmacy that a distributor considered in the past but ultimately denied the pharmacy’s application. Maintaining and consulting such due diligence files allows distributors to be more attuned to any possible red flags associated with a pharmacy as well as any potential discrepancies that may exist on the pending new customer application. However, it appears that McKesson did not always follow those practices.

***i. McKesson’s Initial Engagement with Family Discount Pharmacy***

Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, was McKesson’s biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017.<sup>463</sup> McKesson supplied Family Discount Pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014.<sup>464</sup> Between 2006 and 2007 alone, McKesson provided Family Discount Pharmacy with more than 3.82 million doses of hydrocodone.<sup>465</sup> As will be described below, McKesson terminated this pharmacy prior to 2008 for “compliance reasons” but elected to onboard the customer again two times thereafter.

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<sup>462</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>463</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).

<sup>464</sup> *Id.*

<sup>465</sup> *Id.*

<b>McKesson Distribution to Family Discount Pharmacy<sup>466</sup></b>	
<b>2006</b>	
<b>Drug</b>	<b>Dosage Units</b>
Hydrocodone	1,846,850
Oxycodone	96,680
<b>2007</b>	
Hydrocodone	1,753,732
Oxycodone	126,070
<b>2008</b>	
Hydrocodone	0
Oxycodone	0
<b>2009</b>	
Hydrocodone	0
Oxycodone	0
<b>2010</b>	
Hydrocodone	81,900
Oxycodone	8,690
<b>2011</b>	
Hydrocodone	0
Oxycodone	0
<b>2012</b>	
Hydrocodone	382,260
Oxycodone	57,320
<b>2013</b>	
Hydrocodone	987,831
Oxycodone	297,930
<b>2014</b>	
Hydrocodone	175,758
Oxycodone	104,600
<b>Total</b>	<b>5,919,621</b>

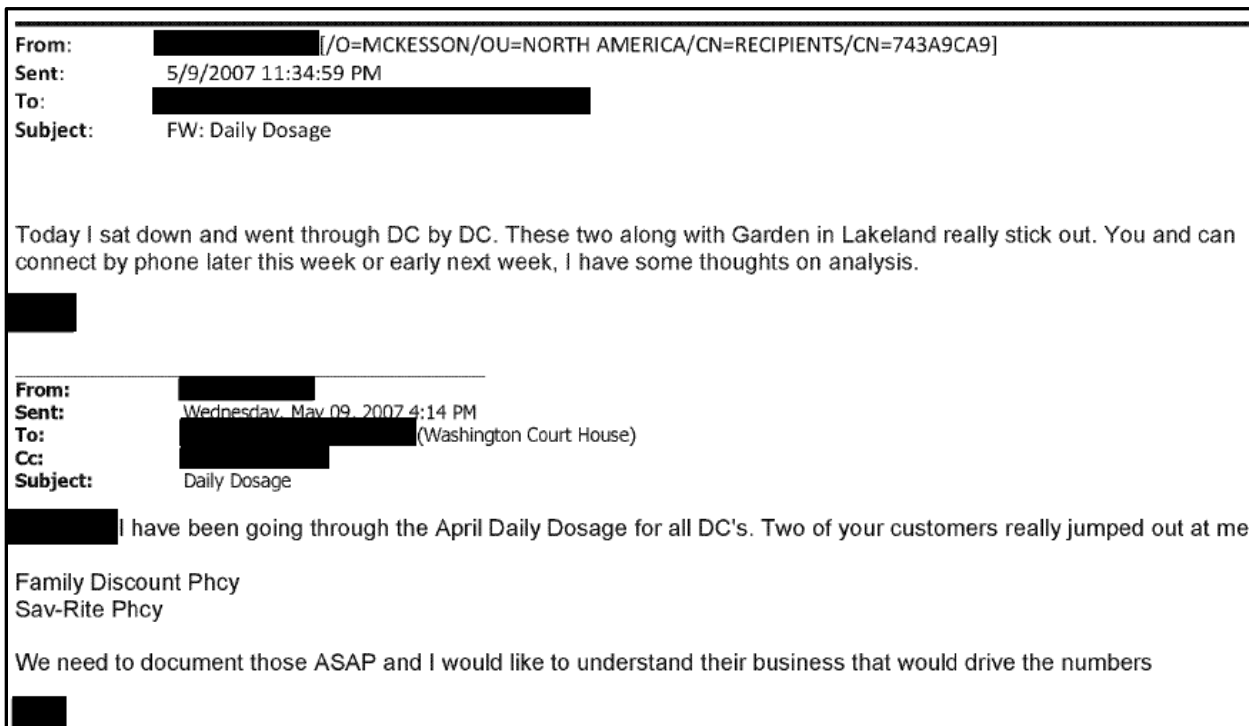
**FINDING:** Family Discount Pharmacy in Mount Gay-Shamrock was McKesson’s biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017. McKesson supplied the pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014, including more than 3.82 million doses in between 2006 and 2007 alone.

Among other information related to McKesson’s relationship with Family Discount Pharmacy, the Committee requested that McKesson provide “all documents related to

<sup>466</sup> *Id.*



McKesson's due diligence files for Family Discount Pharmacy of Mount Gay-Shamrock."<sup>467</sup> Aside from a single e-mail sent in May 2007, and produced in response to a supplemental question the Committee posed regarding Sav-Rite No. 1,<sup>468</sup> the earliest document McKesson produced to the Committee for Family Discount Pharmacy of Mount Gay-Shamrock was from January 2010. Notably, apart from the May 2007 e-mail, which is reproduced below, McKesson did not produce any due diligence documents from 2006 or 2007, in which it supplied this pharmacy with more than 3.82 million doses of hydrocodone, or earlier than 2006.



This e-mail is the only document the Committee received from McKesson that may relate to its apparent termination of the pharmacy, which, based on the data, appears to have occurred in 2007.<sup>469</sup> As seen in the chart above, McKesson did not supply any opioids to Family Discount Pharmacy in Mount Gay-Shamrock in 2008 and 2009. When asked about the cessation of distribution in these years, McKesson told the Committee that it “believes” it terminated the customer “for compliance reasons.” Specifically, McKesson told the Committee:

<sup>467</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018 *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>.

<sup>468</sup> See E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 11:34 pm) (On file with Committee); See also E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee). This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Family Discount Pharmacy.

<sup>469</sup> McKesson did not produce any documents to the Committee that included the date that Family Discount Pharmacy in Mount Gay-Shamrock was terminated as a customer. The Committee infers from the data that this occurred in 2007, given that no distribution occurred in 2008. The Committee cannot determine from the data and documents the date on which this customer was terminated in 2007.

McKesson did not sell the Family Discount Pharmacy in Mount Gay any oxycodone or hydrocodone products in 2008, 2009 and 2011 and, compared to other years, a significantly smaller quantity of those products in 2010. McKesson has conducted a diligent search of its records and has not located a due diligence file for 2008 and 2009. In an e-mail to DEA on February 6, 2009, McKesson provided the agency with a list of pharmacies that had been terminated for compliance reasons. McKesson included Family Discount Pharmacy in Mount Gay on this list. Based on this e-mail, McKesson believes that the lack of sales in 2008 and 2009 can be attributed to a decision to terminate Family Discount Pharmacy in Mount Gay as a customer.<sup>470</sup>

The February 2009 e-mail to the DEA was not produced to the Committee as part of the due diligence file for Family Discount Pharmacy, indicating that it was not included with McKesson's due diligence materials for this pharmacy. In fact, aside from that e-mail, the due diligence file did not contain a single document related to the apparent termination of this customer.

**FINDING: McKesson did not retain sufficient due diligence files documenting its relationship with Family Discount Pharmacy in Mount Gay-Shamrock during 2006 and 2007, including documentation regarding the company's apparent decision to terminate the pharmacy as a customer for "compliance reasons."**

*ii. McKesson's Second Engagement with Family Discount Pharmacy*

Notwithstanding the decision to terminate the pharmacy "for compliance reasons," McKesson reinstated Family Discount Pharmacy as a customer in 2010 and supplied the pharmacy with controlled substances.<sup>471</sup> The due diligence materials produced to the Committee to support this decision included a six-page new customer questionnaire and dispensing information for the pharmacy. In the questionnaire component of McKesson's new customer due diligence in January 2010, Family Discount Pharmacy represented that its ability to purchase controlled substances had never been terminated or restricted by a distributor in the past.<sup>472</sup> The portion of the 2010 questionnaire where Family Discount Pharmacy made this representation is reproduced below:

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<sup>470</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>471</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).

<sup>472</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).

vii. Has any previous wholesaler ceased shipping or restricted purchases of controlled substances?

Yes  No

That representation, however, seems directly contradicted by McKesson's claim that it terminated Family Discount as a customer "for compliance reasons," likely in 2007. The documents produced to the Committee give no indication to suggest that McKesson made any further inquiry to resolve this discrepancy or otherwise considered its prior termination "for compliance reasons" when reinstating Family Discount as a customer in 2010.

The Committee asked McKesson whether it addressed this contradiction when it was considering Family Discount's application in 2010.<sup>473</sup> In response, McKesson told the Committee "[b]ased on the available due diligence files, McKesson conducted an onboarding review of the customer, which included having the customer submit a questionnaire. At this time, McKesson has not located additional information to explain this issue[.]"<sup>474</sup>

In its response to the Committee's question, McKesson did provide an e-mail chain among McKesson personnel during the time it was considering Family Discount's application in 2010, which, according to McKesson, "provides some additional context."<sup>475</sup> The e-mail chain produced by McKesson makes no mention of the company's previous engagement with Family Discount and its decision to terminate the pharmacy "for compliance reasons." In one e-mail, for example, a member of McKesson's regulatory affairs division stated, "I cannot see any reason we should be hesitant even with the large numbers he is talking about."<sup>476</sup> This e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Wednesday, January 27, 2010 2:47 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]; [REDACTED]  
**Subject:** RE: Family Pharmacy

Guys

I have done some internet research and find no mention of the pharmacy or the pharmacist except good stories of community assistance, etc. I cannot see any reason we should be hesitant even with the large numbers he is talking about. (155k hydro and 110k alpraz, etc)

You are welcome, [REDACTED] Thank you all too.

[REDACTED] DRA North Central

<sup>473</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

<sup>474</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>475</sup> *Id.*

<sup>476</sup> E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 2:47 pm) (On file with Committee).

**FINDING: McKesson did not consider its prior relationship with Family Discount Pharmacy when evaluating the pharmacy’s new customer application in 2010, with a member of McKesson’s regulatory affairs division at one point stating, “I cannot see any reason we should be hesitant” with respect to the pharmacy.**

The e-mails provided by McKesson suggest that the company viewed itself as being in competition with other distributors to obtain Family Discount’s account. For example, in an e-mail to a McKesson Vice President and General Manager referencing a pricing proposal for Family Discount Pharmacy, a member of McKesson’s sales division noted the pharmacy had a “very aggressive buy plan with Cardinal. I would approve this based on where we have to be to have an opportunity.”<sup>477</sup> The e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Monday, February 01, 2010 11:37 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** FW: Family Pharmacy - EPIC

[REDACTED]

Please see attached. He currently has a very aggressive buy plan with Cardinal. I would approve this based on where we have to be to have an opportunity.

Thanks  
[REDACTED]

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**From:** [REDACTED]  
**Sent:** Monday, February 01, 2010 12:14 PM

**To:** [REDACTED]  
**Subject:** FW: Family Pharmacy - EPIC

[REDACTED]

I would like to request approval to offer the pricing in the attachment to Family Discount – Mt Gay. The offering is for cost -3.40% on 700K per month, EPIC with a 2.90% ebit. Please advice.  
Thanks,  
[REDACTED]  
McKesson WCH

In another e-mail, a member of McKesson’s sales division said that he was sure either H.D. Smith or Cardinal Health would offer to be Family Discount’s secondary distributor if McKesson were to “win” Family Discount’s business.<sup>478</sup>

In the January 2010 questionnaire, and referenced above, Family Discount Pharmacy estimated that it dispensed an average of 155,000 doses of hydrocodone a month, which equals 1.86 million doses a year. The pharmacy also estimated that it dispensed an average of 110,000

<sup>477</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Feb. 1, 2010 11:37 am) (On file with Committee).

<sup>478</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 4:39 pm) (On file with Committee).

doses of alprazolam a month, which equals 1.32 million doses a year.<sup>479</sup> For reference, according to U.S. Census data, Mount Gay-Shamrock, West Virginia had a population of 1,779 in 2010.<sup>480</sup> On its new customer questionnaire, McKesson required pharmacies provide six months of dispensing data if estimated dispensing data exceeded 5,000 doses a month for certain controlled substances, including hydrocodone and alprazolam.<sup>481</sup> The due diligence documents provided to the Committee do not give any indication that McKesson analyzed the dispensing data that Family Discount Pharmacy provided.

According to documents produced to the Committee, McKesson onboarded Family Discount and set the pharmacy's hydrocodone ordering threshold at 155,000 dosage units a month—a level 31 times more than what McKesson determined warranted supplementary documentation on its new customer questionnaire.<sup>482</sup>

One day after Family Discount submitted its new customer questionnaire, a McKesson sales representative sent an e-mail to McKesson staff, saying, “[j]ust talked to [redacted] he said that those thresholds sound good.”<sup>483</sup> The e-mail from the McKesson sales representative is reproduced below:

**From:** [redacted]  
**Sent:** Wednesday, January 27, 2010 4:39 PM  
**To:** [redacted]  
**Cc:** [redacted]  
**Subject:** RE: Family Pharmacy

Thanks [redacted] I appreciate the time you took on this prospect. Just talked to [redacted] he said that those thresholds sound good.

**FINDING:** In 2010, McKesson set the hydrocodone threshold for Family Discount Pharmacy, a pharmacy previously terminated by McKesson for compliance reasons, at a level that was 31 times higher than what the company determined warranted supplementary explanation on its new customer questionnaire.

In 2010, McKesson's relationship with Family Discount Pharmacy only lasted a little over three weeks. McKesson told the Committee:

McKesson records indicate that Family Discount Pharmacy (Mount Gay-Shamrock)'s first controlled substances order in 2010 was on March 2, and its last controlled substances order in 2010 was on March 26. Currently

<sup>479</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).

<sup>480</sup> American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (<https://factfinder.census.gov>).

<sup>481</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).

<sup>482</sup> McKesson Corp., Hydrocodone thresholds – Family Discount Pharmacy, Mount Gay-Shamrock, (On file with Committee).

<sup>483</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 4:39 pm) (On file with Committee).

available records do not make clear why McKesson discontinued supplying controlled substances to the pharmacy in 2010.<sup>484</sup>

In the brief time it supplied the pharmacy with controlled substances in March 2010, McKesson supplied Family Discount Pharmacy with more than 90,000 doses of hydrocodone and oxycodone.<sup>485</sup> As indicated, however, McKesson did not provide the Committee with any documents that would indicate why its relationship with the pharmacy was discontinued after March 26, 2010.

*iii. McKesson's Third Engagement with Family Discount Pharmacy*

McKesson resumed a business relationship with Family Discount Pharmacy in Mount Gay-Shamrock in September 2012, when McKesson agreed to onboard the pharmacy as a customer for a third time.<sup>486</sup> The 2012 due diligence file on Family Discount Pharmacy that was produced to the Committee included a seven-page new customer questionnaire, a six-month dispensing report, photos of the pharmacy, and e-mails to pharmaceutical manufacturers seeking additional information on the pharmacy. The due diligence file also included internal McKesson e-mails which indicate that McKesson evaluated the pharmacy's prescribing physicians and performed a site visit to the pharmacy, though the due diligence file did not include McKesson's analysis of the prescribing physicians or a report of the site visit. McKesson also contacted the West Virginia Board of Pharmacy, which reported that the pharmacy was "a reliable high volume account" and noted that the pharmacy "may have had an issue a long time ago, but according to the West Virginia Board of Pharmacy that issue had been resolved and was a reliable pharmacy."<sup>487</sup>

In the questionnaire component of McKesson's new customer due diligence process, and as indicated below, the pharmacy disclosed that its ability to purchase controlled substances had been restricted or terminated in the past, citing a "new Cardinal policy cap on Hydrocodone."<sup>488</sup>

<p>viii. Has any previous wholesaler ceased shipping or restricted purchases of controlled substances?</p> <p><input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p><i>New Cardinal policy cap on Hydrocodone</i></p>
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The pharmacy did not disclose, however, that McKesson had also previously terminated its ability to purchase controlled substances, as discussed earlier. Nor does McKesson appear to

<sup>484</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>485</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).

<sup>486</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).

<sup>487</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>488</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).

have examined its own two prior engagements with the pharmacy. In the documents that were produced to the Committee, the only mention of the pharmacy's history with McKesson appears to be in an e-mail from a member of McKesson's sales staff, sent days after receiving the pharmacy's 2012 application, noting "[t]his account had been previous [sic] approved to purchase CSMP items from us, but has since switched to Cardinal. We have a chance to get them back pending your approvals."<sup>489</sup> This e-mail is reproduced below:

**From:** [REDACTED] /O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=TK7JBSW]  
**Sent:** 8/28/2012 7:20:59 PM  
**To:** [REDACTED]  
**CC:** [REDACTED]  
**Subject:** prospective customer CSMP Questionnaire Family Discount Pharmacy

Please see attached CSMP Questionnaire 6 month usage report and facility photos for a prospect (Family Discount Pharmacy) [REDACTED] and I have been working on. This account had been previous approved to purchase CSMP items from us, but has since switched to Cardinal. We have a chance to get them back pending your approvals.

In addition to the attached 6 month usage report I have an additional report that shows usage by prescription and physician who wrote prescription. This report is rather large and will have to be Fed Ex to [REDACTED].. [REDACTED] you should receive tomorrow or no later than Thursday. Once you receive and review please call to discuss.

Thanks,  
[REDACTED]

Moreover, based upon the documents reviewed by the Committee, McKesson does not appear to have asked the pharmacy for any additional information regarding why Cardinal restricted purchases of controlled substances. Rather, e-mails produced to the Committee suggest that McKesson was concerned that other distributors, and potentially Cardinal, would acquire Family Discount's business if McKesson did not act fast enough. For example, in an e-mail to a member of McKesson's regulatory affairs division, a McKesson distribution center manager stated, "[t]he customer is ready to make the change, and if we put [a site visit] off that will give our competitors time to come back in and try to keep it."<sup>490</sup> The e-mail also noted that McKesson was evaluating some of the physicians that had been provided by the pharmacy. This e-mail is reproduced below:

<sup>489</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Aug. 28, 2012 7:20 pm) (On file with Committee).

<sup>490</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Sept. 5, 2012 8:52 pm) (On file with Committee).

**From:** [REDACTED]  
**Sent:** Wednesday, September 05, 2012 8:52 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Family Discount

[REDACTED]  
I spoke with [REDACTED] and [REDACTED] about this account and they want to know if there is any way at all you can visit this account this week. The customer is ready to make the change, and if we put it off that will give our competitors time to come back in and try to keep it. Can you make the visit? I will have [REDACTED] check on some of the doctors they gave us. If there is anything else that you want me to do let me know and [REDACTED] or I will work on it, but they really want to get moving on this one way or the other.

Thanks  
[REDACTED]

In a separate e-mail a member of McKesson's sales division characterized the pharmacy as a "real opportunity" and requested that the scheduling of the site visit be expedited.<sup>491</sup> This e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Tuesday, September 04, 2012 10:18 PM  
**To:** [REDACTED]; [REDACTED]; [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Prospect Family Discount Pharmacy

Real opportunity here. Please expedite and thanks

In the 2012 new customer questionnaire, Family Discount Pharmacy estimated that it dispensed 112,000 dosage units of hydrocodone per month, on average, which equals more than 1.34 million doses per year.<sup>492</sup> On its questionnaire, McKesson required pharmacies to provide six months of dispensing data if they estimated dispensing more than 5,000 dosage units a month of certain controlled substances, including hydrocodone. In addition to providing the dispensing data, and to justify its dispensing levels, which were more than 22 times the amount necessary to trigger a supplemental examination, the pharmacy explained, "[w]e do a large volume of business [and] we live [in] a coal mining area where a lot of disabled patients reside."<sup>493</sup> The

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<sup>491</sup> E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Sept. 4, 2012 10:18 pm) (On file with Committee).

<sup>492</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).

<sup>493</sup> *Id.*



portion of the 2012 new customer questionnaire where Family Discount provided its estimated dispensing data and supplemental explanation is reproduced below:



**V. Controlled Substance Purchases**

a. Estimate dose units (tablets/capsules) dispensed per month for each of the following Controlled Substances. Total of all brand and generic for the base items, including combination products. (Initial visit entries here. Please use table at end of document for subsequent visits.)

✓ Hydrocodone	<u>112,000</u>	See attached reports
✓ Phentermine	<u>6,000</u>	
✓ Oxycodone	<u>18,000</u>	
Methadone	<u>      </u>	
✓ Alprazolam	<u>57,000</u>	✓ Suboxone <u>8,000</u>

b. If any of the above is greater than 5000 dose units please provide information (6 month dispensing information (less than 6 months if approved by DRA), frequent referrals from pain clinics, etc.) to support purchase levels. *We do a large volume of business & we*  
**Explanation:** live in a coal mining area where a lot of disabled

c. Has the pharmacy established policies and procedures to verify controlled substances prescriptions? If so, how? **Explanation:** \_\_\_\_\_  
*Check out new customers on our controlled website also check out doctors we are not familiar with*

Documents produced to the Committee indicate McKesson onboarded Family Discount after less than one month of review in September 2012 and set the pharmacy’s hydrocodone ordering threshold at 112,000 dosage units a month.<sup>494</sup> McKesson told the Committee:

In October 2012, Family Discount Pharmacy (Mount Gay-Shamrock)’s first full month of ordering through McKesson, it ranked first among McKesson’s retail customers for controlled substance ordering in West Virginia and among customers with Washington Courthouse as their home distribution center, and nineteenth nationally. The pharmacy was a large account overall. It ranked third for *non-controlled* substance ordering among McKesson’s West Virginia retail customers in October 2012, and first in controlled and non-controlled ordering combined among McKesson’s West Virginia retail customers that month<sup>495</sup>

<sup>494</sup> McKesson Corp., Hydrocodone thresholds – Family Discount Pharmacy, Mount Gay-Shamrock, (On file with Committee).

<sup>495</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (Emphasis in original) (On file with Committee).

In April 2014, McKesson prohibited the pharmacy from ordering controlled substances after the company “determined that Family Discount Pharmacy was also filling prescriptions from physicians who had been identified by another McKesson customer as potentially having questionable prescribing patterns.”<sup>496</sup>

As noted above, during McKesson’s three engagements with Family Discount Pharmacy, it supplied more than 5.91 million doses of hydrocodone and oxycodone, making the pharmacy McKesson’s biggest customer in West Virginia between 2006 and 2017. Had McKesson maintained robust due diligence files for Family Discount Pharmacy and consulted these files when it was considering the pharmacy’s applications in 2010 and 2012, it would have been aware that it terminated the pharmacy for compliance reasons on at least one prior occasion. In addition, conducting a retrospective review of the due diligence files would have also alerted McKesson to the pharmacy’s failure to disclose its previous termination by McKesson on its 2010 and 2012 new customer applications, with the pharmacy seemingly providing the company with a misrepresentation on its 2010 application in particular. Such information may have prompted McKesson to deny Family Discount’s applications on multiple occasions. Instead, McKesson accepted Family Discount as a customer a total of at least three times, only to ultimately restrict its ability to purchase controlled substances again in 2014.

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<sup>496</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). *See also* McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

c. *Case Study on McKesson: Following up on Red Flags Identified During the Due Diligence Process*

During the prospective customer due diligence process, distributors may come across potential red flags of diversion that warrant additional analysis or explanation. This information may be disclosed to distributors in a prospective customer questionnaire, through the production of a pharmacy's dispensing data, or through a distributor's independent efforts such as performing internet searches of the pharmacy and its prescribing physicians. When a distributor does identify potential red flags, it should seek further explanation from the pharmacy in addition to performing its own analysis, documenting both.

As has been documented by the Committee's investigation, Tug Valley Pharmacy and Hurley Drug Company, both located in Williamson, West Virginia, a town with a population of roughly 3,000 people, received more than 20.8 million dosages of hydrocodone and oxycodone over an eleven-year period.<sup>497</sup> McKesson was one of multiple distributors that supplied the town of Williamson. At the time it began supplying Williamson with opioids, the endemic nature of the town's and its surrounding area's prescription drug abuse problem had been publicly reported, along with the town's moniker of "Pilliamson."<sup>498</sup> According to McKesson's policies, if "[t]he pharmacy [is] located in a geographic area known or suspected of having higher than normal prescription drug diversion or level of prescribing[,]" that is a "Non-Statistical Red Flag" and a potential cause for concern.<sup>499</sup>

i. *McKesson's Initial Engagement with Tug Valley Pharmacy*

On May 12, 2015, Tug Valley Pharmacy submitted a new customer questionnaire to McKesson.<sup>500</sup> In this questionnaire, Tug Valley represented that another wholesale distributor had previously taken action to discontinue or restrict its ability to purchase controlled substances, noting "Miami Luken ceased all sales non-controlled and controls recently."<sup>501</sup> McKesson policies, with respect to the pharmacy customer questionnaire, include the example of "red flag" for diversion as a scenario wherein "[a] previous wholesaler or manufacturer ceased selling controlled substances to the pharmacy within past five years[,]."<sup>502</sup> The relevant portions of the questionnaire are reproduced below:

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<sup>497</sup> See Gabe Gutierrez, et. al, *Welcome to Williamson, W.Va., where there are 6,500 opioid pills per person*, NBC NEWS, Feb. 1, 2018, <https://www.nbcnews.com/news/us-news/welcome-williamson-w-va-where-there-are-6-500-opioid-n843821>. Documents indicate that McKesson supplied both Williamson pharmacies with opioids, beginning with Hurley Drug Company in 2014 and then Tug Valley Pharmacy the following year, 2015. See U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>498</sup> See Alison Knezevich, *Prescription drug abuse plagues small W. Va. town*, CHARLESTON GAZETTE, Jan. 22, 2011 (On file with Committee); see also Evelyn Nieves, *Prescription pill epidemic has spiraled out of control*, SALON, Apr. 8, 2013, [https://www.salon.com/2013/04/08/prescription\\_pill\\_epidemic\\_has\\_spiraled\\_out\\_of\\_control\\_partner/](https://www.salon.com/2013/04/08/prescription_pill_epidemic_has_spiraled_out_of_control_partner/); Fox News, *Fatally shot West Virginia county sheriff Eugene Crum took aim at drug dealers*, FOX NEWS, Apr. 4, 2013, <https://www.foxnews.com/us/fatally-shot-west-virginia-county-sheriff-eugene-crum-took-aim-at-drug-dealers>.

<sup>499</sup> McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).

<sup>500</sup> McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, May 12, 2015 (On file with Committee).

<sup>501</sup> *Id.*

<sup>502</sup> McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).

ix. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to this pharmacy in the past 5 years?

Yes  No

Explanation: *Miami Luken - ceased*

*All sales non-controlled and controls recently.*

x. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to a pharmacy that was owned or is owned by current owner/s during the past ten years?

Yes  No

Explanation:

*Miami Luken ceased All med sales - control + non controlled*

Upon receiving the questionnaire, and as documented by the due diligence files produced to the Committee, McKesson conducted supplemental due diligence, including verifying the pharmacy's and staff's state and DEA registrations as well as checking for any past disciplinary actions.<sup>503</sup> McKesson also reviewed the pharmacy's dispensing data for the previous three months.<sup>504</sup>

Less than a week after receiving Tug Valley's new customer application, a McKesson Regulatory Affairs Manager authored a due diligence report referencing Tug Valley's disclosure that Miami-Luken recently discontinued selling the pharmacy controlled and non-controlled substances, as well as pending litigation involving the pharmacy.<sup>505</sup> The report stated:

Derogatory information on Tug Valley Pharmacy, LLC and pharmacist/owner [redacted] was found during a search of Internet

<sup>503</sup> McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).

<sup>504</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee). *See also* McKesson Corp., Tug Valley Pharmacy – Dispensing Data (Feb. 13, 2015 – May 13, 2015) (On file with Committee).

<sup>505</sup> McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).

websites. Tug Valley Pharmacy, LLC and [redacted] are mentioned in a civil action (no. 10-c-251) and a circuit court order (no. 14-0144).<sup>506</sup>

The litigation referenced in the due diligence report involved a number of civil actions alleging that a number of West Virginia pharmacies and doctors, including Tug Valley, negligently and/or recklessly provided the plaintiffs prescriptions for controlled substances.<sup>507</sup> The diligence report also provided hyperlinks to court documents associated with the litigation, which were also included in the due diligence documents that were produced to the Committee. Thus, McKesson managers had knowledge of a lawsuit involving allegations related to Tug Valley's dispensing of controlled substances only days after receiving the pharmacy's new customer application.

The court documents linked in this report provide more context regarding the pharmacy's potential red flags and its alleged role in diversion of controlled substances. For example, a June 2014 brief included testimony, taken during a deposition, from an individual who had prescriptions filled at Tug Valley, and is reproduced below:<sup>508</sup>

This description of the environment at Tug Valley was provided by Respondent [REDACTED]

[REDACTED]

“ So, I would go in and I would wait for so long. And there were so many people. So many people. I mean, there was such a line. And there were people coming in from everywhere. I mean, I noticed and I heard there were people coming from like Ohio. There were people coming in from like way over in West Virginia. I can't remember the name of it. And there were people slumped over. I mean, totally out of their mind. I know when I seen them, somebody like that, I know...And they were just like selling drugs outside of the place...I kept hearing people, you know, stating where they can get this and that and how much for, [REDACTED], J.A. 1374.

According to the same filing, the owner of Tug Valley Pharmacy testified in a deposition that the pharmacy filled between 150 to 200 prescriptions per day from the Mountain Medical Center,<sup>509</sup> a facility shut down following a federal raid in 2010.<sup>510</sup>

<sup>506</sup> *Id.*

<sup>507</sup> See *Shaun Collins, et al. v. Tug Valley, LLC, et al.* No. 10-C-251 (Mingo County, W.Va. Circuit Court) (Feb. 18, 2014) available at <http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144order.pdf>.

<sup>508</sup> *Tug Valley Pharmacy et al. v. All Plaintiffs Below* No. 14-0144 at 12 (W. Va. June 2014) (Respondents' Brief) available at <http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf>.

<sup>509</sup> *Tug Valley Pharmacy et al. v. All Plaintiffs Below* No. 14-0144 at 12 (W. Va. June 2014) (Respondents' Brief) available at <http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf>.

<sup>510</sup> Lawrence Messina, *W.Va. doctor defends raided pain clinic*, CHARLESTON GAZETTE-MAIL, Apr. 14, 2010, [https://www.wvgazette.com/news/w-va-doctor-defends-raided-pain-clinic/article\\_e9099268-dbff-5164-bf89-b562b0ceea39.html](https://www.wvgazette.com/news/w-va-doctor-defends-raided-pain-clinic/article_e9099268-dbff-5164-bf89-b562b0ceea39.html).

On July 23, 2015, McKesson’s Director of Regulatory Affairs approved Tug Valley as a customer. The Regulatory Investigative Report accompanying the decision referenced Miami-Luken’s decision to cease all medication sales to Tug Valley, noting “[i]t was later learned that Tug Valley Pharmacy had experienced credit issues thus the reasoning behind the termination by the wholesaler.”<sup>511</sup> The report also stated that the pharmacy was named as a defendant in a civil lawsuit in West Virginia state court, and noted that the lawsuit “allows patients who have become addicted to opiate medications to sue their prescribing physician and/or dispensing pharmacy for monetary damages[,]” making reference to the hyperlinks provided in the May 18, 2015 due diligence report.<sup>512</sup>

The Committee asked McKesson whether it obtained more information on, or asked the pharmacy’s owner about, the litigation prior to approving Tug Valley as a customer.<sup>513</sup> In response, McKesson told the Committee:

To the best of McKesson’s current understanding, McKesson did not have a discussion with the owner regarding the pending litigation against the pharmacy. During the onboarding review, McKesson considered the litigation. McKesson found that the litigation had been ongoing for several years; that the pharmacy and its owner/pharmacist continued to have active licenses from the State of West Virginia; that there were no known disciplinary actions related to the litigation or other relevant matters; and that the pharmacy had an active DEA registration.<sup>514</sup>

On January 7, 2016, a *CBS News* report focused on the role wholesale distributors may have played in exacerbating the opioid epidemic in West Virginia prominently featured Tug Valley.<sup>515</sup> The next day, January 8, 2016, McKesson suspended Tug Valley’s ability to purchase controlled substances.<sup>516</sup>

A Regulatory Investigative Report dated January 8, 2016 and supporting the suspension cited the litigation pending against Tug Valley Pharmacy—and featured in the *CBS News* report—as the impetus for McKesson’s decision to suspend the pharmacy.<sup>517</sup> The Regulatory Investigative Report is reproduced in its entirety below:

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<sup>511</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee).

<sup>512</sup> *Id.*

<sup>513</sup> E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

<sup>514</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>515</sup> Jim Axelrod and Ashley Velie, *Drug distributors under fire in West Virginia painkiller epidemic*, CBS NEWS, Jan. 7, 2016, <https://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/>.

<sup>516</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, Jan. 8, 2016 (On file with Committee).

<sup>517</sup> *Id.*

McKesson's Controlled Substance Monitoring Program  
Regulatory Investigative Report

**Date of Final Report: January 8, 2016**

**By:** [REDACTED]

**Report RE: Suspension of Controlled Substances**

**Customer's Name: Tug Valley Pharmacy**

**Customer's DEA Number:** [REDACTED]

**DETAILS**

Tug Valley Pharmacy is an existing McKesson customer located at 54 West 2nd Avenue, Williamson, WV 25661. In light of a recent news article concerning Tug Valley Pharmacy and McKesson's re-evaluation of this customer, a decision to suspend Tug Valley's Pharmacy's ability to order controlled substances was rendered.

On January 8, 2016, Sr. DRA [REDACTED] notified DRA [REDACTED] of an Internet article he had seen referencing Tug Valley Pharmacy, a McKesson customer. This article, <http://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/> dated January 7, 2016, from CBS News noted that Tug Valley Pharmacy was being sued for negligently filling prescriptions. Records indicated that Tug Valley Pharmacy filled more than 150 prescriptions daily from one clinic alone.

This case is based on a recent decision naming Tug Valley Pharmacy as a defendant, Tug Valley Pharmacy et al v All Plaintiffs (2015 W.Va.). In this case, the State of West Virginia Supreme Court ruled that opiate dependent patients in West Virginia may sue those providers and pharmacies who prescribed and dispensed the opiates, thus causing the patients' addiction to these medications.

The court also ruled while the patients are partially responsible for their own addictions and may have committed illegal acts to obtain the controlled substances, the providers also engaged in questionable activities which may have factored in their addictions.

This court ruling will allow patients to sue civilly and task juries to allocate fault to both patients and providers for causing addiction.

**LICENSE & REGISTRATION REVIEW**

Not applicable.

**BACKGROUND SEARCH**

Not applicable.

**CUSTOMER'S CORRESPONDING RESPONSIBILITY**

Not applicable.

**ON-SITE REVIEW**

Not applicable.

**PURCHASE HISTORY REVIEW**

Not applicable.

**MISCELLANEOUS**

Not applicable.

**CONCLUSION/RECOMMENDATION**

Because of information contained in news article received on January 8, 2016, ██████████ suspended the pharmacy's ability to order controlled substances.

In addition, on January 8, 2016, ██████████ notified Tug Valley Pharmacy owner ██████████ ██████████ of the decision to suspend.

As stated above, however, McKesson not only had information on this litigation, but also took it into consideration, when it made the decision to approve Tug Valley as a customer in July 2015.<sup>518</sup>

**FINDING: McKesson established a business relationship with Tug Valley Pharmacy in July 2015, despite knowledge of pending litigation against the pharmacy related to the alleged diversion of controlled substances. McKesson did not address the litigation with the pharmacy's owner while conducting its due diligence. McKesson later cited the litigation as the reason it suspended Tug Valley's ability to purchase controlled substances after the pharmacy and litigation were featured on CBS News in January 2016.**

<sup>518</sup> See McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee). See also McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee) and E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).



Less than two weeks later, on January 20, 2016, Tug Valley filed suit against McKesson in West Virginia state court over the suspension, arguing, among other things, that McKesson's decision violated the terms of their contract, and requesting the court to order McKesson to continue selling controlled substances to Tug Valley.<sup>519</sup> To support the company's decision to suspend Tug Valley's ability to purchase controlled substances, McKesson's Senior Director of Regulatory Affairs submitted an affidavit to the West Virginia court, stating:

As part of my own efforts, I reviewed a brief in the Mingo County lawsuit against Tug Valley Pharmacy. In that lawsuit, plaintiffs are suing Tug Valley Pharmacy, other pharmacies, and doctors for causing their addiction to opiates. I learned from the brief that Tug Valley Pharmacy's owner, [redacted], testified that he filled more than 150 prescriptions daily from one pain clinic alone. I also learned from that brief that a pharmacist testified that Tug Valley Pharmacy was improperly filing prescriptions for class 3 and 4 narcotics.<sup>520</sup>

The affidavit also stated that, based on this information, "continued shipments to Tug Valley Pharmacy put McKesson in jeopardy of being noncompliant with federal and/or state laws and regulations concerning the distribution of controlled substances."<sup>521</sup> Such an assessment raises the question of why McKesson did not flag this issue earlier since, as discussed above, McKesson referenced the litigation involving Tug Valley and provided hyperlinks to relevant court documents in its Regulatory Investigative Report just days after receiving Tug Valley's new customer application.<sup>522</sup> The litigation was also referenced when McKesson elected to onboard Tug Valley as a customer in July 2015.<sup>523</sup>

Press reports indicate that a West Virginia judge scheduled a hearing on January 29, 2015 to hear Tug Valley's claims against McKesson, but the hearing was canceled after the pharmacy withdrew its lawsuit.<sup>524</sup>

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<sup>519</sup> *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 20, 2016) (Emergency Verified Petition for Ex Parte Temporary Restraining Order and Preliminary Injunction) (On file with Committee).

<sup>520</sup> *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee).

<sup>521</sup> *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee) (internal quotation marks omitted).

<sup>522</sup> See McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).

<sup>523</sup> See McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee).

<sup>524</sup> Kate White, *After lawsuit, drug company shuts off supply to Mingo pharmacy*, CHARLESTON GAZETTE-MAIL, Feb. 3, 2016, [https://www.wvgazette.com/business/after-lawsuit-drug-company-shuts-off-supply-to-mingo-pharmacy/article\\_e874be9d-16b1-5f7c-8829-b3250df21055.html](https://www.wvgazette.com/business/after-lawsuit-drug-company-shuts-off-supply-to-mingo-pharmacy/article_e874be9d-16b1-5f7c-8829-b3250df21055.html).

ii. McKesson's Second Engagement with Tug Valley Pharmacy

McKesson's suspension of Tug Valley was not the end of the business relationship, however. On February 4, 2016, approximately two weeks after Tug Valley sued McKesson, McKesson received a new customer application from the pharmacy, representing that it was under new ownership.<sup>525</sup> A review of the pharmacy questionnaire, included with the application, shows that the new owner was unable to answer many of the questions posed therein, simply supplying question marks as answers when asked about the types of facilities the pharmacy serves and how the pharmacy receives customers.<sup>526</sup> Portions of the pharmacy questionnaire are reproduced below:

<p>d. How do new prescriptions come to the pharmacy (please express as a percentage)?</p> <p>Walk-in _____ ?</p> <p>Phone _____</p> <p>Fax / E-prescribing _____</p> <p>Internet _____</p>
<p>g. Pain Management Clinics ?</p> <p>i. Does pharmacy provide direct service to Pain Management Clinics? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>ii. If yes, what % of scripts does the pharmacy receive from pain management clinics? _____</p> <p>iii. If yes, what % of the pain management scripts are for controlled substances? _____</p>

<sup>525</sup> McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee). It should be noted, and will be discussed later in this report, documents show that the pharmacy's original owner was later discovered to be working at the pharmacy after the change in ownership was reportedly effectuated and even though the original owner was to have no association with Tug Valley Pharmacy, according to a February 29, 2016 Regulatory Investigative Report. *See infra* Section VI (D)(2)(a).

<sup>526</sup> McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee).

- h. Does pharmacy service nursing homes, long term care or hospice facilities? <sup>?</sup>  
 Yes  No
- i. Is pharmacy located within a medical center or clinic? <sup>?</sup>  
 Yes  No
- j. Does pharmacy regularly fill controlled substance prescriptions written by out of state providers? <sup>?</sup>  
 Yes  No

McKesson policies maintain that upon receipt of a questionnaire, a McKesson Regulatory Affairs Administrator shall review the questionnaire for completeness, and “[n]otify the submitter if the questionnaire is incomplete/illegible or if there are any missing items (e.g., photos or dispensing data).”<sup>527</sup> McKesson’s policies also maintain that “[i]nvalid/inaccurate/inconsistent answers on questionnaire(s)” are “red flags” that may be a cause for concern, and “when ‘red flags’ are identified they are reviewed to ensure appropriate due diligence.”<sup>528</sup>

A Regulatory Investigative Report from August 2016 stated with respect to the customer questionnaire, McKesson “found no ‘red flags’ or anomalies” regarding Tug Valley’s new ownership.<sup>529</sup> The report stated, in relevant part:

local physicians only. The customer questionnaire dated February 3, 2016 and February 15, 2016 found no “red flags” or anomalies regarding the new ownership of JCL Management and Consulting, dba: Tug Valley Pharmacy.

The Committee asked McKesson whether the company considered the new owner’s inability to answer basic questions about the pharmacy on the questionnaire as a red flag.<sup>530</sup> McKesson replied, in part, “[a]s this pharmacy was an existing McKesson customer, the regulatory team was familiar with the pharmacy and was aware, for example, that the pharmacy was not located within a medical clinic.”<sup>531</sup> The Committee also asked McKesson, its existing

<sup>527</sup> McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, 11 (Effective Date June 1, 2015 and last revised May 17, 2017) (On file with Committee).

<sup>528</sup> McKesson Corp., McKesson CSMP “Red Flags,” May 2015 (On file with Committee).

<sup>529</sup> McKesson Corp., Regulatory Investigative Report – JCL Management and Consulting, dba: Tug Valley Pharmacy, Aug. 24, 2016 (On file with Committee).

<sup>530</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

<sup>531</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee). McKesson’s response to the Committee’s question also referred the Committee to a February 29, 2016 Regulatory Investigative Report which documents a conversation McKesson’s Director Regulatory Affairs had with the new owner on February 26, 2016, discussed in more detail later in this case study, and that this “report notes specifically that [McKesson’s Director Regulatory Affairs] reviewed the questionnaire

knowledge of the pharmacy notwithstanding, whether an owner, or even a prospective owner, of a pharmacy should have knowledge of the pharmacy's basic characteristics and operations.<sup>532</sup> In response, McKesson did not directly address the Committee's question, instead directing the Committee to its prior response, which is cited above.<sup>533</sup>

With respect to the question marks provided on pharmacy questionnaire, McKesson later told the Committee, "[i]t is not clear what [new owner] meant by adding question marks, and the possibilities include that he was unsure how to interpret the questions or how to answer them."<sup>534</sup> It strains credulity, however, that the owner of a pharmacy or even a prospective owner of a pharmacy would be unable to answer or could misinterpret a yes or no question such as "[i]s pharmacy located within a medical center or clinic?"

In addition, documents produced to the Committee indicate that the new owner provided inconsistent corporate names on the customer application and the pharmacy questionnaire.<sup>535</sup> Documents also indicate that the new owner listed his own home address incorrectly on the customer application in addition to repeatedly providing the wrong zip code for Williamson, West Virginia, the location of Tug Valley Pharmacy.<sup>536</sup>

**FINDING: In February 2016, McKesson received a new customer application from Tug Valley Pharmacy, representing that it was under new ownership. The application contained multiple errors. McKesson also received a pharmacy questionnaire in which the new owner was unable to answer basic questions about the pharmacy.**

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with [new owner] and the report indicates that [Director of Regulatory Affairs] discussed with [new owner] topics that were noted with a question mark in the questionnaire." In later correspondence with the Committee, and with respect to this conversation, however, McKesson stated, "McKesson is not aware that it discussed the reasons why the pharmacy owner was unable to respond to the "question mark" answers at the time the questionnaire was filled out." E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee). McKesson also told the Committee, "a McKesson employee specifically discussed with [the new owner] the questionnaire and his responses, and so whatever the reasons for [new owner's] manner of filling out the form, McKesson did talk through the answers with the applicant, as memorialized in the February 29, 2016 Regulatory Investigative Report." Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee).

<sup>532</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).

<sup>533</sup> See E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>534</sup> Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee).

<sup>535</sup> See McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee) and McKesson Corp., Customer Application, Feb. 3, 2016 (On file with Committee). The Committee's research also indicates the organizing documents for both corporate entities, listed on the February 3, 2016, customer application and pharmacy questionnaire, were drafted on February 4, 2016, and filed with the Kentucky Secretary of State on February 8, 2016. See Articles of Organization of Eastridge General Management, LLC, Ky. Sec'y of State, Feb. 4, 2016, available at <https://app.sos.ky.gov/corpscans/86/0943686-06-99999-20160208-KLC-6375884-PU.pdf>. See also Articles of Organization of JCL Management and Consulting, LLC, Ky. Sec'y of State, Feb. 4, 2016, available at <https://app.sos.ky.gov/corpscans/84/0943684-06-99999-20160208-KLC-6375878-PU.pdf>.

<sup>536</sup> McKesson Corp., Customer Application, Feb. 3, 2016 (On file with Committee).

Documents also indicate that at the time of purchase, the new owner of Tug Valley Pharmacy was of fairly limited financial means<sup>537</sup> and that another individual listed as a guarantor on the customer application likely provided \$200,000 to cover the entire down payment for the purchase.<sup>538</sup> In an e-mail to the new owner, a McKesson Retail Sales Manager requested, among other things, the contract between the new owner and the guarantor related to the purchase of Tug Valley.<sup>539</sup> The documents produced to the Committee indicate that McKesson received a fax transmitting information related to the purchase of Tug Valley Pharmacy. Included in this fax was a document purportedly providing the contract between the new owner and the guarantor.<sup>540</sup> This contract, is undated and does not contain any signatures. The Committee has seen no indication to suggest that McKesson made any further attempts to obtain an executed contract between the new owner and the guarantor. The contract is reproduced in its entirety below:

FEB-12-2016 17:19 From: [REDACTED] Page: 7/34

[REDACTED]

The contract between [REDACTED] and [REDACTED] is as followed.

[REDACTED] (South Fork General Management) will give 200,000 for operating capital. In return South Fork General Management will receive 45% of the monthly net profit. The percentage is done so that on the occasion a reimbursement check circle from insurance companies fall unfavorably I will not have to dip into operating capital to pay the management fees that South Fork will be providing.

<sup>537</sup> Specifically, according to a document supplied by the new owner to McKesson at the time of purchase, the new owner represented that he owed more in outstanding personal loans than he had cash on hand, in addition to having a mortgage. This document appears to have been produced to McKesson in response to an e-mail sent by a McKesson Retail Sales Manager in which the Retail Sales Manager stated, among other things, “[o]ur credit guy would like your personal financial statement (Assets and liabilities, cash on hand).” E-Mail from Retail Sales Manager, McKesson Corp., to [redacted] (Feb. 8, 2016 4:46 pm) (On file with Committee).

<sup>538</sup> At the time of purchase, this individual owned other pharmacies that were also McKesson customers. See Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee). As stated, this individual was listed as the guarantor on the February 3, 2016 McKesson customer application. Based on the documents provided to the Committee, this individual was not a guarantor to the underlying sale of the pharmacy. Rather, pursuant to a Guaranty Agreement, the new owner, in his individual capacity, was responsible for the repayment of the loan that was obtained to facilitate the purchase of the pharmacy. See McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb. 11, 2016 (On file with Committee).

<sup>539</sup> See E-Mail from Retail Sales Manager, McKesson Corp., to [redacted] (Feb. 8, 2016 4:46 pm) (On file with Committee).

<sup>540</sup> See McKesson Corp., Due Diligence Document – Tug Valley Pharmacy (On file with Committee).

The documents faxed to McKesson related to the sale of Tug Valley Pharmacy also indicate that the new owner acquired the pharmacy through a financing arrangement with the former owner wherein the former owner financed the sale of the pharmacy through a corporation of which he was the sole shareholder, and retained a security interest in the pharmacy as collateral for making the loan to the new owner.<sup>541</sup> This financing arrangement meant that, should the new owner default on his loan, ownership of the pharmacy would revert back to the prior owner. As stated above, under the former owner, McKesson terminated Tug Valley Pharmacy as a customer on January 8, 2016 after the pharmacy was featured on the *CBS News* related to allegations about its opioid dispensing practices. McKesson policies advise that “a questionable change in ownership” is a potential “red flag” of concern.<sup>542</sup> In addition, the documents related to the sale of Tug Valley Pharmacy, and produced to the Committee, reference a promissory note for the repayment of an outstanding balance of \$160,000. The Committee requested that McKesson produce the promissory note, but the company was unable to do so.<sup>543</sup>

**FINDING: In February 2016, Tug Valley Pharmacy was sold through a financing arrangement under which the former owner retained a security interest in the pharmacy as collateral for making a loan to the new owner to facilitate the purchase.**

According to a February 29, 2016 Regulatory Investigative Report, McKesson elected to onboard Tug Valley as a customer again on the same day its Director of Regulatory Affairs conducted an interview with the new owner of Tug Valley.<sup>544</sup> The report indicates that McKesson performed internet searches on the pharmacy and its personnel, and verified that the new owner’s pharmacy technician’s license was active.<sup>545</sup> The report also indicates that the new owner was asked about any experience he had owning or managing a pharmacy, noting that he was the manager of another pharmacy which was also a McKesson customer at the time.<sup>546</sup> The pharmacy questionnaire discussed above was reviewed as well.<sup>547</sup>

With respect to the Director of Regulatory Affairs’ interview and review of the pharmacy questionnaire with the new owner, McKesson told the Committee:

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<sup>541</sup> Specifically, the former owner financed the sale of the pharmacy through a corporation of which he was the sole shareholder. See McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Security Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Agreement, Feb. 11, 2016 (On file with Committee).

<sup>542</sup> McKesson Corp., McKesson CSMP “Red Flags,” May 2015 (On file with Committee).

<sup>543</sup> See E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Nov. 29, 4:55 pm) (On file with Committee).

<sup>544</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

<sup>545</sup> *Id.*

<sup>546</sup> *Id.*

<sup>547</sup> *Id.*

Furthermore, regulatory personnel did have a follow-up discussion with [new owner] regarding the questionnaire and his background that is documented in a February 29, 2016 Regulatory Investigative Report. The report notes specifically that [McKesson’s Director of Regulatory Affairs] reviewed the questionnaire with [new owner] and the report indicates that [Director of Regulatory Affairs] discussed with [the new owner] topics that were noted with a question mark in the questionnaire. For example, the report indicates there was discussion with [new owner] about the pharmacy’s service area, whether the pharmacy will fill controlled substance prescriptions from pain management providers, whether the pharmacy is located in a medical center or medical clinic, and whether the pharmacy will service nursing homes, long term care, or hospice facilities.<sup>548</sup>

Despite McKesson’s policies indicating that invalid answers are “red flags,” the report makes no mention of whether McKesson questioned why the new owner was unable to answer multiple questions on the pharmacy questionnaire.<sup>549</sup> The Committee highlighted the latter point to McKesson.<sup>550</sup> In response, McKesson stated, “McKesson is not aware that it discussed the reasons why the pharmacy owner was unable to respond to the ‘question mark’ answers at the time the questionnaire was filled out.”<sup>551</sup>

**FINDING: Despite McKesson policies stating that invalid, inaccurate, or inconsistent answers on a questionnaire are a cause for concern, it does not appear that McKesson sought further explanation from the pharmacy’s new owner as to why he was unable to answer several basic questions about the pharmacy as posed in McKesson’s pharmacy questionnaire.**

The February 2016 Regulatory Investigative Report also noted that “Tug Valley Pharmacy was a former McKesson customer until January 8, 2016, when McKesson terminated its ability to order controlled substances because of derogatory information regarding the pharmacy’s controlled substance dispensing practices.”<sup>552</sup> The report indicates that the new owner was questioned about Tug Valley’s previous owner who sued McKesson after the company suspended the pharmacy’s ability to purchase controlled substances after being featured on the *CBS News*, stating, “[Tug Valley’s new owner] said that former owner [redacted] has no association with Tug Valley Pharmacy II. [New owner] said he did retain other employees from the pharmacy including pharmacy technicians and cashiers.”<sup>553</sup>

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<sup>548</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>549</sup> See McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

<sup>550</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).

<sup>551</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>552</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

<sup>553</sup> *Id.*

However, as discussed previously, documents produced to the Committee indicate the former owner did, in fact, retain an association to the pharmacy through the financing arrangement made between the former owner and the new owner, and known to McKesson. The February 2016 report does not mention, nor has the Committee seen any indication, that McKesson asked about, or had concerns regarding, the former owner's retention of a security interest in the pharmacy or the fact that he provided the financing arrangement to facilitate the pharmacy's sale.

**FINDING: In February 2016, Tug Valley Pharmacy's new owner told McKesson that the former owner no longer had an association with the pharmacy. Not only was this statement not true, but McKesson was in possession of a document at the time of its 2016 approval indicating that the former owner maintained a security interest in the pharmacy. The Committee has seen no indication to suggest that McKesson asked the pharmacy about the former owner's continuing security interest.**

As will be discussed in greater detail later in this report, despite the new owner's representation that the former owner would have no association with the pharmacy, documents show that, in addition to the security interest retained in the pharmacy, the former owner also worked at the pharmacy for an indeterminate period of time after the pharmacy was reinstated by McKesson.<sup>554</sup>

The Regulatory Investigative Report that accompanied McKesson's decision to onboard Tug Valley as a customer again also references a Power of Attorney authorizing the new owner to use the pharmacy's existing DEA registration number, and indicates McKesson's Director of Regulatory Affairs asked the new owner whether the "change of ownership had been properly vetted for approval with the local DEA office in Charleston, WV."<sup>555</sup> In response to McKesson's question, the report indicates the new owner represented that the DEA informed him agency approval was not required for this transaction, noting:

[New Owner] stated that on the day the power of attorney was executed, February 11, 2016, he contacted [redacted], a DEA Diversion Investigator, with DEA – Charleston, telephone # [redacted]. According to [new owner], [redacted] said that [new owner] didn't need DEA's permission for this type of acquisition. [New owner] added that based on [redacted's] comment, he surmised the change of ownership was authorized by DEA.<sup>556</sup>

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<sup>554</sup> See *infra* Section VI(D)(2)(a).

<sup>555</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee); see also Limited Power of Attorney, Feb. 11, 2016 (On file with Committee).

<sup>556</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).



DEA regulations allow for a transfer of registration only if certain conditions are met and require the DEA's written consent.<sup>557</sup> The documents produced to the Committee give no indication to suggest that McKesson contacted the DEA to verify whether the agency did in fact approve this transaction. Considering Tug Valley's history, the Committee asked McKesson whether it contacted the DEA itself to obtain the written approval from DEA authorizing the new owner to use Tug Valley's existing DEA registration.<sup>558</sup> In response, McKesson told the Committee:

It is McKesson's general practice to request, from the prospective customer or individual who is selling their pharmacy, any communications with DEA regarding the sale and transfer. In McKesson's experience, DEA rarely issues written approval of sales. As to Tug Valley specifically, as recorded in the [February 29, 2016 Regulatory Investigative Report], McKesson asked the new owner of Tug Valley if he had contacted DEA. The new owner indicated he had spoken to a DEA Diversion Investigator who was known to McKesson's Regulatory Affairs personnel. As noted in the [February 29, 2016 Regulatory Investigative Report], the investigator informed the new owner that DEA permission was unnecessary in this instance. We understand that this is consistent with DEA's typical practice in these circumstances.<sup>559</sup>

The DEA told Committee staff, while the manner by which DEA communicates its approval may vary in certain circumstances, agency approval is always required when transferring or authorizing the use of an existing DEA registration.<sup>560</sup> In an e-mail to Committee staff, DEA stated:

DEA registrations are not regarded as being 'transferable,' but 21 CFR 1301.52 is clear on what registrants must do if they wish to have DEA consider a proposal to transfer a registration. Pursuant to the regulations, they must submit a request to DEA in writing (both to the head of the Diversion Control Program and the Special Agent in Charge). The intent of this formal process is to ensure that any such transfer remains consistent

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<sup>557</sup> Specifically, the DEA regulations governing the transfer of registration require: "[n]o registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration." See 21 CFR §1301.52(b).

<sup>558</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).

<sup>559</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>560</sup> Phone call between Staff, U.S. Drug Enforcement Admin. and Staff, H. Comm. on Energy and Commerce (Oct. 23, 2018).

with the DEA's statutory obligation to ensure that the registration is consistent with the public interest factors.<sup>561</sup>

The response provided by McKesson suggests that it did not contact the DEA itself to ensure that the agency had approved the new owner's use of Tug Valley's existing DEA registration, instead relying on the representation of the new owner. Failing to independently contact the DEA and verify whether the agency approved the transfer of a registration to dispense controlled substances creates a serious risk that a distributor could facilitate drug diversion by providing controlled substances to a person that has not been vetted by the appropriate regulatory authorities. In July 2016, McKesson finally received notice that the pharmacy obtained a new DEA registration number.<sup>562</sup>

As will be discussed in more detail in section VI(D)(2)(a), McKesson suspended Tug Valley Pharmacy's ability to purchase controlled substances for a second time on February 28, 2018. Had McKesson performed additional due diligence with respect to red flags associated with the pharmacy, the company may have identified information that could have prompted it to deny the pharmacy's 2016 application, thereby avoiding entering a relationship with an owner whom the company later took action against, attributable to his deceit. Not following up on, and documenting its analysis of, red flags concerning a prospective or existing customer undermines the completeness and utility of a distributor's due diligence file.

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<sup>561</sup> E-Mail from Staff, U.S. Drug Enforcement Admin., to Staff, H. Comm. on Energy and Commerce (Nov. 16, 2018 4:35 p.m.) (On file with Committee).

<sup>562</sup> McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, July 27, 2016 (On file with Committee).

*d. Case Study on AmerisourceBergen: Evaluation of a Pharmacy's Prescribing Physicians*

When conducting prospective and existing customer due diligence, a distributor may obtain information regarding a pharmacy's prescribing physicians which raises concerns about possible diversion, thereby meriting additional examination. Similar to other aspects of the due diligence process, when a distributor does identify potential red flags related to a pharmacy's prescribing physicians, it should seek further explanation from the pharmacy in addition to performing its own substantive analysis, documenting both. Doing so offers distributors the chance to make a better-informed decision regarding a pharmacy's application, and also provides a more robust record for future reviews.

Westside Pharmacy, located in Oceana, West Virginia, had a population of 1,394 in 2010.<sup>563</sup> Oceana is located in Wyoming County, West Virginia, which, according to media reports, was determined to have the highest prescription overdose death rate in the nation, on average, between 1999 and 2014,<sup>564</sup> in addition to seeing a 6,973.1 percent increase in drug overdose deaths between 1980 and 2014 which ranked second in the nation.<sup>565</sup> AmerisourceBergen was one of multiple distributors that supplied Westside Pharmacy, which received nearly 8.62 million doses of hydrocodone and oxycodone from all distributors between 2006 and 2016.<sup>566</sup>

*i. AmerisourceBergen's Initial Encounter with Westside Pharmacy*

In June 2011, AmerisourceBergen approved Westside Pharmacy as a new customer and agreed to provide the pharmacy with controlled substances.<sup>567</sup> AmerisourceBergen produced 11 total pages of due diligence material to the Committee related to its engagement with Westside Pharmacy in 2011 and 2012.<sup>568</sup>

The documents produced in the due diligence material include license verifications with the DEA and the West Virginia Board of Pharmacy, photographs that were taken at the pharmacy, and a Retail Pharmacy Questionnaire. The due diligence documents also included a document titled 'Westside Pharmacy Pain Doctors,' which was simply a list of names and addresses of six doctors, two of which were located outside of West Virginia. The 'Westside

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<sup>563</sup> American FactFinder, *Oceana town, West Virginia* (<https://factfinder.census.gov>).

<sup>564</sup> See Wendy Holdren, *Report shows Wyoming County worst in country for prescription drug deaths*, REGISTER-HERALD, Aug. 21, 2016, [https://www.register-herald.com/news/report-shows-wyoming-county-worst-in-country-for-prescription-drug/article\\_123649b7-d708-5896-8cd6-040aae835ebd.html](https://www.register-herald.com/news/report-shows-wyoming-county-worst-in-country-for-prescription-drug/article_123649b7-d708-5896-8cd6-040aae835ebd.html).

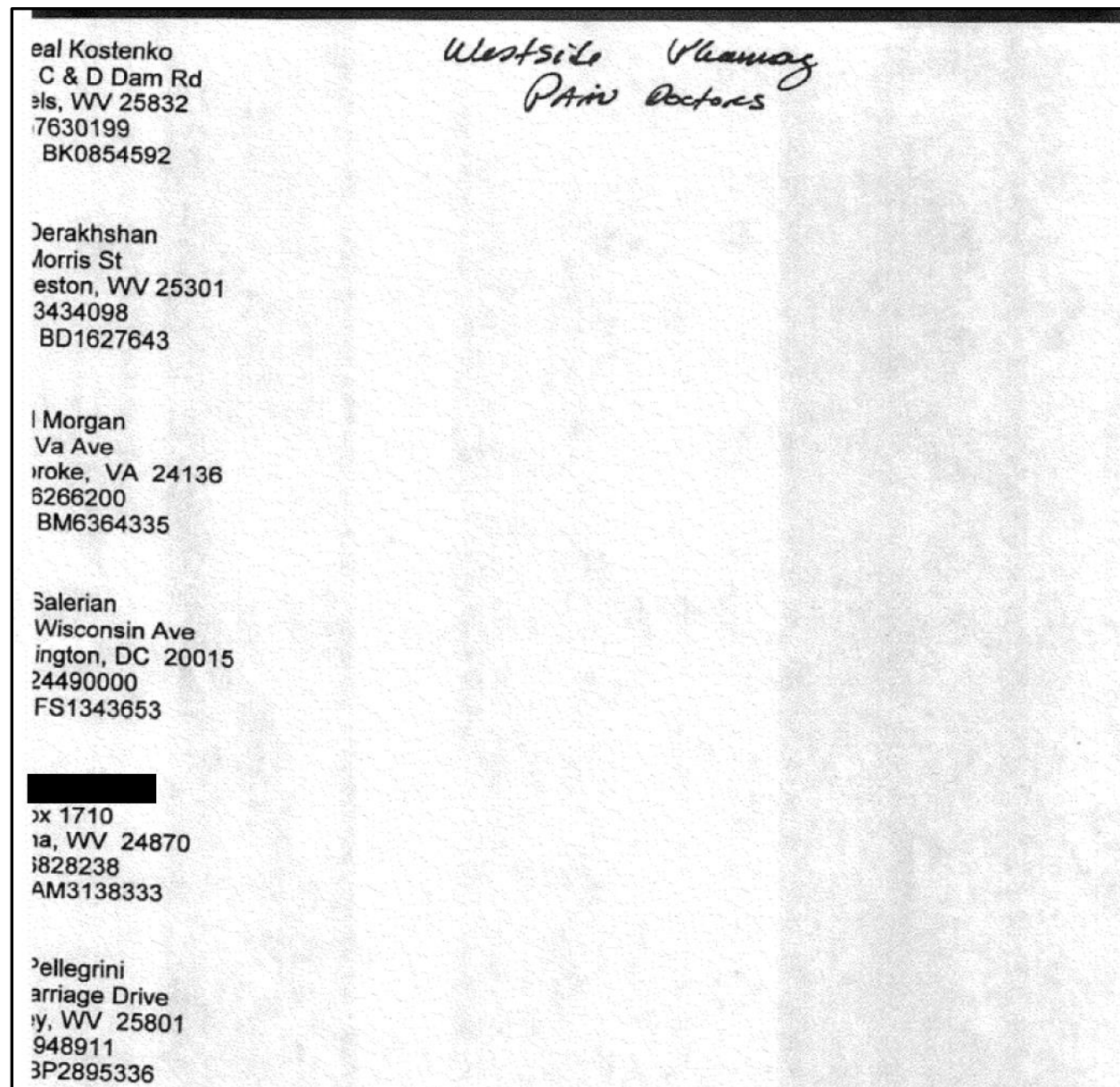
<sup>565</sup> See Jen Christensen, *Drug deaths rose 8,370% in some US counties over 34 years*, CNN, Mar. 13, 2018, <https://www.cnn.com/2018/03/13/health/drug-deaths-increase-study/index.html>.

<sup>566</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>567</sup> E-Mail from Corporate Security & Regulatory Affairs, AmerisourceBergen Corp. to NRCM, AmerisourceBergen Corp. (June 13, 2011 4:59 pm) (On file with Committee).

<sup>568</sup> See AmerisourceBergen Corp., Westside Pharmacy Due Diligence Documents (On file with Committee); see also E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

Pharmacy Pain Doctors' document is reproduced in its entirety below and in the condition that it was produced to the Committee.<sup>569</sup>



<sup>569</sup> AmerisourceBergen Corp., Westside Pharmacy Due Diligence Document (On file with Committee). The Committee asked AmerisourceBergen whether the document produced to the Committee was the most complete copy in the company's records, and if not, the Committee requested AmerisourceBergen provide the Committee with an updated copy. See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (Nov. 1, 2018 11:41 am) (On file with Committee). In response, AmerisourceBergen told the Committee, "[t]he document produced at [bates number] appears to be a document provided to ABDC by the pharmacy. From the best of our due diligence efforts, ABDC appears to only have it captured in this form at this time, which could be the result of how is [sic] was copied or input at the time. In any case, we could not find a better a [sic] copy in the records available." E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Nov. 2, 2018 5:16 pm) (On file with Committee).

One doctor, Dr. David Morgan, had an address in Pembroke, VA while another, Dr. Alen Salerian,<sup>570</sup> had an address located in Washington, D.C. Pembroke, VA and Washington, D.C. are a four-hour and an eleven-and-a-half-hour round-trip drive from the pharmacy, respectively. In total, five of the six doctors listed on the ‘Westside Pharmacy Pain Doctors’ document included in AmerisourceBergen’s 2011 due diligence file have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing or are currently under federal investigation.<sup>571</sup>

**FINDING: AmerisourceBergen’s due diligence documents for Westside Pharmacy included a list of six “Pain Doctors.” Two of the doctors were located a four-hour and eleven-and-a-half-hour round-trip drive from the pharmacy respectively. Five of the six doctors have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing, or are currently under federal investigation.**

The Committee requested that AmerisourceBergen provide any due diligence documents that would demonstrate the company’s efforts to examine why certain physicians were located such substantial distances from the pharmacy.<sup>572</sup> In response to the Committee’s request, AmerisourceBergen was unable to produce any documents that would demonstrate it undertook such an examination.<sup>573</sup> Instead, the company referred the Committee to the 11-page due

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<sup>570</sup> After his office and home were raided by federal agents in March 2011, a grand jury indicted Dr. Alen Salerian in April 2013 on 36 charges, alleging that he conspired to distribute controlled substances without a legitimate medical purpose and beyond the bounds of medical practice. See Press Release, Federal Bureau of Investigation, Washington, D.C. Doctor Indicted on Prescription Drug Distribution Charges (Apr. 25, 2013), <https://archives.fbi.gov/archives/richmond/press-releases/2013/washington-d.c.-doctor-indicted-on-prescription-drug-distribution-charges>. The grand jury issued a superseding indictment against Dr. Salerian in June 2013, bringing the total number of charges brought by the government to 144. See *United States v. Salerian*, No. 1:13CR00017, 2 (W.D. Va. Jan. 28, 2014) (Opinion and Order) available at <http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017.mot.dismiss.opinion.pdf>. The charges against Dr. Salerian were dismissed in 2016, however, after a federal judge determined that he was not mentally competent to stand trial. See *United States v. Salerian*, No. 1:13CR00017 (W.D. Va. Mar. 10, 2016) (Opinion and Order) available at <http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017%20dismiss%20op.pdf>.

<sup>571</sup> See Press Release, Dep’t of Justice, U.S. Attorney’s Office, S.D. W.Va., Beckley area physician sentenced to 20 years in federal prison for oxycodone crime (Aug. 23, 2017), <https://www.justice.gov/usao-sdww/pr/beckley-area-physician-sentenced-20-years-federal-prison-oxycodone-crime>; *United States v. Salerian*, No. 1:13CR00017 (W.D. Va. Mar. 10, 2016) (Opinion and Order) available at <http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017%20dismiss%20op.pdf>; Jeff Surgeon, *Former Giles County doctor, stripped of license, faces federal criminal probe*, ROANOKE TIMES, Apr. 18, 2017, [http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article\\_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html](http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html); Wendy Holdren, *HOPE Clinic doctor Pellegrini pleads guilty in drug case*, REGISTER-HERALD, Apr. 27, 2018, [https://www.register-herald.com/news/hope-clinic-doctor-pellegrini-pleads-guilty-in-drug-case/article\\_f7307f96-4a2e-11e8-8b0d-3307804bc901.html](https://www.register-herald.com/news/hope-clinic-doctor-pellegrini-pleads-guilty-in-drug-case/article_f7307f96-4a2e-11e8-8b0d-3307804bc901.html); and Press Release, Dep’t of Justice, U.S. Attorney’s Office, S.D. W.Va., Charleston doctor pleads guilty to Federal crime involving dispensing fentanyl (Apr. 21, 2016), <https://www.justice.gov/usao-sdww/pr/charleston-doctor-pleads-guilty-federal-crime-involving-dispensing-fentanyl>.

<sup>572</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>573</sup> E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

diligence file and noted “ABDC also received information on prescribing physicians[,]” making reference to the ‘Westside Pharmacy Pain Doctors’ list that is reproduced above.<sup>574</sup> As indicated, this document, which is an incomplete photocopy, only provides names and addresses, and does not contain any other information that would indicate AmerisourceBergen performed any additional due diligence. Similarly, the Committee has not seen any indication, nor has it received any documentation to suggest, that AmerisourceBergen questioned the pharmacy as to why it was filling prescriptions for physicians that were located hours away from the pharmacy.

**FINDING: Based on documents provided to the Committee, in 2011, AmerisourceBergen did not investigate why Westside Pharmacy filled prescriptions for physicians located hours away from the pharmacy.**

Publicly available information at the time of AmerisourceBergen’s due diligence review also documented disciplinary action taken in 2008 by the Virginia Board of Medicine against Dr. Morgan related to inappropriate prescribing of controlled substances.<sup>575</sup> When asked by the Committee about any due diligence conducted on Dr. Morgan in 2011, AmerisourceBergen responded, “[w]hile the [due diligence] file does not contain details of the searches done on Dr. Morgan, or the other prescribing physicians identified on [the document titled “Westside Pharmacy Pain Doctors”], it appears that in 2011, Dr. Morgan’s license to prescribe was clear of any restrictions.”<sup>576</sup> To demonstrate this point, AmerisourceBergen cited a July 24, 2009 letter from the Board of Medicine, certifying that Dr. Morgan complied with the terms of the 2008 order.<sup>577</sup> The Committee has not seen any indication, nor has it received any documentation to suggest, that AmerisourceBergen queried the Board or any other sources when it was conducting due diligence on Westside Pharmacy in 2011.

The Committee’s review of DEA ARCOS data showed that AmerisourceBergen discontinued supplying Westside Pharmacy with opioids at some point during 2012. The Committee requested that the company provide the reason for this. In response, AmerisourceBergen told the Committee, “[a]fter a comprehensive search, we believe that Westside Pharmacy voluntarily moved its business from ABDC to another wholesaler in late 2012, shortly after ABDC placed stricter limits on its purchasing of controlled substances.”<sup>578</sup> The documents produced to the Committee do not contain any information related to any limitations AmerisourceBergen may have imposed on Westside Pharmacy or the pharmacy’s apparent decision to discontinue its business relationship with the company.

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<sup>574</sup> *Id.*

<sup>575</sup> *In re: David Lee Morgan, D.O.*, Consent Order, 1-2 (Va. Board of Medicine, Oct. 14, 2008) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order10142008.pdf>. More information regarding Dr. Morgan can be found at *infra* Section VI(A)(2)(d)(ii)(c).

<sup>576</sup> E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

<sup>577</sup> See E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee). See also Letter from William L. Harp, M.D., Exec. Dir., Va. Bd. of Md. to David. K. Morgan, D.O., July 24, 2009 (On file with Committee).

<sup>578</sup> Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce et al., May 7, 2018 (On file with Committee).

**FINDING: AmerisourceBergen told the Committee that it placed stricter limits on Westside Pharmacy’s purchasing of controlled substances in late 2012. The Committee received no documents that reference these limitations or the pharmacy’s apparent decision to subsequently end its business relationship with AmerisourceBergen.**

The next year, in 2013, Oceana, West Virginia, where Westside Pharmacy is located, was the subject of a documentary titled “Oxyana” which depicts the toll the opioid epidemic has taken on the West Virginia town.<sup>579</sup> A press report highlighting some of the documentary’s findings stated, “[o]ne drug dealer in the film, who likens the situation there to ‘the Wild West,’ claims to pay a doctor in Washington, D.C., \$1,000 to receive a one-month prescription of 450 30mg Oxy pills. That’s 15 pills a day. And since a single 30mg Oxy pill sells for \$45 on the street, the dealer stands to make \$20,250 per ‘transaction.’”<sup>580</sup>

*ii. AmerisourceBergen’s Second Encounter with Westside Pharmacy*

In January 2016, AmerisourceBergen approved a new customer application for Westside Pharmacy.<sup>581</sup> The due diligence files make no reference to the pharmacy’s prior engagement with Westside Pharmacy, including the company’s apparent decision to impose stricter limits on the pharmacy’s ability to purchase controlled substances in 2012.<sup>582</sup> When asked by the Committee whether AmerisourceBergen considered the prior engagement, AmerisourceBergen referred the Committee to Westside’s 2016 due diligence file.<sup>583</sup> Given that the due diligence file makes no mention of the pharmacy’s previous history with the company, the Committee infers that it was not a factor in AmerisourceBergen’s analysis.

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<sup>579</sup> See Leora Arnowitz, ‘Oxyana’ premieres at Tribeca Film Festival, gives an up-close look at drug use in West Virginia, FOX NEWS, Apr. 19, 2013, <https://www.foxnews.com/entertainment/oxyana-premieres-at-tribeca-film-festival-gives-an-up-close-look-at-drug-use-in-west-virginia>; see also Sheila O’Malley, *At the Tribeca Film Festival: A message to you from a West Virginia town ruined by Oxycontin*, POLITICO, Apr. 26, 2013, <https://www.politico.com/states/new-york/albany/story/2013/04/at-the-tribeca-film-festival-a-message-to-you-from-a-west-virginia-town-ruined-by-oxycontin-067223>; Dave Boucher, *Oceana officials admit drugs pose problem, search for solution*, CHARLESTON GAZETTE-MAIL, May 10, 2013, [https://www.wvgazettemail.com/news/oceana-officials-admit-drugs-pose-problem-search-for-solution/article\\_a22eb20e-79b8-50c1-ae44-e2bd74f4fcbc.html](https://www.wvgazettemail.com/news/oceana-officials-admit-drugs-pose-problem-search-for-solution/article_a22eb20e-79b8-50c1-ae44-e2bd74f4fcbc.html); Dave Boucher, *Small town faces up to film’s image of Oxyana*, CHARLESTON GAZETTE-MAIL, May 13, 2013, [https://www.wvgazettemail.com/news/small-town-faces-up-to-film-s-image-of-oxyana/article\\_ed5b0d1a-4072-5f70-b0e9-53434e92870f.html](https://www.wvgazettemail.com/news/small-town-faces-up-to-film-s-image-of-oxyana/article_ed5b0d1a-4072-5f70-b0e9-53434e92870f.html).

<sup>580</sup> Marlow Stern, ‘Oxyana’ Documentary, at Tribeca, Exposes the OxyContin Epidemic, DAILY BEAST, Apr. 23, 2013, <https://www.thedailybeast.com/oxyana-documentary-at-tribeca-exposes-the-oxycontin-epidemic?ref=scroll>.

<sup>581</sup> AmerisourceBergen Corp., Customer Due Diligence Questionnaire Checklist – Westside Pharmacy, Jan. 11, 2016 (On file with Committee).

<sup>582</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>583</sup> See E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).



**FINDING: AmerisourceBergen began doing business with Westside Pharmacy again in January 2016. Documents produced to the Committee give no indication to suggest that AmerisourceBergen considered the company’s 2012 decision to place stricter limits on the pharmacy’s ability to purchase controlled substances.**

Setting aside the prior engagement, the due diligence materials provided by Westside Pharmacy in December 2015 should have raised other red flags which, based on the documents provided to the Committee, were apparently not adequately investigated by AmerisourceBergen.

In the Retail Pharmacy Questionnaire completed by Westside Pharmacy, the pharmacy noted its ability to purchase controlled substances had been either terminated or restricted by a wholesale distributor in the past.<sup>584</sup> Based on the questionnaire, it is not clear whether Westside Pharmacy was referring to the prior restriction on controlled substance ordering imposed by AmerisourceBergen, or a different distributor that suspended or ceased controlled substance sales in the past. The Committee’s investigation found that Westside Pharmacy submitted its Retail Pharmacy Questionnaire to AmerisourceBergen on the same day it was terminated by Miami-Luken after the company received an Order to Show Cause from the DEA, which included allegations regarding Miami-Luken’s distribution to Westside Pharmacy.<sup>585</sup>

In the prospective customer questionnaire, the pharmacy also provided AmerisourceBergen with its top five prescribing physicians for either hydrocodone or oxycodone.<sup>586</sup> Three of the five names on the list should have raised concerns—Dr. Sanjay Mehta, Dr. Michael Kostenko, and Dr. David Morgan.

A. Dr. Sanjay Mehta

Dr. Mehta practiced at the HOPE Clinic in Beaver, West Virginia. In March 2015, approximately nine months prior to Westside Pharmacy’s application to AmerisourceBergen, federal and state law enforcement officials raided Dr. Mehta’s office,<sup>587</sup> and the West Virginia

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<sup>584</sup> AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

<sup>585</sup> See E-Mail from Dir. Compliance and Security, Miami-Luken, Inc. to Diversion Investigator, U.S. Drug Enforcement Admin. and Diversion Investigator, U.S. Drug Enforcement Admin. (Dec. 11, 2015 3:36 pm) (On file with Committee). In this e-mail to the DEA, Miami-Luken told the DEA “[o]n 12/09/2015, Miami-Luken terminated the controlled substance business relationship with Westside Pharmacy in Oceana, WV[.]” See also U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

<sup>586</sup> AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

<sup>587</sup> Daniel Tyson, *Update: Hope Clinic raided by various agencies*, REGISTER-HERALD, Mar. 19, 2015, [http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article\\_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html](http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html).



Department of Health and Human Resources subsequently ordered him to close his practice.<sup>588</sup> According to a press report from May 2015, citing documents obtained from the West Virginia Department of Health and Human Resources:

Patient records at the Beaver HOPE clinic didn't contain enough information to identify patients. The records didn't support patient diagnosis or justify treatment, [West Virginia Department of Health and Human Resources] investigators reported. HOPE staff didn't document patients' health histories, current medications, or whether or not they were dependent on controlled substances or being treated at another pain clinic.<sup>589</sup>

Press reports also indicate that prior to the forced closure of the Beaver HOPE clinic, the West Virginia Department of Health and Human Resources also ordered a related HOPE clinic in Charleston, West Virginia to close in February 2015 for similar infractions.<sup>590</sup>

A press report available at the time AmerisourceBergen onboarded Westside Pharmacy indicates that following the forced closure of the Beaver HOPE clinic, Dr. Mehta relocated to Wytheville, Virginia in June 2015 where he continued to practice at another HOPE clinic.<sup>591</sup> Wytheville, Virginia is located approximately a four-hour round-trip drive from Westside Pharmacy, and the DEA license verification AmerisourceBergen had on file in its due diligence documents for Westside Pharmacy also reflects a Wytheville, Virginia address for Dr. Mehta. The press report also indicates that the Wytheville HOPE clinic was raided by the DEA on the same day the Beaver location was raided, March 19, 2015, and noted “[f]inding a pharmacy to

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<sup>588</sup> Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, [http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article\\_bf69155e-bec2-5ce6-9a19-53a26ce88670.html](http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html). Dr. Mehta was indicted by a federal grand jury on charges related to improperly prescribing controlled substances. If convicted, Dr. Mehta faces a minimum 40-year sentence up to life imprisonment. See Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., U.S. Attorney announces 69-count indictment charging owners, managers and physicians associated with Hope Clinic (Feb. 20, 2018), <https://www.justice.gov/usao-sdvw/pr/us-attorney-announces-69-count-indictment-charging-owners-managers-and-physicians>.

<sup>589</sup> Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, [http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article\\_bf69155e-bec2-5ce6-9a19-53a26ce88670.html](http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html).

<sup>590</sup> See Eric Eyre, *W.Va. pain clinics scrutinized; 3 facilities shut down*, CHARLESTON GAZETTE-MAIL, Mar. 29, 2015, [https://www.wvgazette.com/news/w-va-pain-clinics-scrutinized-facilities-shut-down/article\\_3a5ee5b4-6b2c-53a9-a7c7-38bfe21c3422.html](https://www.wvgazette.com/news/w-va-pain-clinics-scrutinized-facilities-shut-down/article_3a5ee5b4-6b2c-53a9-a7c7-38bfe21c3422.html); see also Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, [http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article\\_bf69155e-bec2-5ce6-9a19-53a26ce88670.html](http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html); Associated Press, *Report: Closed pain clinic's practices put patients at risk*, WASH. TIMES, May 25, 2015 <https://www.washingtontimes.com/news/2015/may/25/report-closed-pain-clinics-practices-put-patients-/>; Daniel Tyson, *Update: Hope Clinic raided by various agencies*, REGISTER-HERALD, Mar. 19, 2015, [http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article\\_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html](http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html).

<sup>591</sup> See Wayne Quesenberry, *Wytheville clinic's neighbors complain*, SWVA TODAY, July 3, 2015, [https://www.swvatoday.com/news/wytheville/article\\_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html](https://www.swvatoday.com/news/wytheville/article_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html).

fill their prescriptions is a problem for many of the clinic's patients. Most local pharmacies won't accept them."<sup>592</sup>

B. Dr. Michael Kostenko

Dr. Kostenko practiced at and operated the Coal Country Clinic in Daniels, West Virginia. In July 2015, the West Virginia Department of Health and Human Resources ordered the Coal Country Clinic to close after a state inspection found "incomplete record keeping with little documentation of patient diagnosis or assessment."<sup>593</sup> The clinic was ordered to close a second time in August 2015 and assessed civil money penalties after state inspectors found the clinic continued to operate in contravention of the July 2015 order.<sup>594</sup> Following a November 2015 hearing, Dr. Kostenko was ordered to discontinue operating the Coal Country Clinic as a pain clinic and to provide complete patient records to the West Virginia Department of Health and Human Resources.<sup>595</sup> At the hearing, an Assistant Attorney General for West Virginia noted, among other things, that Board of Pharmacy record showed that Dr. Kostenko had prescribed "an exorbitant amount of controlled substances."<sup>596</sup> In January 2016, only days before AmerisourceBergen approved Westside Pharmacy's application, Dr. Kostenko was prominently featured in a *CBS News* report where it was noted that Dr. Kostenko had written more than 40,000 opioid prescriptions over a two-year period.<sup>597</sup>

All of this information on Dr. Mehta and Dr. Kostenko had been publicly reported and was accessible to AmerisourceBergen at the time it was conducting its due diligence on Westside Pharmacy in late 2015 and early 2016.<sup>598</sup>

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<sup>592</sup> Wayne Quesenberry, *Wytheville clinic's neighbors complain*, SWVA TODAY, July 3, 2015, [https://www.swvatoday.com/news/wytheville/article\\_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html](https://www.swvatoday.com/news/wytheville/article_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html).

<sup>593</sup> Press Release, W. Va. Dep't of Health and Human Res., DHHR Petitions Court to Close Coal Country Clinic (Hearing scheduled for November 23, 2015) (Nov. 19, 2015), <https://dhhr.wv.gov/News/2015/Pages/DHHR-Petitions-Court-to-Close-Coal-Country-Clinic.aspx>.

<sup>594</sup> See Press Release, W. Va. Dep't of Health and Human Res., DHHR Petitions Court to Close Coal Country Clinic (Hearing scheduled for November 23, 2015) (Nov. 19, 2015), <https://dhhr.wv.gov/News/2015/Pages/DHHR-Petitions-Court-to-Close-Coal-Country-Clinic.aspx>. See also Eric Eyre, *DHHR goes to court to shut down Raleigh pain clinic*, CHARLESTON GAZETTE-MAIL, Nov. 19, 2015, [https://www.wvgazettemail.com/news/cops\\_and\\_courts/dhhr-goes-to-court-to-shut-down-raleigh-pain-clinic/article\\_36816010-f278-5304-b603-b201de85fd6a.html](https://www.wvgazettemail.com/news/cops_and_courts/dhhr-goes-to-court-to-shut-down-raleigh-pain-clinic/article_36816010-f278-5304-b603-b201de85fd6a.html) and Kyla Asbury, *WVDHHR wants Raleigh County pain clinic shut down*, WEST VIRGINIA RECORD, Nov. 20, 2015, <https://wvrecord.com/stories/510649252-wvdhhr-wants-raleigh-county-pain-clinic-shut-down>.

<sup>595</sup> Sarah Plummer, *Coal Country Clinic to remain open as non-pain clinic, must prove compliance*, REGISTER-HERALD, Nov. 24, 2015, [http://www.register-herald.com/news/coal-country-clinic-to-remain-open-as-non-pain-clinic/article\\_1153b547-4bcf-55a9-b8a5-ec8dbef08b66.html](http://www.register-herald.com/news/coal-country-clinic-to-remain-open-as-non-pain-clinic/article_1153b547-4bcf-55a9-b8a5-ec8dbef08b66.html).

<sup>596</sup> *Id.*

<sup>597</sup> Jim Axelrod and Ashely Velie, *West Virginia allows painkiller addicts to sue prescribing doctors*, CBS NEWS, Jan. 6, 2016, <https://www.cbsnews.com/news/west-virginia-allows-painkiller-addicts-to-sue-doctors-who-got-them-hooked/>.

<sup>598</sup> Subsequently, Dr. Kostenko was arrested on federal charges related to improperly prescribing controlled substances and was eventually sentenced to 20 years in federal prison and ordered to pay a \$50,000 fine after entering a guilty plea. See Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., Beckley area physician sentenced to 20 years in federal prison for oxycodone crime (Aug. 23, 2017), <https://www.justice.gov/usao-sdww/pr/beckley-area-physician-sentenced-20-years-federal-prison-oxycodone-crime>.

The Committee asked AmerisourceBergen whether the company consulted or considered press reports related to Dr. Mehta and Dr. Kostenko when it was considering Westside Pharmacy’s application.<sup>599</sup> In response, AmerisourceBergen informed the Committee that “[n]ews searches for prescribing physicians are not a standard part of ABDC’s new customer review and there is no record of their having been performed in this instance.”<sup>600</sup> Similarly, the due diligence documents that were produced to the Committee give no indication that AmerisourceBergen questioned the pharmacy about its relationship with either doctor.

**FINDING: Prior to onboarding Westside Pharmacy as a customer in January 2016, AmerisourceBergen does not appear to have consulted public news reports that would have alerted the company to red flags related to some of the pharmacy’s top prescribing physicians. According to AmerisourceBergen, “[n]ews searches for prescribing physicians are not a standard part of ABDC’s new customer review[.]”**

As part of its due diligence, AmerisourceBergen did verify the DEA and state licenses for the pharmacy’s top-prescribing physicians, including Dr. Mehta and Dr. Kostenko. AmerisourceBergen also told the Committee that, notwithstanding that it did not conduct news searches on the top-prescribing physicians, it did conduct a search for any board actions that were taken against them.<sup>601</sup> With respect to Dr. Kostenko, the due diligence file contained a 2005 complaint issued by the West Virginia Board of Osteopathy which alleged that Dr. Kostenko allowed staff to perform unauthorized and medically unnecessary tasks.<sup>602</sup>

C. Dr. David Morgan

Dr. David Morgan was listed as Westside Pharmacy’s top prescriber of hydrocodone or oxycodone on the Retail Pharmacy Questionnaire.<sup>603</sup> As mentioned previously, Dr. Morgan’s medical practice was located an approximate four-hour round-trip drive from Westside Pharmacy. Setting this aside, not only did the due diligence materials produced to the Committee contain derogatory information related to Dr. David Morgan, but external investigators hired by AmerisourceBergen independently flagged Dr. Morgan as cause for concern earlier in 2015.<sup>604</sup>

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<sup>599</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>600</sup> E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

<sup>601</sup> *Id.*

<sup>602</sup> *In re: Michael Kostenko, D.O.*, Complaint and Notice of Hearing (W. Va. Bd. of Osteopathy) (On file with Committee).

<sup>603</sup> See AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

<sup>604</sup> The Virginia Board of Medicine sanctioned Dr. Morgan for releasing a patient with known substance abuse issues but failing to provide a referral to substance abuse treatment while simultaneously providing the patient with five prescriptions for opioids, some of which were post-dated. The patient had recently been hospitalized for overdosing on Lortab, which is a pharmaceutical that contains hydrocodone and acetaminophen. *In re: David Lee*

The due diligence documents produced to the Committee illustrate that AmerisourceBergen attempted to verify Dr. Morgan's DEA and state registrations but discovered that a registration number for Dr. Morgan indicated that his license was expired. An AmerisourceBergen business development manager e-mailed Westside pharmacy's owner, requesting an updated DEA license number for Dr. Morgan. Rather than provide an updated DEA license number, the pharmacy owner instead gave a long explanation of the town's relationship with Dr. Morgan in an e-mail to an AmerisourceBergen employee, stating, in part, "[y]ou tell compliance that I will agree to not fill any of his scripts regardless [sic] if he practiced here in my town or not."<sup>605</sup> The e-mail from the pharmacy owner is reproduced below:

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*Morgan, D.O.*, Consent Order, 1-2 (Va. Board of Medicine, Oct. 14, 2008) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order10142008.pdf>. In December 2016, Dr. Morgan had his license to practice medicine suspended indefinitely by the Virginia Board of Medicine upon the board's determination that his practice of medicine presented "substantial danger to the public health and safety." See *In re: David Lee Morgan, D.O.*, Notice (Va. Board of Medicine, Dec. 15, 2016) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Notice12152016.pdf>. Dr. Morgan is currently under federal investigation for his controlled substance prescribing practices. According to an affidavit submitted by federal investigators, twenty of Dr. Morgan's patients died of drug overdoses between January 2011 and August 2016. Jeff Surgeon, *Former Giles County doctor, stripped of license, faces federal criminal probe*, ROANOKE TIMES, Apr. 18, 2017, [http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article\\_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html](http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html).

<sup>605</sup> E-Mail from Owner, Westside Pharmacy to Business Development Manager, AmerisourceBergen Corp. (Dec. 23, 2015 3:22 pm) (On file with Committee). In contrast to the representation made by Westside Pharmacy's owner in the December 23, 2015 e-mail that the pharmacy was "not disciplined by Miami Luken [sic] for any wrong doing [sic] or finding[.]" Miami-Luken represented to the Committee that its decision to terminate Westside Pharmacy as a customer on December 9, 2015 was based on multiple factors, including, "the pharmacy's failure to identify top opioid prescribers who were subject to, or a party to, disciplinary action" and "deceitful practices on the part of the owner[.]" The latter concern related to Westside Pharmacy's continuing to fill prescriptions written by Drs. Morgan and Mehta, months after representing to Miami-Luken that it would no longer fill prescriptions that were written by either doctor. See Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee). Miami-Luken terminated its relationship with Westside Pharmacy after it received an Order to Show Cause from the DEA, which included allegations regarding Miami-Luken's distribution to Westside Pharmacy. See U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee); see also Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, 91 (On file with Committee).

**From:** [REDACTED]  
**Date:** December 23, 2015 at 3:22:36 PM EST  
**To:** [REDACTED]  
**Subject:** Re: FW: CSRA Review Requested for WESTSIDE PHARMACY (21355)

listen...even though dr morgan was in this town for 14 years and then relocated across the border 1 hr 45 min away people still go there. He has treated these patients for 20 plus years. We are 1 hour 1/2 from closest pain treatment clinic. So my decisions to treat his patients were for the customers. It seems this Dr David Morgan which I do feel I know him on a very personal professional level if creating problems. You tell compliance that I will agree to not fill any of his scripts regardless if he practiced here in my town or not. I have to take care of my children that need add meds etc. Miami Luken assured me that my account was only moderate dispensing 17% control and 7 percent c2. I don't understand. I have always been compliant. but I will prove to your company that I am trustworthy. You make the guidelands and I will follow 100 percent... I need this account NOW before I have to file bankruptcy. Dougs Drugs are opening in a few weeks.. I can't turn business away. This is detrimental to my business..I was not disciplined by Miami Luken for any wrong doing or finding. That can be verified. I will abide by any policies you have with controls.

Thanks [REDACTED]

The due diligence documents provided to the Committee do not indicate whether AmerisourceBergen attempted to address the e-mail that was sent by the pharmacy's owner or if the company conducted any additional due diligence on the pharmacy's relationship with Dr. Morgan.

AmerisourceBergen should have been particularly attuned to Dr. Morgan's prescribing, however, given that external investigators hired by AmerisourceBergen to review another West Virginia pharmacy highlighted Dr. Morgan's prescribing practices in a February 2015 report.<sup>606</sup> The investigators determined that Dr. Morgan was one of the top prescribing physicians at this pharmacy and noted, "Dr. David Morgan, DO wrote for 1,852 oxycodone prescriptions and 212 Oxycontin prescriptions in 2012. Dr. Morgan currently has a case pending with the Virginia Board of Medicine."<sup>607</sup> AmerisourceBergen told the Committee it placed the pharmacy at issue in the report on the company's 'Do Not Ship list' following the February 2015 review.<sup>608</sup>

AmerisourceBergen, however, does not appear to have applied this information to other pharmacies where it knew Dr. Morgan was a top prescriber. At a minimum, the materials AmerisourceBergen provided to the Committee documenting its late 2015 and early 2016 due diligence of Westside Pharmacy contain no reference to the company's February 2015 findings relating to Dr. Morgan.

AmerisourceBergen's due diligence file for its 2015-2016 examination of Westside Pharmacy did include documentation from the Virginia Board of Medicine (Board) related to previous disciplinary actions that had been taken against Dr. Morgan. Included in the due

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<sup>606</sup> See The Pharma Compliance Group, Observations and Recommendations Report, Feb. 15, 2015 (On file with Committee).

<sup>607</sup> *Id.*

<sup>608</sup> See Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., May 7, 2018 (On file with Committee). AmerisourceBergen stated that it removed this pharmacy from the Do Not Ship list in May 2016 after conducting additional due diligence.

diligence files were consent orders that were entered in 2008 and 2014, including the Board’s certification of Dr. Morgan’s compliance thereof.<sup>609</sup>

The 2014 consent order also should have served as a significant cause for concern for AmerisourceBergen during its evaluation of Westside Pharmacy, considering Dr. Morgan was identified as the pharmacy’s top prescriber of hydrocodone or oxycodone on the Retail Pharmacy Questionnaire. For example, the consent order—including in AmerisourceBergen’s due diligence file for the pharmacy—included multiple instances in which Dr. Morgan prescribed medications, including oxycodone, without having seen the patient.<sup>610</sup> Relevant excerpts from the consent order are reproduced below:

5/22/03,12/16/03, 3/15/05, 1/26/07, 11/25/08, 12/18/10, 2/11/11,3/21/12	On each of these dates, Dr. Morgan wrote renewal prescriptions, including oxycodone, OxyContin 40, OxyContin 20, MS Contin, Percocet, Oxy IR 5, Demerol, Duragesic, morphine sulfate, Adderall, and/or Xanax without having seen the patient.
5/24/05, 12/11/06, 2/4/08, 3/31/08, 5/27/08,5/25/10	On each of these dates, Dr. Morgan wrote renewal prescriptions, including OxyContin, morphine sulfate, Roxicodone, oxycodone, and/or Xanax without having seen the patient.
4/2/07, 5/31/07, 6/9/07, 7/27/07 8/28/07, 10/25/07, 12/20/07, 2/18/08, 3/17/08, 8/4/09, 9/29/10	On each of these dates, Dr. Morgan wrote renewal prescriptions for OxyContin 40, OxyContin 20, OxyIR5, Endocet, and/or Xanax without having seen the patient.
2/5/07, 7/27/07, 5/27/08, 12/22/09, 6/17/10, 9/9/10, 4/20/11,6/15/11	On each of these dates, Dr. Morgan wrote renewal prescriptions for Lorcet, Oxy IR5, oxycodone, Percocet, and/or Xanax without having seen the patient.
4/19/05	Dr. Morgan noted that the patient was taking excessive amounts of Percocet, but took no action to address this and in fact increased the daily dose at the patient’s next visit.
5/18/06, 7/24/06, 7/12/07, 3/31/08, 5/27/08, 6/15/11, 9/29/11, 11/1/11, 2/23/12,3/21/12,	On each of these dates, Dr. Morgan wrote renewal prescriptions for Percocet, Oxy IR5, Roxicodone, morphine sulfate, Dilaudid, and/or Xanax without having seen the patient.

The Board also found that Dr. Morgan failed to take any corrective action after learning that some of his patients used multiple pharmacies to have their prescriptions filled. In one

<sup>609</sup> The due diligence file from AmerisourceBergen’s 2011 review of Westside Pharmacy did not include the 2008 consent order involving Dr. Morgan, even though Dr. Morgan was one of six physicians listed on a document entitled “Westside Pharmacy Pain Doctors.”

<sup>610</sup> *In re: David Lee Morgan, D.O.*, Order, 6 -7 (Va. Bd. of Med., Mar. 24, 2014) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order03242014.pdf>.

instance, the Board noted “Dr. Morgan failed to take corrective action when presented with information that Patient H had utilized at least eleven (11) different pharmacies in at least three (3) states to obtain his narcotic and benzodiazepine prescriptions authorized by Dr. Morgan between 2008 and 2011.”<sup>611</sup>

The Committee asked AmerisourceBergen whether it took Dr. Morgan’s history of disciplinary action into account when it was performing due diligence on Westside Pharmacy in late 2015 and early 2016, and to provide any due diligence material that would document any such consideration.<sup>612</sup> In response, AmerisourceBergen stated “[r]egarding Dr. Morgan, the file contains licensure information, a follow-up exchange with Westside Pharmacy regarding Dr. Morgan’s licensure, and multiple disciplinary records.”<sup>613</sup> AmerisourceBergen went on to state, “ABDC reviewed those records for Dr. David Morgan and considered his disciplinary record.”<sup>614</sup>

In a one-page Customer Due Diligence Questionnaire Checklist included in the due diligence file and described by the company as “[a] record of the review conducted on the due diligence file[,]”<sup>615</sup> AmerisourceBergen indicated that it performed due diligence on the pharmacy’s high prescribing physicians and verified the distance between the pharmacy and prescribers.<sup>616</sup> The Customer Due Diligence Questionnaire Checklist stated:

<u>Prescribers</u>	
<input type="checkbox"/>	Start-up entity
<input checked="" type="checkbox"/>	Due Diligence has been completed on listed high prescribing physicians (verify DEA, verify state license and board actions)
<input checked="" type="checkbox"/>	Verified Suspect Prescriber List
<input checked="" type="checkbox"/>	Verified distance between prescribers and pharmacy

Despite the indication on this document, however, the due diligence documents produced to the Committee give no indication that AmerisourceBergen actually considered the distances between Westside Pharmacy and its prescribing physicians. As mentioned earlier, Drs. Morgan and Mehta were located approximate four-hour round-trip drives from Westside Pharmacy. The DEA has identified a pharmacy filling prescriptions written by physicians located significant distances from the pharmacy as being a red flag of diversion.<sup>617</sup>

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<sup>611</sup> *In re: David Lee Morgan, D.O.*, Order, 3 (Va. Bd. of Med., Mar. 24, 2014) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order03242014.pdf>.

<sup>612</sup> E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>613</sup> E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

<sup>614</sup> *Id.*

<sup>615</sup> *Id.*

<sup>616</sup> AmerisourceBergen Corp., Customer Due Diligence Questionnaire Checklist – Westside Pharmacy, Jan. 11, 2016 (On file with Committee).

<sup>617</sup> See 77 Fed. Reg. 62,321, Oct. 12, 2012 (In the order, the DEA Administrator adopted the ruling of the DEA ALJ that found expert testimony credible that prescribing doctors located more than 200 miles from pharmacies were red flags that were not resolvable and controlled substances should not have been dispensed by the pharmacies.).



**FINDING:** In December 2015, when Westside Pharmacy submitted a prospective customer application to AmerisourceBergen, two of the pharmacy's top prescribers of opioids were located four-hour round-trip drives from the pharmacy.

During two separate prospective customer reviews, AmerisourceBergen was provided with information regarding some of Westside Pharmacy's prescribing physicians that should have raised serious red flags for the company. Had the company examined these red flags and sought an explanation from the pharmacy in 2011, it may have reached a different conclusion regarding the pharmacy's initial new customer application. When AmerisourceBergen received Westside Pharmacy's new customer application in December 2015, it should have examined its prior history with the pharmacy. Had the company done so, it would have seen that the pharmacy had a history of supplying opioids to distant physicians with disciplinary and criminal histories related to improper prescribing, and that the company itself took previous action to limit the pharmacy's ability to order controlled substances. While such a retrospective review should be standard due diligence practice, the factors presented to AmerisourceBergen in 2015 and 2016 alone provided the company with a more than sufficient basis for it to have reached a different conclusion regarding Westside Pharmacy's application.

*e. Case Study on H.D. Smith: Analyzing a Prospective Customer's Existing Due Diligence File*

In the course of this investigation, the Committee identified many instances where a distributor received a new customer application from a pharmacy that a distributor had a preexisting relationship with, either as a former customer or as a past applicant. In such situations, consulting the existing due diligence files for the pharmacy may provide a distributor with important background information, aiding a distributor's ability to assess the pharmacy's current new customer application. This is especially so in situations where—unlike other case studies in this section where the due diligence files from previous encounters were incomplete—the due diligence files maintained by a distributor indicate that it had previously identified red flags related to the pharmacy's dispensing practices or had documented action taken to restrict a pharmacy's ability to purchase controlled substances.

Family Discount Pharmacy, located in Mount-Gay Shamrock, West Virginia, had a population of 1,779 in 2010.<sup>618</sup> H.D. Smith was one of multiple distributors that supplied Family Discount Pharmacy, which received more than 16.59 million dosages of hydrocodone and oxycodone from all distributors between 2006 and 2016.<sup>619</sup> Between December 2007 and February 2011, H.D. Smith supplied Family Discount Pharmacy with more than 1.5 million doses of hydrocodone and oxycodone.<sup>620</sup> Between April 2015 and December 2016, H.D. Smith supplied Family Discount Pharmacy with an additional 628,020 doses of hydrocodone and oxycodone.<sup>621</sup>

<sup>618</sup> American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (<https://factfinder.census.gov>).

<sup>619</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>620</sup> *Id.*

<sup>621</sup> *Id.*



*i. H.D. Smith's First Encounter with Family Discount Pharmacy*

In December 2007, H.D. Smith entered into a business relationship with Family Discount Pharmacy in Mount-Gay Shamrock, West Virginia.<sup>622</sup> With respect to its 2007 decision to onboard Family Discount Pharmacy, H.D. Smith provided the Committee with a total of five pages of documents, consisting of: a three-page customer profile questionnaire; an affidavit from the pharmacy owner, affirming the pharmacy maintained controls to prevent diversion; and two photos of the pharmacy.<sup>623</sup>

According to documents produced to the Committee, between 2008 and 2009, H.D. Smith reported 109 orders from Family Discount Pharmacy to the DEA as suspicious.<sup>624</sup> In addition, in November 2009, the company noted in Family Discount's account file that a single doctor, Dr. Katherine Hoover, was responsible for writing 51 percent of the hydrocodone prescriptions filled by the pharmacy.<sup>625</sup> The account file stated:

11/12/09	LAK	Discussed acct with [REDACTED] Hydrocodone URL is static at 30,000 but acct continues to suspend. 51% of their scripts are being filled Dr. Katherine Hoover. Will continue to cancel any orders over URL.
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At the time, H.D. Smith was aware of Dr. Hoover's prescribing practices at other nearby pharmacies, which were also H.D. Smith customers. For example, H.D. Smith told the Committee:

[I]n February 2008, H.D. Smith requested, obtained, and evaluated dispensing and prescribing data from Hurley Drug Company ("Hurley Drug"), Tug Valley Pharmacy ("Tug Valley") and Strosnider Pharmacy d/b/a Save-Rite Pharmacy No. 1 ("Sav-Rite No. 1"). Upon completing its analysis, H.D. Smith determined that Dr. Katherine Hoover and Dr. Diane Shafer were frequently writing prescriptions for hydrocodone, and that these doctors' prescribing habits were cause for concern. H.D. Smith reported its concerns and its analysis to the DEA on April 25, 2008.<sup>626</sup>

<sup>622</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

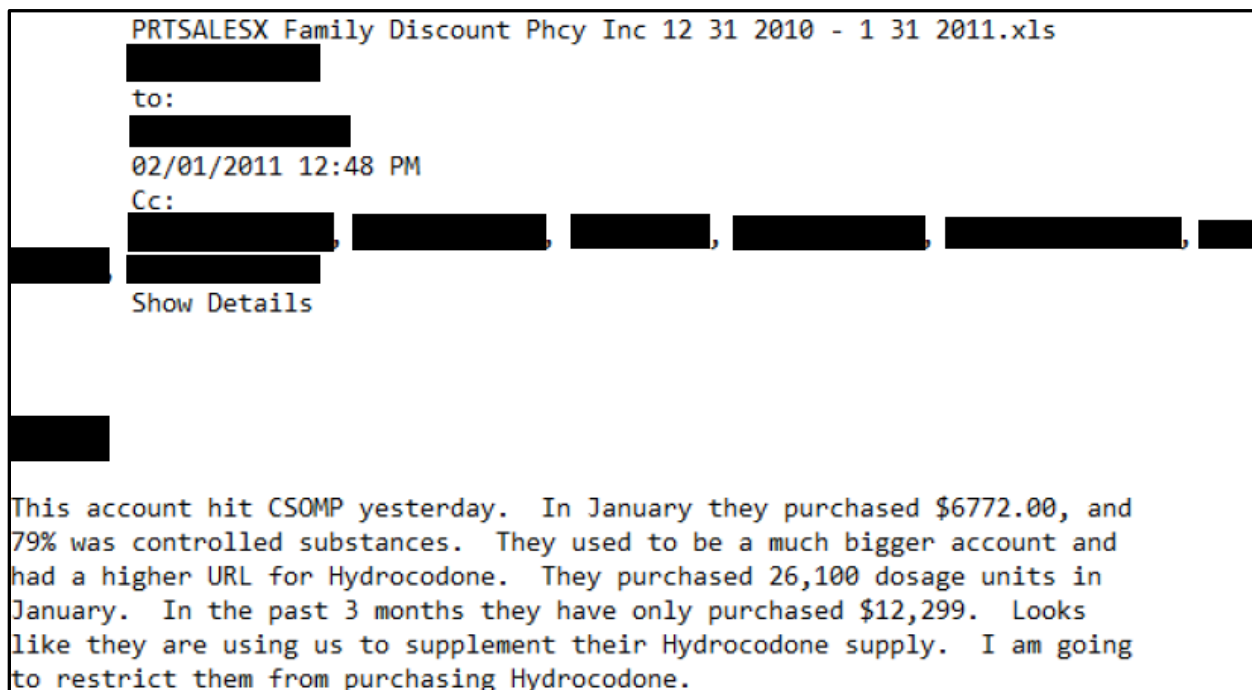
<sup>623</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>624</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>625</sup> More information on Dr. Katherine Hoover can be found at *infra* Section VI (B)(2)(c)(i).

<sup>626</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

In 2011, H.D. Smith suspended the pharmacy's ability to order hydrocodone; as a result, the pharmacy discontinued its relationship with H.D. Smith.<sup>627</sup> In a February 2011 e-mail supporting its decision to block the pharmacy's ability to order hydrocodone H.D Smith compliance staff indicated that, at the time, controlled substances constituted nearly 80 percent of the pharmacy's overall purchases and that it appeared that the pharmacy was using distribution from H.D. Smith to "supplement" its hydrocodone supply.<sup>628</sup> This e-mail is reproduced below:



The DEA has identified pharmacies "[o]rdering the same controlled substance from multiple distributors" as being a circumstance that might be indicative of diversion.<sup>629</sup>

With respect to its decision to restrict Family Discount Pharmacy from ordering hydrocodone, H.D. Smith told the Committee:

H.D. Smith's decision to block the account was based on a decrease in Family Discount's overall sales volume and was not based on diversion concerns. Specifically, H.D. Smith determined that the amounts being

<sup>627</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee); e-mail from Dir., Corporate Compliance and Security, H.D. Smith to Vice President, H.D. Smith (Feb. 1, 2011 12:48 pm) (On file with Committee).

<sup>628</sup> E-Mail from Dir., Corporate Compliance and Security, H.D. Smith, to Vice President, H.D. Smith (Feb. 1, 2011 12:48 pm) (On file with Committee).

<sup>629</sup> 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 Committee) and 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 Committee).

purchased by Family Discount were inconsistent with its historical sales volume, and H.D. Smith subsequently determined that Family Discount had transitioned to another primary wholesaler. As such, the decision to terminate the relationship with Family Discount was an administrative one.<sup>630</sup>

This statement, however, does not appear to be consistent with H.D. Smith's November 2009 finding that 51 percent of the pharmacy's hydrocodone was prescribed by one doctor, whom the company previously reported its concerns about to the DEA.

**FINDING: In February 2011, H.D. Smith suspended Family Discount Pharmacy's ability to order hydrocodone, after controlled substances constituted nearly 80 percent of the pharmacy's overall purchases the month prior.**

*ii. H.D. Smith's Second Encounter with Family Discount Pharmacy*

In April 2015, H.D. Smith approved a new application from Family Discount Pharmacy to purchase controlled substances.<sup>631</sup> H.D. Smith's decision was made upon completion of its prospective customer due diligence review which included license verifications for pharmacy personnel and prescribing doctors as well as any disciplinary history, an evaluation of the pharmacy's dispensing data, and a site visit to the pharmacy.<sup>632</sup>

In the customer profile questionnaire that Family Discount Pharmacy provided to H.D. Smith, the pharmacy disclosed that McKesson had restricted its ability to purchase controlled substances in the past, citing the pharmacy's hydrocodone ordering volume when compared to the population.<sup>633</sup> The customer profile questionnaire is reproduced in relevant part below:

6. Is identification required to pick up a controlled substance prescription?  Yes  No

7. Has any supplier restricted your purchases of controlled substances?  Yes  No

If yes, list supplier and please explain McKesson - our hydrocodone levels exceeded what ~~the~~ the review regulatory guy said was based on the size of our town. At time it was 83,000

In a full-page handwritten note that was included with the due diligence materials provided to the Committee, the pharmacy appears to have continued its explanation associated with McKesson's decision to restrict its ability to purchase controlled substances. The pharmacy stated, among other things, "[t]his past January we had 10 days of over 1000Rx's filled[,] and

<sup>630</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>631</sup> E-Mail from Vice President, Corporate Compliance & Security, H.D. Smith LLC, to Senior Regulatory Compliance Analyst, H.D. Smith (Apr. 22, 2015 5:26 pm) (On file with Committee).

<sup>632</sup> See H.D. Smith Wholesale Drug Co., Customer Profile Management Checklist– Family Discount Pharmacy, Mar. 10, 2015 (On file with Committee); See also H.D. Smith Wholesale Drug Co., Due Diligence Notes– Family Discount Pharmacy (On file with Committee).

<sup>633</sup> H.D. Smith Wholesale Drug Co., Customer Profile– Family Discount Pharmacy, Mar. 10, 2015 (On file with Committee).

noted that it had been recently been terminated by Miami-Luken.<sup>634</sup> The note is reproduced in its entirety below:

We have had no problems or violations either with the state or DEA but he said according to the population on last census we should not be doing the kind of volume we are. We have been the only surviving independent pharmacy in our area & have built up a large customer base but he refused to listen & said he was only concerned with the total number. This past January we had 10 days of over 1000 Rx's filled. These numbers put us with a high volume but we also have high volume for NON-contrals, Our percentage is probably average for our area, & less than several of the pharmacies McKesson sells to in adjacent towns but they are not big volume stores. We fill more than double any other store except Wal-Mart which does about 70% of what we do.

2) Miami Luken took us on when McKesson cut us off & they cut us off this week due to what they say was we did not tell them McKesson cut us off. They asked for documents of who else we were ordering from & when we went in McKesson last month of 2010 they were upset & said they didn't know about McKesson. (I told the salesman this beforehand but the regulatory officer said it was not conveyed to him so we were in breach of contract)

In addition to reviewing the pharmacy's questionnaire, H.D. Smith also conducted a site visit to Family Discount Pharmacy in April 2015. A document summarizing this site visit noted

<sup>634</sup> H.D. Smith Wholesale Drug Co., Due Diligence Notes— Family Discount Pharmacy (On file with Committee).

the pharmacy was located across the street from a Rite Aid and a Kroger grocery store.<sup>635</sup> Considering the apparent high volume of prescriptions and the pharmacy's close proximity to two other pharmacies, the Committee asked H.D. Smith whether it made any further inquiry to the pharmacy's representation that it had "10 days of over 1000 Rx's" in January 2015.<sup>636</sup> In response, H.D. Smith told the Committee, "H.D. Smith did analyze dispensing information available at that time (as referenced above), and did not identify any issues that presented cause for concern."<sup>637</sup> The dispensing information H.D. Smith produced to the Committee was for February 2015; based on the documents produced to the Committee, it does not appear that H.D. Smith analyzed or asked about the pharmacy's representation that it had "10 days of over 1000 Rx's" in January 2015.

**FINDING: In 2015, Family Discount Pharmacy disclosed to H.D. Smith that it had "10 days of over 1000 Rx's filled" in January 2015. The dispensing volume was despite the pharmacy's location across the street from two other pharmacies in a town of less than 2,000 people.**

The February 2015 dispensing information was mentioned in the summary of the April site visit. In this report, H.D. Smith also identified issues that presented cause for concern regarding the pharmacy's controlled substance dispensing, including multiple prescriptions with concerns combinations of drugs, and one prescription with a seemingly excessive quantity of oxycodone.<sup>638</sup> The site visit report states:

The dispensing report obtained from Pro Compliance for February 2015 was then reviewed with [REDACTED] [REDACTED] was shown some instances of commonly abused combinations, cases of multiple IR prescriptions and a couple of cases of methadone being prescribed with an IR. [REDACTED] was interested and concerned with this information. In some cases he took notes and left the conference room to find out what the patient's diagnosis was. In one case, a patient was prescribed 392 dosage units of oxycodone 30 mgs. [REDACTED] researched and conveyed that the patient had a blown ACL, torn meniscus and bulging disc in their back. We commented that the quantity still seemed high and that at a minimum he should be following up with the physician, questioning the quantity and documenting the response. In another case he

The site visit report also documented that the co-owner of Family Discount Pharmacy disclosed that the pharmacy had been terminated by McKesson and Miami-Luken, citing the pharmacy's hydrocodone ordering volume with respect to McKesson's decision. The site visit report states:<sup>639</sup>

<sup>635</sup> H.D. Smith Wholesale Drug Co., Due Diligence Notes– Family Discount Pharmacy (On file with Committee).

<sup>636</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to H.D. Smith Wholesale Drug Co. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>637</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>638</sup> H.D. Smith Wholesale Drug Co., Due Diligence Notes– Family Discount Pharmacy (On file with Committee).

<sup>639</sup> *Id.*



█████ was asked about his current wholesaler and explained that he had used McKesson for some time but that McKesson dropped him because his hydrocodone quantities were high – when they hired “that new guy that came from DEA”. Assume he is referring to ██████ but not confirmed. ██████ said he tried to explain that he has a large pharmacy and that the hydrocodone quantities were in line with all other non-controlled dispensing but that McKesson only cared about the number.

He then went with Miami Luken who dropped him approximately one month ago. Miami Luken had done a compliance review and learned during that review that McKesson had dropped them previously. ██████ indicated he had conveyed the history to the Sales Rep originally but ██████ assumes the Sales Rep never conveyed it to the corporate office.

In addition, the summary of the April 2015 site visit also noted that H.D. Smith had restricted Family Discount’s ability to purchase hydrocodone in 2011, stating.<sup>640</sup>

In reviewing our files, it appears that this account was a previous H. D. Smith customer that had been cut off in 2011 as a result of hitting the hydrocodone URL. The reason given in the file was that the robotic dispensing system needed to be filled and that would require them to order an increased quantity. When ██████ was questioned about that he seemed bewildered and noted that using those machines shouldn’t cause an order increase; he didn’t recall that information being conveyed.

**FINDING: When H.D. Smith onboarded Family Discount Pharmacy for a second time in 2015, the pharmacy had recently been terminated by two other wholesale distributors – with the pharmacy disclosing that one termination was based on the volume of the pharmacy’s hydrocodone orders.**

However, the statement in this April 2015 report that Family Discount Pharmacy “had been cut off in 2011 as a result of hitting the hydrocodone URL” is not consistent with H.D. Smith’s statement to the Committee that the 2011 “decision to block the account was based on a decrease in Family Discount’s overall sales volume and was not based on diversion concerns” and that the decision to terminate the account was “administrative.”<sup>641</sup>

The Committee asked H.D. Smith whether it took its prior engagement with the pharmacy into account when it was conducting its review of Family Discount in 2015.<sup>642</sup> In response, the company said, “H.D. Smith did take into consideration Family Discount’s prior engagement with the Company, including the 2011 decision to suspend the pharmacy’s ability to purchase hydrocodone.”<sup>643</sup> Beyond the excerpt referenced above, however, the Committee has not seen any documentation that would illustrate H.D. Smith’s consideration of its prior

<sup>640</sup> *Id.*

<sup>641</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>642</sup> E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to H.D. Smith Wholesale Drug Co. (July 23, 2018 3:13 pm) (On file with Committee).

<sup>643</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

engagement with Family Discount Pharmacy, including the pharmacy's prior history of filling prescriptions written by Dr. Hoover.

Following the April 2015 site visit, and despite the information reviewed during the due diligence process, H.D. Smith approved Family Discount Pharmacy as a customer after receiving the pharmacy's updated policies and procedures for controlled substance dispensing.<sup>644</sup>

H.D. Smith supplied Family Discount Pharmacy with controlled substances until February 16, 2018, at which time it blocked Family Discount Pharmacy from ordering controlled substances.<sup>645</sup> This action was taken by H.D. Smith three weeks after receiving a letter from the Committee wherein the Committee requested information regarding H.D. Smith's relationship with Family Discount Pharmacy as well as other West Virginia pharmacies.<sup>646</sup>

Had H.D. Smith meaningfully reviewed its due diligence file on Family Discount Pharmacy when evaluating the pharmacy's application in 2015, it would have identified that, at one point, 51 percent of the pharmacy hydrocodone prescriptions were written by a single doctor whom the company had documented concerns about. Such information would be highly relevant in any prospective customer review but more so in this instance given that the pharmacy's application to H.D. Smith came after its ability to purchase controlled substances had been terminated by two other distributors.

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The case studies examined above demonstrate the importance of conducting meaningful due diligence on prospective customers. As suggested by the DEA in the *Masters* final order, conducting meaningful due diligence requires active engagement on the part of a distributor and cannot be accomplished merely through the pharmacy's completion of a new customer questionnaire or through the submission of any requested data.

Rather, in order to effectively reduce the potential for the diversion of controlled substances, a distributor must critically analyze and follow up on any red flags it may identify through the due diligence process. Effective due diligence can only be accomplished if a distributor maintains and consults due diligence files it records throughout its relationship with a pharmacy, even if the relationship is limited to the review of a pharmacy's prospective customer application. If due diligence files are maintained by a distributor yet not meaningfully consulted, this inhibits the ability to conduct meaningful due diligence.

Moreover, in the case studies examined above, the red flags that were either missed, not followed up on, or seemingly not meaningfully considered were associated with pharmacies in

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<sup>644</sup> E-Mail from Vice President, Corporate Compliance & Security, H.D. Smith LLC, to Senior Regulatory Compliance Analyst, H.D. Smith (Apr. 22, 2015 5:26 pm) (On file with Committee); H.D. Smith Wholesale Drug Co., Due Diligence Notes— Family Discount Pharmacy (On file with Committee).

<sup>645</sup> H.D. Smith Wholesale Drug Co., Due Diligence Notes – Family Discount Pharmacy, Aug. 2015 – Feb. 2018 (On file with Committee).

<sup>646</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. to J. Christopher Smith, President and CEO, H.D. Smith, Jan. 26, 2018 *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126HDSmith.pdf>.

West Virginia, a segment of the country that distributors should have been acutely aware struggled with prescription drug abuse. This is especially so for the case studies that examined the actions distributor undertook with respect to prospective customer due diligence as late as 2015 and 2016, after distributors represented they implemented and enhanced their policies and procedures for prospective customer due diligence.



## **B. The Use of Drug Thresholds by Wholesale Drug Distributors**

### **1. The Legal Framework and Distributor Policies Regarding Drug Thresholds**

Federal regulations require wholesale distributors to design and implement systems to report customers' suspicious orders as a way to recognize and prevent drug diversion.<sup>647</sup> Regulations outlining requirements for manufacturers, distributors and dispensers of controlled substances were issued by Bureau of Narcotics and Dangerous Drugs in 1971 in furtherance of the objectives of the CSA.<sup>648</sup> These regulations include:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.<sup>649</sup>

Neither federal regulations nor the DEA, however, require distributors to use any particular method or system to flag those orders. As a result, individual distributors have designed and implemented their own unique detection systems to flag suspicious orders, which are defined as orders of unusual size, frequency, or those that deviate substantially from typical ordering patterns.<sup>650</sup>

A common system devised by wholesale distributors to prevent controlled substance diversion utilizes thresholds or parameters, which limit the amount of controlled substances in a specific drug family that an individual pharmacy may receive each month.<sup>651</sup> For instance, all drugs that contain hydrocodone would be counted against the threshold established for the hydrocodone drug family.<sup>652</sup> Threshold systems are meant to combat diversion by setting a baseline purchase pattern for monitoring controlled substances that allows a distributor to know

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<sup>647</sup> 21 C.F.R. 1301.74(b).

<sup>648</sup> 21 C.F.R. 1301.74.

<sup>649</sup> 21 C.F.R. 1301.74(b).

<sup>650</sup> *Id.* However, the definition of "suspicious" is not limited to orders of unusual size, frequency, or those that deviate substantially from typical ordering patterns. Pursuant to a 2015 order issued by the DEA's Acting Administrator, which has been upheld by the United States Court of Appeals for the District of Columbia Circuit, a pharmacy could have characteristics that "might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency." 80 Fed. Reg. 55,417, Sept. 15, 2015; *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).

<sup>651</sup> See Letter from Counsel to AmerisourceBergen Corp. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017, (On file with Committee); Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce et al., June 30, 2017, (On file with Committee).

<sup>652</sup> Some distributors have indicated that they established separate drug family thresholds for certain strengths of commonly abused drugs, such as 30mg oxycodone. See Letter from Counsel to AmerisourceBergen to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee); McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, Jan. 6, 2017 (On file with Committee).

when customers deviate substantially from their normalized ordering pattern.<sup>653</sup> When an order hits a pharmacy’s threshold for a particular drug family, all shipments within that drug family are held for evaluation.<sup>654</sup> Under such a threshold system, a distributor would then undertake a review to decide whether the drug order qualifies as suspicious, and should be cancelled and reported to the DEA and any applicable state regulator, or if there are legitimate reasons for meeting the threshold and should be released.<sup>655</sup> Orders that hit thresholds but are not reported to the DEA may include those that include entry errors.<sup>656</sup>

Distributors that have threshold systems regard them as an important part of their suspicious order monitoring programs.<sup>657</sup> Not all distributors utilize threshold systems, however. According to a survey of DEA registrants released by the U.S. Government Accountability Office in 2015, only 62 percent of individual pharmacies reported doing business with distributors who limit their controlled substance orders through thresholds.<sup>658</sup> Thirty-six percent of independent pharmacies reported that distributors had not set thresholds on the quantity of drugs they could order. Chain pharmacies were more likely to be subject to thresholds, as 91 percent indicated they were subject to drug thresholds.<sup>659</sup>

The DEA does not require registrants to utilize a threshold system, though in the late 1990s, the DEA attempted to develop parameters that distributors could use to identify suspicious orders. A report issued in 1998 by the DEA’s Suspicious Order Task Force created a baseline system that could be used by distributors to identify suspicious orders.<sup>660</sup> The system calculated a baseline using an equation that took into account the quantity of drugs purchased by all customers from a single distribution center in the last 12 months as well as an individual customer’s monthly drug purchases.<sup>661</sup> At the end of each month, the reporting system would create reports for any customer whose purchases “exceed the acceptable parameters in the ‘baseline’ system in two (2) consecutive months or in three (3) of any moving six (6) month

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<sup>653</sup> See, e.g. Cardinal Health Inc., Process to establish SOM threshold limits, (Jan. 29, 2010) (On file with Committee).

<sup>654</sup> See, e.g. McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, Jan. 6, 2017 (On file with Committee); Cardinal Health Inc., Standard Operating Procedure, Detecting and Reporting Suspicious Orders and Responding to Threshold Events (Oct. 17, 2016) (On file with Committee).

<sup>655</sup> See, e.g. *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 6 (2018) (statement of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.); AmerisourceBergen, Diversion Control Program Policies and Procedures OMP Methodology, Jan. 1, 2017 (On file with Committee).

<sup>656</sup> See, e.g. Cardinal Health Inc., Detecting and reporting suspicious orders and responding to threshold events (Apr. 12, 2012) (On file with Committee).

<sup>657</sup> See, e.g. Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee).

<sup>658</sup> U.S. Gov’t Accountability Office, Prescription Drugs: More DEA Information about Registrants Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 at 27 (June 25, 2015), available at <https://www.gao.gov/assets/680/671032.pdf>.

<sup>659</sup> U.S. Gov’t Accountability Office, Prescription Drugs: More DEA Information about Registrants Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 at 72 (June 25, 2015), available at <https://www.gao.gov/assets/680/671032.pdf>.

<sup>660</sup> U.S. Drug Enforcement Admin., *Report to the U.S. Attorney General*, Oct. 1998 (On file with Committee).

<sup>661</sup> *Id.*

period.”<sup>662</sup> In more recent years, DEA has indicated that it will not endorse any specific suspicious order monitoring program.<sup>663</sup> In a written response to the 2015 GAO report, DEA stated:

DEA would like to emphasize that it has no authority to control otherwise legitimate business decisions of registrants. As a result, DEA cannot direct how distributors conduct their businesses, including the amount of controlled substances lawfully distributed or dispensed to customers, i.e., pharmacies and practitioners. In addition, DEA and our state partners have repeatedly and emphatically informed distributors that arbitrary thresholds are inappropriate, negatively impact legitimate patients, and are an inadequate substitute for fulfilling their obligations under the CSA.<sup>664</sup>

Distributors’ own threshold systems have evolved since then. Distributors that use thresholds incorporate a wide variety of factors into their systems, including a pharmacy customer’s size, whether the customer is a chain or independent pharmacy, the customer’s own order history, and the order history of similarly-sized pharmacies across varying geographical areas.<sup>665</sup> To establish thresholds today, several distributors indicated they rely on data analytics or algorithms that provide in-depth analysis and comparison of pharmacy customers.<sup>666</sup>

*a. AmerisourceBergen’s Threshold Policies*

AmerisourceBergen began using a daily order monitoring program in the 1980s; in 2007, the company made “significant enhancements to that program in consultation with the DEA.”<sup>667</sup> Updates to the company’s order monitoring program came after AmerisourceBergen entered into a settlement agreement with the DEA regarding allegations that it failed to maintain effective controls against diversion of controlled substances.<sup>668</sup> The terms and conditions of the settlement stipulated that, among other things, AmerisourceBergen would “maintain a compliance program designed to detect and prevent diversion of controlled substances,” and that it would “inform

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<sup>662</sup> *Id.*

<sup>663</sup> 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 Committee).

<sup>664</sup> U.S. Gov’t Accountability Office, Prescription Drugs: More DEA Information about Registrants Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471, 77 (June 25, 2015) (Appendix IV, Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin., to Linda T. Kohn, Dir., Health Care, U.S. Gov’t Accountability Office, May 29, 2015) available at <https://www.gao.gov/assets/680/671032.pdf>.

<sup>665</sup> Distributors provided threshold policies and procedures that described a multitude of factors each company considers. *See e.g.* AmerisourceBergen Corp., *Diversion Control Program Policies and Procedures, Customer Peer Group Maintenance, Policy number: DCP-12.1.0*, Jan. 1, 2017 (On file with Committee).

<sup>666</sup> *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 8, 2017 (On file with Committee); Cardinal Health Inc., Process to establish SOM threshold limits, (Jan. 29, 2010) (On file with Committee).

<sup>667</sup> Letter from Counsel to AmerisourceBergen, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Mar. 19, 2018 (On file with Committee).

<sup>668</sup> *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with Committee).

DEA Headquarters of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters.”<sup>669</sup>

AmerisourceBergen described the 2007 system:

Beginning in 2007, ABDC established a system to compare the purchases by pharmacies and hospitals against their peers to identify orders that were then held for additional review (“Orders of Interest”). If, based on that review, ABDC determined the order was of unusual size, deviated substantially from a normal pattern, or was of unusual frequency, the order was reported to DEA and was not shipped.<sup>670</sup>

AmerisourceBergen’s 2007 Controlled Substance and Listed Chemical Order Monitoring Program (OMP) policy outlined numerous threshold procedures, including:<sup>671</sup>

- “Each customer will have a threshold established based on the customer’s DEA Business Type, Customer Size, and Generic Code Number (GCN) “Item Family.” An “Item Family” will represent a grouping of GCNs that will be monitored. All controlled substances and listed chemicals will be grouped into item families.”<sup>672</sup>
- “The order quantity for controlled substances or listed chemicals will be compared against the threshold and the Customer’s accumulated order quantity for the month.”<sup>673</sup>
- “ABC will calculate the customer’s monthly usage and allow the customer to purchase up to a specific threshold. Once the quantity ordered exceeds the threshold, the order will be placed on OMP Hold for review.”<sup>674</sup>
- “Order quantities that are under the threshold will process normally. Order quantities for items that are not Controlled Substances or Listed Chemicals will process normally.”<sup>675</sup>
- “Once an order quantity for an Item Family is in OMP Hold for review, any subsequent orders for an item within that Item Family will be

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<sup>669</sup> *Id.*

<sup>670</sup> Letter from Counsel to AmerisourceBergen, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>671</sup> AmerisourceBergen Corp., Controlled substance and listed chemical order monitoring program (OMP), June 30, 2007 (On file with Committee).

<sup>672</sup> *Id.*

<sup>673</sup> *Id.*

<sup>674</sup> *Id.*

<sup>675</sup> *Id.*

rejected. The order quantity on OMP Hold will be released or canceled pending the completion of the review process.”<sup>676</sup>

- “Customers who have legitimate needs will have their size or thresholds increased. Customers with suspicious ordering patterns may have their ability to order control substances turned off or the account may be shut down completely.”<sup>677</sup>

AmerisourceBergen undertook another comprehensive review of its diversion control program in 2014. According to the company, “[t]his resulted in the roll-out of an enhanced diversion control and order monitoring program beginning in August 2015, which remains in place today.”<sup>678</sup> AmerisourceBergen’s current order monitoring program evaluates customers’ drug orders by cumulative volume parameters and order size parameters, and it also establishes a fail-safe parameter.<sup>679</sup> Orders that exceed either the cumulative volume parameter and the order size parameter or the fail-safe parameter are automatically held for review and investigation as “orders of interest.”<sup>680</sup> According to the current policies, orders of interest are reviewed either at the distribution center or escalated to the Diversion Control Team for review.<sup>681</sup> Orders can be rejected as administrative errors and not reported as suspicious, rejected and reported as suspicious to the DEA and state authorities, or released and processed for shipment.<sup>682</sup>

#### **b. Cardinal Health’s Threshold Policies**

Before formal standard operating procedures (SOP) were adopted, Cardinal complied with its order monitoring obligations by having distribution center employees “identify any orders that appeared excessive in relation to what other customers were buying and/or the customer’s purchase history.”<sup>683</sup> The company also submitted monthly “Ingredient Limit Reports” to the DEA. According to Cardinal, “[t]he reports were generated based on a computer algorithm established by the DEA, which was meant to be used to calculate the quantity which, if exceeded in one month, constituted an order which may be excessive or suspicious.”<sup>684</sup> In December 2008, Cardinal implemented SOPs, which outline its processes for setting customer thresholds, among other policies.<sup>685</sup>

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<sup>676</sup> *Id.*

<sup>677</sup> *Id.*

<sup>678</sup> Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Mar. 19, 2018 (On file with Committee).

<sup>679</sup> *Id.*

<sup>680</sup> AmerisourceBergen Corp., Diversion Control Program Policies and Procedures OMP Methodology, Jan. 1, 2017 (Emphasis in original) (On file with Committee).

<sup>681</sup> AmerisourceBergen Corp., Diversion Control Program Policies and Procedures OMP Methodology, Jan. 1, 2017 (On file with Committee).

<sup>682</sup> *Id.*

<sup>683</sup> Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

<sup>684</sup> *Id.*

<sup>685</sup> *See* Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

Cardinal described its threshold system as functioning in 2008 as follows:

As part of this new system, Cardinal Health began establishing custom thresholds for controlled substance distribution for all customers based on the customer's size and class of trade, using historical controlled substance ordering data for all customers. The system was designed to alert analysts automatically whenever a customer's order volume exceeded its assigned threshold. All orders that triggered threshold events were held and reviewed to determine whether the order was justified or was suspicious. Orders that were determined to be suspicious were not shipped.<sup>686</sup>

Cardinal's policies from the time indicate that when a customer hit a threshold, Cardinal's Quality and Regulatory Affairs (QRA) division and sales team evaluated the threshold event.<sup>687</sup>

In May 2012, Cardinal reached a settlement related to allegations raised by the DEA regarding a Florida distribution center that required it to update or implement new policies. A memorandum of agreement Cardinal signed as part of the settlement required Cardinal to, among other things, adopt new processes for increasing thresholds, and establish a Large Volume – Tactical and Analytical Committee (LV-TAC) to review high volume customers.<sup>688</sup>

The memorandum of agreement described the LV-TAC requirement:

Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The Committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.<sup>689</sup>

The memorandum of agreement also described the new threshold policies, which require two-person concurrence before certain thresholds can be raised:

Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve

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<sup>686</sup> Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

<sup>687</sup> Cardinal Health Inc., standard operating procedures, Sales – threshold event, (Dec. 22, 2008) (On file with Committee).

<sup>688</sup> *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012 (On file with Committee).

<sup>689</sup> *Id.*

threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.<sup>690</sup>

Cardinal issued new policies regarding the LV-TAC in April 2012. The responsibilities of the LV-TAC included “periodic review and scrutiny of large purchasers of commonly diverted Controlled Substances or other drugs of interest,” assessing the “potential risk for diversion” posed by certain customers, and deciding to “continue or terminate the ability of customers to purchase controlled substances,” among other responsibilities.<sup>691</sup>

Though Cardinal agreed to require two-person concurrence for large controlled substance purchases as part of the 2012 agreement, the first SOP policy identified by the Committee that explicitly outlines that requirement was issued in 2016.<sup>692</sup> The policy stated that two-person concurrence is required when drug thresholds for certain drug families were increased above 20,009 doses and 40,009 doses. When asked which controlled substances require two-person approval, Cardinal said it now requires two-person concurrence for all controlled substance drug families once they reach certain threshold levels.<sup>693</sup>

*c. McKesson's Threshold Policies*

In 2007, McKesson implemented a threshold program it called the “Lifestyle Drug Monitoring Program,” which initially set monthly thresholds at 8,000 dosages for four controlled substances—oxycodone, hydrocodone, alprazolam and phentermine.<sup>694</sup> The same dosage threshold was put in place for “all classes of customers.”<sup>695</sup> In an April 25, 2007 letter to the DEA, McKesson described how it developed the 8,000-a-month dosage threshold, stating, “[b]ased on a review of all McKesson pharmacy accounts and relying on estimates provided by DEA, this amount appears to be a conservative yet realistic threshold to begin the program.”<sup>696</sup>

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<sup>690</sup> *Id.*

<sup>691</sup> Cardinal Health Inc., Standard Operating Procedure, Large Volume – Tactical and Analytical Committee Periodic Review Process (Apr. 15, 2012) (On file with Committee).

<sup>692</sup> Cardinal issued updates of its LVTAC periodic review process in 2014 and 2015, but neither policy contained the two-person concurrence requirement. *See* Cardinal Health Inc., Standard Operating Procedure, Large Volume – Tactical and Analytical Committee Periodic Review Process (May 29, 2014) (On file with Committee) and Cardinal Health Inc., Standard Operating Procedure, Large Volume – Tactical and Analytical Committee Periodic Review Process (July 20, 2015) (On file with Committee).

<sup>693</sup> Letter from Counsel to Cardinal Health Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>694</sup> McKesson Corp. *Operations Manual, Lifestyle Drug Monitoring Program*, May 16, 2007 (On file with Committee). McKesson’s 2007 development of the lifestyle drug monitoring program was a product of negotiations with the DEA after the company received an OTSC from the DEA in August 2006, informing the company that the DEA was taking action to revoke the registration for the McKesson’s Lakeland, Florida distribution center for its failure to maintain effective controls against diversion and report suspicious orders to the DEA. *See* Letter from Counsel to McKesson Corp. to Linden Barber, Assoc. Chief Counsel, Office of Chief Counsel, U.S. Drug Enforcement Admin., Apr. 25, 2007 (On file with Committee).

<sup>695</sup> McKesson Corp., *Lifestyle Drug Monitoring Program*, May 16, 2007 (On file with Committee).

<sup>696</sup> *See* Letter from Counsel to McKesson Corp., to Linden Barber, Assoc. Chief Counsel, Office of Chief Counsel, U.S. Drug Enforcement Admin., Apr. 25, 2007 (On file with Committee).

This program established “a three-level escalating review system to conduct an evaluation when a customer exceeded its monthly threshold for any of these four controlled substances.”<sup>697</sup> McKesson described the three levels to the Committee:

Level I: The first level of review involved an analysis of previous purchases by the pharmacy. At this stage of the review process, McKesson’s evaluation could include internet research on the pharmacy and interviews of the account representative responsible for the pharmacy. In some cases, McKesson’s program contemplated telephonic interviews of the pharmacy owner to learn more about the circumstances surrounding the amounts that had been ordered. If McKesson was unable to conclude through this initial evaluation that the orders were reasonable or the review was inconclusive, McKesson was required to conduct a second level of review.

Level II: Under the terms of McKesson’s program manual, the second level review required a physical site visit to the pharmacy. During the site visit, the manual required McKesson to conduct an in-person interview of the owner using a standard questionnaire. McKesson personnel were also required to review relevant documentation during the site visit. If after conducting a review, McKesson resolved the outstanding issues, that determination was required to be documented and included in the files maintained for the pharmacy in question. If the results of the Level II review were still inconclusive, the program manual required a third level of review.

Level III: As provided in the program manual, the Vice President of the Regulatory Affairs department was responsible for the third level of review. Depending on the circumstances, this level of review could involve senior management and consultation with the legal department. The program manual also contemplated contact with local DEA and DEA headquarters, under certain circumstances, based on decisions related to the discontinuation of sales to the customer.<sup>698</sup>

While McKesson’s Lifestyle Drug Monitoring Program policy states that customers who exceed thresholds “must be evaluated to the legitimacy of their order quantity,” it does not state that orders exceeding thresholds should be blocked.<sup>699</sup>

In May 2008, McKesson finalized a \$13.25 million settlement with the DEA regarding its failure to report suspicious orders to the DEA and implemented its Controlled Substance Monitoring Program (CSMP). Under the 2008 program, McKesson would, for the first time,

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<sup>697</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee).

<sup>698</sup> *Id.*

<sup>699</sup> McKesson Corp., Lifestyle Drug Monitoring Program, May 16, 2007 (On file with Committee).



block any controlled substance orders that exceeded monthly thresholds.<sup>700</sup> McKesson told the Committee:

As part of the CSMP, McKesson implemented an order management system that assigned each pharmacy monthly thresholds for orders of controlled substances. Each month, under this system, a pharmacy's orders for controlled substances were monitored against the applicable thresholds. If an order exceeded an established monthly threshold, the order was automatically blocked and not shipped to the pharmacy. If an order was blocked because it exceeded the applicable threshold, the customer would be unable to order any additional products from the category or family of controlled substances (referred to as a "DEA base code") until the following month.<sup>701</sup>

This iteration of the program included a revised process to review pharmacies that exceeded monthly thresholds, requiring McKesson personnel to contact pharmacy staff during the first step of the review to determine the reason why a threshold was reached.<sup>702</sup> McKesson told the Committee:

McKesson's CSMP also implemented a revised three-level review process to evaluate pharmacies whose orders exceeded monthly thresholds. As provided by the CSMP, during the first level of review, McKesson personnel were required to contact the pharmacy to determine the reason why the applicable threshold had been reached. They were authorized to conduct additional analysis as appropriate. If the evaluation conducted during the first level of review was inconclusive, the review was escalated to Level II.

During the second level of review, McKesson's regulatory affairs team was expected to conduct additional due diligence to determine whether the pharmacy's ordering was appropriate. The second level of review could include a site visit, a customer interview, and other investigation or analysis as appropriate.

If the results of the second level of review raised issues of concern, the matter was required to be escalated to Level III. Once a matter reached Level III, McKesson blocked the pharmacy's ability to order controlled substances and the matter was required to be escalated to the Senior Vice President of Distribution Operations, among others, for review.<sup>703</sup>

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<sup>700</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee).

<sup>701</sup> *Id.*

<sup>702</sup> *Id.*

<sup>703</sup> *Id.*

The company updated its CSMP again in 2013, advancing its threshold analytics capabilities. The 2013 policies maintain the requirement that orders exceeding monthly thresholds are blocked.<sup>704</sup> With respect to thresholds, the changes made in 2013 included the addition of a program that used “complex data analytics to set and manage individual customer thresholds for certain controlled substances.”<sup>705</sup> CSMP policies from 2013 state that thresholds for existing customers were based on a review of purchases over a 12-month period.<sup>706</sup> The policies further state that existing customers “may request a re-evaluation or increase to their existing controlled substances threshold due to business requirements and/or an emergency situation” and that all change requests must be documented.<sup>707</sup>

McKesson also made additions to its CSMP as part of a 2017 settlement with the DEA. In a 2017 administrative memorandum of agreement, McKesson acknowledged that it did not identify or report certain orders placed by pharmacies that should have been detected as suspicious, as was required in the 2008 settlement.<sup>708</sup> According to a 36-page compliance addendum included in the 2017 settlement’s memorandum of agreement, McKesson was to make numerous updates to its threshold policies. One update called for in the addendum included implementation of new methodologies for calculating and establishing monthly customer thresholds:<sup>709</sup>

McKesson acknowledges that the CSMP it employs must be and remain effective in identifying and reporting suspicious orders, as required by the CSA and the implementing regulations. Prior to the Effective Date, McKesson implemented a system

for detecting suspicious orders that utilized monthly thresholds. After the Effective Date, McKesson intends to continue to utilize monthly thresholds to detect suspicious orders and report such orders to DEA. In addition, after the Effective Date, McKesson intends to implement enhanced methodologies to establish monthly thresholds which will take into account customer specific data and benchmark data for customers of similar sizes in specified geographic regions.

The compliance addendum to the memorandum of agreement also banned the McKesson sales department from having the final say over any threshold determinations:<sup>710</sup>

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<sup>704</sup> McKesson Corp., McKesson Operations Manual for Pharma Distribution - Controlled Substance Monitoring Program (Document created Feb. 11, 2008 and last revised Sept. 24, 2013) (On file with Committee).

<sup>705</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee).

<sup>706</sup> McKesson Corp., McKesson Operations Manual for Pharma Distribution - Controlled Substance Monitoring Program (Document created Feb. 11, 2008 and last revised Sept. 24, 2013) (On file with Committee).

<sup>707</sup> *Id.*

<sup>708</sup> *In re McKesson*, Administrative Memorandum of Agreement, Jan. 17, 2017 (On file with Committee).

<sup>709</sup> *In re McKesson*, Compliance Addendum, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928481/download>.

<sup>710</sup> *Id.*

McKesson agrees that the CSMP policies and procedures, however amended during the term of this Addendum, shall not authorize: (i) final threshold determinations to be made by any member of the McKesson Sales Department; or (ii) improper continuous temporary threshold increases in order to circumvent the threshold review investigation and due diligence process.

McKesson's 2017 CSMP guide for independent and small to medium chain retail pharmacies states that new start-up pharmacies are assigned default thresholds based on national average purchases by similarly sized customers. New customers that are not start-up pharmacies are assigned thresholds which are "either default thresholds or customer-specific thresholds established based on the customer's recent dispensing history as determined through the Customer Script and Dose Data Analyzer tool, and the overall due diligence evaluation of the customer as a part of the Customer Onboarding process."<sup>711</sup>

*d. H.D. Smith's Threshold Policies*

Prior to 2008, H.D. Smith "did not have specific dosage limits for any of its customers."<sup>712</sup> That changed in 2008 with the issuance of a new controlled substance order monitoring program (CSOMP) which outlined numerous policies, including the establishment of thresholds or unit reporting levels (URL) for customers.<sup>713</sup> Testing for H.D. Smith's CSOMP began in January 2008 and the system went live at H.D. Smith's Kentucky division, which distributed to West Virginia, in May 2008.<sup>714</sup>

H.D. Smith described how URLs were established under the CSOMP:

In the initial phase of H.D. Smith's program, the data for CSOMP was analyzed based on 28 drug families. Each of these drug families was then broken down by dosage type (e.g., oral, solids, liquids, injectables). Each customer was then placed into one of ten account classes based on monthly sales volume, ranging from \$0 to \$10,000 to \$1,000,000 plus. An algorithm was developed to calculate the average sales volume of each drug family within each sales volume class. In accordance with the guidance in the DEA's Chemical Handler's Manual, each average was subject to a 3x multiplier. The resulting unit reporting level ("URL") would then apply to that drug family for all customers in the sales volume class (absent a modification by H.D. Smith).

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<sup>711</sup> McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, Jan. 6, 2017 (On file with Committee).

<sup>712</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>713</sup> *Id.*

<sup>714</sup> *Id.*

If a customer exceeded its URL during a rolling 30-day period, that customer's order would be suspended and placed on the daily CSOMP report for review.<sup>715</sup>

The Corporate Security Procedures section of H.D. Smith's 2008 CSOMP outlines the procedures for daily reviews of suspended orders:<sup>716</sup>

A review of suspended and then released orders will be made to determine:

- Have orders been released according to guidelines set by the Director of Compliance and Security.
- Do any of the account's URLs need to be adjusted.
- Should division management be contacted reference any released orders.
- Is further investigation required.
- Should the released order be identified as suspicious and be reported to DEA.

A review of suspended orders will be made and contact with division management will be initiated. During discussions with division management the Diversion Investigator, with the assistance of the Director of Corporate Compliance and Security shall attempt to determine:

- Was there adequate reason to suspend the order.
- Is there a Customer Profile on file for the account.
- Is there dispensing information available.
- Is further investigation required.
- Do any of the account's URLs need to be adjusted.
- Are there any extenuating circumstances.
- Has division management contacted the account reference the suspended order.
- Should all or any part of the order be released.
- Should the order be cancelled.
- Should the order be identified as suspicious and reported to DEA.
- Do we continue to service the controlled substance needs of this account.
- Do we continue to service this account at all.

The Corporate Policy section of the CSOMP was updated in 2013 and provides a list of factors to be analyzed by Corporate Compliance before determining whether a unit reporting level may be adjusted. Those factors include:<sup>717</sup>

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<sup>715</sup> *Id.*

<sup>716</sup> H.D. Smith Wholesale Drug Co., Controlled Substance Order Monitoring Program (CSOMP Corporate Security Procedures, Mar. 22, 2008 (On file with Committee).

<sup>717</sup> H.D. Smith Wholesale Drug Co., Controlled Substance Order Monitoring Program (CSOMP) Corporate Policy, June 2, 2013, (On file with Committee).

- a. Analysis of dispensing information
  - i. Volume;
  - ii. Review of doctors;
  - iii. Drug cocktails;
  - iv. Abused drugs;
  - v. Percentage of Controlled Substances to all Rx.
- b. Analysis of purchase data.
  - i. Drug cocktails;
  - ii. Abused drugs;
  - iii. Percentage of Controlled Substances to all Rx.
- c. Size of account.
- d. Discussions with division personnel.
- e. Outside information.
- f. Review of Customer Profile.
- g. Any information discrepancies.

H.D. Smith told the Committee that it previously utilized URLs based on customers' purchase history or sales volume class but did not specify when it did away with this system. Instead, the company's CSOMP sets unit reporting levels for all drug families "based on the national sales averages for all of H.D. Smith's customer [sic] for the previous year. H.D. Smith compares the calculated URLs to national averages provided by the DEA."<sup>718</sup>

e. *Miami-Luken's Threshold Policies*

Miami-Luken did not implement a suspicious order monitoring (SOM) system until 2015. Before the system was implemented, the company's efforts at suspicious order monitoring were described by the Chairman of the Board as "rudimentary" in nature.<sup>719</sup> For example, prior to late 2012, Miami-Luken did not track the number of controlled substances it distributed to customers.<sup>720</sup> Instead the company tracked the percentage of controlled substance sales to overall pharmacy sales rather than the amount of controlled substances sold.<sup>721</sup>

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<sup>718</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>719</sup> Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce at 10, Dec. 13, 2017 (On file with Committee).

<sup>720</sup> See Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>721</sup> *Id.*

Miami-Luken described this practice to the Committee:

According to the former CEO and former Compliance Officer, the Company tracked the percentage of controlled substances to overall sales, rather than the total number of pills sold, until sometime in late 2012 when the Company started tracking pill quantities. Although the Company's IT department may have previously created a variety of reports that examined customer ordering by pill quantities, neither the Company's former CEO nor the Company's former Compliance officer recall ever seeing or using such reports prior to late 2012.<sup>722</sup>

In the course of its investigation, the Committee asked Miami-Luken about threshold policies or dosage order limits in place for specific pharmacies at various points in time.<sup>723</sup> In response to questions regarding the company's decision to increase the number of pills it shipped to Tug Valley Pharmacy by 350 percent between 2008 and 2009, Miami-Luken stated:

The Company had no formal policy in place at the time to trigger specific reviews as threshold amounts were increased. Rather, the Company addressed individual threshold increases on a case-by-case basis. It was common for the Company to talk directly with individual pharmacists to address issues and the rationale for requests for threshold increases.<sup>724</sup>

Similarly, in response to a question about any dosage threshold limit the company had for Colony Drug between December 2013 and February 2014, Miami-Luken responded, “[t]he Company does not maintain this data and is unable to provide the order dosage limit for the pharmacy in 2013 and early 2014.”<sup>725</sup>

Although Miami-Luken began tracking the quantity of controlled substances shipped to customers in 2012, the company's former President and CEO told the DEA in 2013 that it was not utilizing a threshold system. According to the DEA, “[w]hen asked about suspicious orders, [former President and CEO] said that Miami-Luken did not rely on a threshold system (to limit the amount of controlled substances a customer could order.) Instead, they used initial customer orders as a baseline.”<sup>726</sup> Miami-Luken's Chairman of the Board Dr. Joseph Mastandrea additionally told Committee staff during a transcribed interview that company employees independently interpreted what constituted a suspicious order.<sup>727</sup> While documents produced to

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<sup>722</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>723</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc. Jan. 26, 2018 (On file with Committee) *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126Miami-Luken.pdf>.

<sup>724</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>725</sup> *Id.*

<sup>726</sup> *In re Miami-Luken*, U.S. Drug Enforcement Admin., No. 16-13 (Jan. 15, 2016) (Government's Prehearing Statement) (On file with Committee).

<sup>727</sup> Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce at 10-11, Dec. 13, 2017 (On file with Committee).

the Committee reference an operations manual issued in 2000,<sup>728</sup> the Committee has not identified documents outlining policies or procedures from prior to 2013 that would aid employees in identifying suspicious orders.

In 2013, Miami-Luken purchased the Buzzeo suspicious order monitoring system.<sup>729</sup> According to Dr. Mastandrea, however, it was “ineffectual until 2015.”<sup>730</sup> A copy of Miami-Luken’s policies and procedures manual, which was produced in response to litigation in 2016, states that the Buzzeo system is used to “provide real time monitoring of our customers’ ordering behavior to identify statistically relevant deviations in our customers’ controlled substance and List 1 chemical orders.”<sup>731</sup>

The manual, issued in October 2015, appears to indicate that thresholds were being utilized.<sup>732</sup> A suspicious order monitoring policy included in the manual states:

All controlled substances orders and list 1 chemical orders are assessed by the system and if the algorithm (looking at order size, frequency, and pattern) determines that the order is suspicious, the Buzzeo System will ‘pend’ or hold the order. This order will be held until it is released or rejected by a member of the compliance division.<sup>733</sup>

Another section of the policies on “event-triggered customer reviews” provides an overview of the process by which a customer can request a threshold increase. The policy states:

Customers requesting an increase for their monthly order allotment of a controlled substance are required to fill out a Controlled Substance Increase Request Form and submit it to the Miami-Luken Compliance Department. Depending on the increase amount requested, the type of customer, and the justification given for the request, additional information may be required for review before approval of the increase is granted. If the increase requested is not reasonable and/or the customer does not provide the information requested, the increase will be denied and may prompt further investigation.<sup>734</sup>

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<sup>728</sup> Policies produced to the Committee that include revisions also state that they were originally drafted in October 2000. *See* Miami-Luken, Inc., Pre-screening of CII orders for Suspicious Quantities, revision Feb. 27, 2014, original draft Oct. 15, 2000 (On file with Committee).

<sup>729</sup> Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce at 11, Dec. 13, 2017 (On file with Committee).

<sup>730</sup> *Id.* at 51.

<sup>731</sup> Miami-Luken, Inc., Policies and Procedures Manual, undated (On file with Committee).

<sup>732</sup> The manual is undated, however Miami-Luken told the Committee it was issued on October 16, 2015. *See* E-mail from Counsel to Miami-Luken, Inc., to Staff, H. Comm. on Energy and Commerce (Oct. 25, 2018 1:44 pm) (On file with Committee).

<sup>733</sup> Miami-Luken, Inc., Policies and Procedures Manual, undated (On file with Committee).

<sup>734</sup> *Id.*

## 2. Case Studies from the Committee's Investigation

In addition to designing an effective system to monitor suspicious orders, many of which include the use of thresholds, distributors must also ensure the systems are enforced properly. In this investigation, however, the Committee found many instances in which distributors allowed West Virginia pharmacies that received a high volume of opioids to exceed or dramatically increase their drug thresholds. It appears that distributors either failed to enforce thresholds or approved pharmacies' requests to increase their thresholds without properly vetting the reasons why increases were sought. This section will expand on four case studies exemplifying the need to set, vet, and enforce thresholds:

- H.D. Smith's lack of thresholds, which allowed Tug Valley Pharmacy's hydrocodone orders to surge unchecked;
- Cardinal's thresholds for Hurley Drug Company, which were set far above the average distribution to the pharmacy;
- Cardinal's thresholds for Family Discount Pharmacy, which were increased without adequate vetting or investigation; and
- McKesson's thresholds for Sav-Rite Pharmacy No. 1, where the average sales of the pharmacy surpassed the monthly threshold on a daily basis, yet McKesson continued to distribute controlled substances.

### *a. Case Study on H.D. Smith: The Importance of Establishing Thresholds*

The failure to establish a threshold limit for controlled substances leaves distributors at risk of violating the CSA; without thresholds, it is much more difficult for distributors to identify and report suspicious orders. As recently as 2015, more than one-third of distributors were estimated to not utilize a threshold system.<sup>735</sup> Through its investigation, the Committee learned that H.D. Smith did not utilize a threshold system prior to 2008.<sup>736</sup> The company's failure to set thresholds or unit reporting limits (URLs) prior to 2008 allowed controlled substance purchases for one pharmacy examined by the Committee to increase rapidly in less than a year.

Between 2007 and 2009, H.D. Smith distributed more than 2.23 million dosage units of hydrocodone to Tug Valley Pharmacy, located in Williamson, West Virginia, population

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<sup>735</sup> U.S. Gov't Accountability Office, Prescription Drugs: More DEA Information about Registrants Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 at 27 (June 25, 2015), available at <https://www.gao.gov/assets/680/671032.pdf>.

<sup>736</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).



3,191.<sup>737</sup> H.D. Smith also supplied Hurley Drug Company, located approximately four blocks away from Tug Valley, with more than 3.42 million dosage units of hydrocodone in the same time period.<sup>738</sup> In total, H.D. Smith provided these two pharmacies with more than 5.65 million doses of hydrocodone between 2007 and 2009.<sup>739</sup> West Virginia court documents suggest that at one point, H.D. Smith provided the two pharmacies with 39,000 doses of hydrocodone over a two-day period in October 2007.<sup>740</sup>

**FINDING: Between 2007 and 2009, H.D. Smith distributed more than more than 5.65 million doses of hydrocodone to two pharmacies located approximately four blocks apart in Williamson, a town of 3,191 people.**

H.D. Smith began doing business with Tug Valley Pharmacy in May 2007.<sup>741</sup> Soon after opening an account with the pharmacy, the pharmacy’s hydrocodone purchases quickly increased. H.D. Smith provided the Committee with documentation of Tug Valley’s monthly alprazolam and hydrocodone purchases for the months of July through the beginning of December 2007:<sup>742</sup>

	Alprazolam	Hydrocodone
<b>Jul-07</b>	<b>10,700</b>	<b>19,100</b>
<b>Aug-07</b>	<b>25,000</b>	<b>32,600</b>
<b>Sep-07</b>	<b>49,900</b>	<b>92,500</b>
<b>Oct-07</b>	<b>102,600</b>	<b>198,400</b>
<b>Nov-07</b>	<b>134,100</b>	<b>224,400</b>
<b>Dec-07</b>	<b>52,200</b>	<b>59,800</b>
<b>Total</b>	<b>374,500</b>	<b>626,800</b>
<b>*December Purchases through December 6th</b>		

<sup>737</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee); U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml).

<sup>738</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>739</sup> *Id.*

<sup>740</sup> *West Virginia ex rel. Patrick Morrissey, et al. v. AmerisourceBergen Drug Corp., et al.* No. 12-C-141 (Boone County, W. Va. Circuit Court) (Second Amended Complaint) (On file with Committee).

<sup>741</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>742</sup> Documents provided by H.D. Smith do not include the monthly hydrocodone and alprazolam purchases for May and June 2007, or the complete purchases for December 2007. H.D. Smith Wholesale Drug Co., Tug Valley Pharmacy 2007 Purchasing Data (On file with Committee).

According to this data, H.D. Smith distributed 567,000 doses of hydrocodone to Tug Valley Pharmacy between July and November 2007.<sup>743</sup> The November dosage count was nearly twelve times the July dosage count. H.D. Smith also distributed 322,300 doses of alprazolam to Tug Valley Pharmacy between July and November 2007. The November dosage count was approximately 12.5 times the July dosage count. Extrapolating the December 2007 figure over the entire month, H.D. Smith was on pace to distribute more than 300,000 dosages of hydrocodone in December 2007. Due diligence documentation H.D. Smith provided to the Committee did not include any justification or explanation regarding the dramatic increase in its distribution of hydrocodone and alprazolam to Tug Valley Pharmacy.

**FINDING: H.D. Smith’s distribution of hydrocodone to Tug Valley Pharmacy increased more than 1,000 percent in a five-month period in 2007, from 19,100 hydrocodone doses to 224,400 hydrocodone doses. Information H.D. Smith provided the Committee did not include documentation to justify or explain the dramatic increase in its distribution of hydrocodone to Tug Valley Pharmacy.**

H.D. Smith began to implement more rigorous policies beginning at the end of 2007, including the implementation of URLs in 2008 as part of its CSOMP. While H.D. Smith was not able to provide comprehensive URL data for Tug Valley, it did provide the Committee date-specific URLs indicating the pharmacy’s hydrocodone limits on specific dates in 2008 and 2009.<sup>744</sup> The pharmacy’s URL was never set at more than 48,000 hydrocodone dosage units a month during this time.<sup>745</sup> The URLs, or thresholds, instituted by H.D. Smith for Tug Valley between April 2008 and August 2009 are reproduced below:

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<sup>743</sup> H.D. Smith Wholesale Drug Co., Tug Valley Pharmacy 2007 Purchasing Data (On file with Committee). According to DEA ARCOS data, H.D. Smith distributed 821,000 doses of hydrocodone to Tug Valley Pharmacy in 2007. U.S. Drug Enforcement Admin., ARCOS data (On file with Committee). The ARCOS data includes distribution from May, June, and all of December, which is not reflected in the purchasing chart produced by H.D. Smith to the Committee.

<sup>744</sup> H.D. Smith told the Committee that the historic URL data was produced through a combination record keeping that occurred at the time, including instances in which H.D. Smith modified a pharmacy’s URL or the pharmacy’s order exceeded its URL level. See E-Mail from Counsel for H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>745</sup> See E-Mail from Counsel for H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

### *Tug Valley Pharmacy*

Date	Product	URL
4/28/2008	Hydrocodone	44,721
5/1/2008	Hydrocodone	47,910
5/5/2008	Hydrocodone	41,190
5/20/2008	Hydrocodone	47,910
5/27/2008	Hydrocodone	41,190
6/17/2008	Hydrocodone	42,531
7/2/2008	Hydrocodone	41,910
10/2/2008	Hydrocodone	37,170
12/4/2008	Hydrocodone	36,186
2/2/2009	Hydrocodone	38,736
3/2/2009	Hydrocodone	23,514
4/2/2009	Hydrocodone	26,424
6/2/2009	Hydrocodone	15,849
7/16/2009	Hydrocodone	17,640
8/2/2009	Hydrocodone	15,000

Despite these new policies and URLs in place, H.D. Smith still supplied Tug Valley Pharmacy with large quantities of opioids in 2008—providing the pharmacy with more than 1.24 million doses of hydrocodone that year.<sup>746</sup> H.D. Smith told the Committee that under the 2008 CSOMP, URLs were “determined based on a customer’s revenue class.”<sup>747</sup> However, documents produced to the Committee do not indicate Tug Valley’s revenue class nor do they address the decrease in distribution from over 200,000 dosages of hydrocodone a month, to thresholds providing for less than 50,000 dosages a month. The sudden reduction of hydrocodone shipped to the pharmacy once thresholds were implemented gives the Committee the impression that efforts to monitor the pharmacy for potential signs of diversion undertaken prior to the adoption of the CSOMP were inadequate.

**FINDING:** H.D. Smith began implementing controlled substance thresholds for its customers, including Tug Valley Pharmacy, in 2008. The thresholds limited Tug Valley’s hydrocodone purchases to under 50,000 doses a month, less than a quarter of what the pharmacy purchased in November 2007 when no thresholds were in place.

<sup>746</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>747</sup> E-Mail from Counsel for H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

Before H.D. Smith launched its CSOMP in May 2008, it conducted additional due diligence of existing customers, seemingly as part of an effort to improve its due diligence process. In 2007, H.D. Smith began requiring customers to complete a customer profile; Tug Valley completed such a profile in December 2007.<sup>748</sup> On this profile, in response to the question “Are one or more practitioners writing a disproportionate share of the prescriptions being filled by the pharmacy?” the owner checked “no.”<sup>749</sup> In early 2008, H.D. Smith requested dispensing and prescribing data from the pharmacy.<sup>750</sup> After analyzing that data, H.D. Smith determined that 87 percent of Tug Valley’s hydrocodone prescriptions were written by two doctors, Diane Shafer<sup>751</sup> and Katherine Hoover.<sup>752</sup> H.D. Smith subsequently reported this information to the DEA on April 25, 2008.<sup>753</sup>

Between May 2008, after the launch of the CSOMP, and August 2009, H.D. Smith reported 93 suspicious orders from Tug Valley to the DEA, 65 of which were for hydrocodone orders.<sup>754</sup> H.D. Smith reported 43 suspicious orders to the DEA—30 of which were for hydrocodone—in May 2008 alone.<sup>755</sup> H.D. Smith told the Committee that it did not ship these orders to Tug Valley.<sup>756</sup> Despite the number of suspicious orders reported, the information regarding Drs. Shafer and Hoover reported to the DEA, and the apparent massive decrease in distribution from late 2007 to the limits imposed by the thresholds in 2008, H.D. Smith continued doing business with Tug Valley until August 2009.

In August 2009, H.D. Smith terminated the pharmacy’s account following a site visit in July, during which the company determined the pharmacy continued to fill prescriptions from

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<sup>748</sup> H.D. Smith Wholesale Drug Co., Customer Profile for Tug Valley Pharmacy, Dec. 19, 2007 (On file with Committee).

<sup>749</sup> *Id.*

<sup>750</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>751</sup> In 2012, Dr. Shafer was sentenced to six months in federal prison for conspiring to misuse her DEA registration number. The Department of Justice noted that between 2003 and 2010, Dr. Shafer wrote more than 118,000 prescriptions for controlled substances which was more than the volume seen at some West Virginia hospitals during the same period. See Press Release, Dep’t of Justice, U.S. Attorney’s Office, S.D. W.Va., Goodwin Awards Former Mingo Pill Mill Bldg. And Forfeited Cash To The West Virginia State Police (Dec. 16, 2013), <https://www.justice.gov/usao-sdww/pr/goodwin-awards-former-mingo-pill-mill-bldg-and-forfeited-cash-west-virginia-state>. At the time, H.D. Smith conducted its analysis, Dr. Shafer also had several disciplinary actions taken against her by the West Virginia Board of Medicine. See W.Va. Board of Medicine, *Diane E. Shafer, M.D.* (last visited July 19, 2018) available at <https://wvbom.wv.gov/public/search/details.asp>.

<sup>752</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee). More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i).

<sup>753</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>754</sup> H.D. Smith Wholesale Drug Co., Suspicious Order Reports 2006-2017 (On file with Committee). H.D. Smith did not report any suspicious orders to the DEA regarding Tug Valley Pharmacy prior to May 2008.

<sup>755</sup> H.D. Smith Wholesale Drug Co., Suspicious Order Reports 2006-2017 (On file with Committee).

<sup>756</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 27, 2018 (On file with Committee).

two doctors it previously flagged as problematic prescribers, Drs. Diane Shafer and Katherine Hoover.<sup>757</sup>

The Committee’s findings regarding H.D. Smith’s distribution to Tug Valley demonstrate the failures that can occur when thresholds are not utilized. H.D. Smith brought Tug Valley on as a customer before its CSOMP and threshold limits were established. Without threshold limits in place, the pharmacy increased its hydrocodone purchases by more than 1,000 percent over a five-month period. Moreover, even after increasing its due diligence of the pharmacy, but before implementing a threshold system, H.D. Smith continued to supply Tug Valley with a higher number of opioids than its later-implemented thresholds would have allowed.

***b. Case Study on Cardinal Health: Accurately Setting Thresholds***

For those distributors that utilize thresholds, it is critical that the thresholds be accurately set. When distributors set thresholds far above the levels at which pharmacies purchase controlled substances, the threshold systems cannot be effective at detecting possible suspicious orders.

Hurley Drug Company (“Hurley”), located in the approximately 3,191-person town of Williamson, West Virginia,<sup>758</sup> received more than 10.58 million doses of hydrocodone and oxycodone from wholesale distributors between 2006 and 2016.<sup>759</sup> Cardinal Health distributed more than one-third of the supply. From 2006 to 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley.<sup>760</sup>

<b>Cardinal’s Distribution to Hurley Drug Company<sup>761</sup></b>	
<b>2006</b>	
<b>Drug</b>	<b>Dosage Units</b>
Hydrocodone	739,800
Oxycodone	67,200
<b>2007</b>	
Hydrocodone	11,400
Oxycodone	3,600
<b>2008</b>	
Hydrocodone	585,700
Oxycodone	0
<b>2009</b>	
Hydrocodone	635,000
Oxycodone	0
<b>2010</b>	

<sup>757</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>758</sup> U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml).

<sup>759</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>760</sup> *Id.*

<sup>761</sup> *Id.*

Hydrocodone	130,830
Oxycodone	0
<b>2011</b>	
Hydrocodone	496,060
Oxycodone	41,100
<b>2012</b>	
Hydrocodone	521,180
Oxycodone	55,100
<b>2013</b>	
Hydrocodone	426,740
Oxycodone	57,100
<b>2014</b>	
Hydrocodone	167,000
Oxycodone	35,720
<b>Total</b>	<b>3,973,530</b>

**FINDING: Between 2006 and 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley Drug Company, located in Williamson, West Virginia.**

Between June 2008 and March 2011, Cardinal set Hurley’s monthly hydrocodone threshold at 155,000 dosage units, allowing the pharmacy to purchase up to that amount of hydrocodone each month without triggering a threshold event and related investigation.<sup>762</sup> In 2009, Cardinal distributed 635,000 doses to Hurley—an average of 52,916 doses a month.<sup>763</sup> In 2010, it distributed 130,830 doses of hydrocodone to Hurley—an average of 10,902 doses a month.<sup>764</sup> The threshold Cardinal set for Hurley would have allowed the pharmacy to purchase nearly three times more hydrocodone a month than it actually received in 2009 and 14 times more than it received in 2010 without triggering a threshold review. While the Committee has not opined on the appropriate threshold level, the fact that Hurley’s hydrocodone threshold remained the same despite the wide variance in the pharmacy’s actual dispensing levels indicates to the Committee that the pharmacy’s actual hydrocodone dispensing was not a factor considered by Cardinal.

**FINDING: From June 2008 to March 2011, Cardinal set Hurley Drug Company’s hydrocodone threshold at 155,000, three times higher than its average monthly purchases in 2009 and 14 times higher than its average monthly purchases in 2010.**

The earliest reference to a threshold limit found in documents Cardinal provided the Committee indicates that Hurley’s hydrocodone threshold was set at 10,000 dosage units a

<sup>762</sup> Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>763</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<sup>764</sup> *Id.*

month in January 2008.<sup>765</sup> The 10,000-dosage threshold remained in place through June of 2008 when Cardinal increased Hurley’s threshold. Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month.<sup>766</sup> This was a fifteen-fold increase in just two weeks. Moreover, the resulting 155,000-dosage per month threshold remained in place for nearly three years.

<b>Hydrocodone Threshold Adjustments for Hurley Drug Company<sup>767</sup></b>		
<b>Date of Change</b>	<b>Initial Monthly Dosage Threshold</b>	<b>New Monthly Dosage Threshold</b>
June 9, 2008	10,000	27,000
June 13, 2008	27,000	37,500
June 17, 2008	37,500	45,000
June 19, 2008	45,000	54,000
June 23, 2008	54,000	155,000
March 8, 2011	155,000	66,501
December 12, 2012	66,501	55,005
November 7, 2013	55,005	42,005
February 13, 2015 <sup>768</sup>	42,005	7,000

**FINDING: Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley Drug Company on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month. This was a fifteen-fold increase in the threshold in two weeks.**

<sup>765</sup> The 10,000-dosage threshold is referenced in a report prepared ahead of a June 2008 site visit to the pharmacy. Cardinal Health, QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee).

<sup>766</sup> Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>767</sup> *Id.*

<sup>768</sup> Cardinal Health stopped distributing oxycodone and hydrocodone to Hurley Drug Company in 2014, and DEA ARCOS data also shows that no hydrocodone or oxycodone were distributed to the pharmacy in 2015 or 2016. Cardinal told the Committee that it lowered Hurley’s thresholds after it stopped distributing those drugs to reflect that Hurley was no longer able to order those products. *See* Letter from Counsel to Cardinal Health, to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018) (On file with Committee).



i. *Cardinal's Documentation of Threshold Increases for Hurley Drug Company*

Cardinal did not formalize its standard operating procedures (SOP) until December 2008, after the five hydrocodone threshold increases for Hurley in June 2008. Before the SOPs took effect, thresholds were monitored by distribution center employees who “were instructed to identify any orders that appeared excessive in relation to what other customers were buying and/or the customer’s purchase history.”<sup>769</sup> As described previously, Cardinal also used an algorithm designed by the DEA<sup>770</sup> to identify order amounts that should be reported to the DEA through a monthly ingredient limit report.

Other than a chart listing Hurley’s hydrocodone threshold increases, Cardinal provided no documentation on the pharmacy’s 2008 threshold increases. Cardinal’s due diligence and threshold documentation for Hurley provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008. Cardinal also appeared not to produce any hydrocodone threshold event reports during the approximately three years from June 2008 to March 2011 when Hurley’s threshold was set at 155,000 dosage units—an indication that Hurley never hit its hydrocodone threshold during that time.<sup>771</sup> Had Hurley hit its hydrocodone threshold, policies implemented by Cardinal in December 2008 state that the pharmacy would have been required to provide documentation validating the order, and that the Quality and Regulatory Affairs team would review the documentation and the pharmacy’s threshold would be evaluated.<sup>772</sup> Moreover, based on documentation provided to the Committee, Cardinal did not independently reevaluate the threshold between June 2008 and March 2011, including by comparing the threshold level to the amount actually distributed by Cardinal, to determine whether it was accurately set.

**FINDING: Cardinal’s due diligence and threshold documentation for Hurley Drug Company provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008.**

**FINDING: Based on documentation provided to the Committee, Hurley Drug Company did not hit its hydrocodone threshold in the approximately three years it was set at 155,000 dosage units a month.**

<sup>769</sup> Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

<sup>770</sup> See U.S. Drug Enforcement Admin., *Report to the U.S. Attorney General*, Oct. 1998 (On file with Committee); see also Letter from Counsel to Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

<sup>771</sup> Cardinal was unable to confirm whether any threshold events occurred between June 23, 2008, and March 8, 2011, when the hydrocodone threshold was set at 155,000 dosage units. See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>772</sup> Cardinal Health Inc., Standard Operating Procedures, Sales – threshold event (Dec. 22, 2008) (On file with Committee).



As the documentation provided by Cardinal did not include any direct explanation for the threshold increases, the Committee examined other documents provided by Cardinal for insight into the threshold increases. Not only does the documentation fail to provide an explanation for the rapid increase in the thresholds, but the documents show that Cardinal learned of derogatory information regarding the pharmacy and failed to reevaluate the thresholds.

Included in Cardinal's due diligence files for Hurley Drug Company was documentation for two site visits conducted at the pharmacy between 2008 and August 2012. One site visit took place on June 3, 2008, just before the pharmacy's hydrocodone thresholds were dramatically increased, and another on June 10, 2009, after the 155,000-dosage unit threshold was in place.<sup>773</sup>

A "QRA Site Visit Preparation" document, seemingly prepared before the June 3, 2008, site visit states that Hurley hit its 10,000-dosage unit threshold for hydrocodone in January 2008 but makes no other reference to the pharmacy's thresholds.<sup>774</sup> The "Data Collection Worksheet-QRA Visit" that follows within the same document and appears to document information collected during the site visit additionally indicates that, among other things, Cardinal was then a secondary supplier to the pharmacy, 28 percent of Hurley's prescription sales were controlled substances, and the pharmacy was projected to see an increase in hydrocodone sales.<sup>775</sup> Both parts of the document—the "QRA Site Visit Preparation" and the "Data Collection Worksheet-QRA Visit"—state that Hurley filled prescriptions for Dr. Katherine Hoover's pain management clinic.<sup>776</sup> The "Data Collection Worksheet-QRA visit" is reproduced in part below:

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<sup>773</sup> Cardinal Health Inc., Memorandum on Hurley Drug Company (June 3, 2008) (On file with Committee); Cardinal Health, Inc., Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).

<sup>774</sup> Cardinal Health Inc., QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee).

<sup>775</sup> Cardinal Health Inc., Data Collection Worksheet – QRA Visit, Hurley Drug Company, undated (On file with Committee).

<sup>776</sup> See Cardinal Health Inc., QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee); see also Cardinal Health, Inc., Data Collection Worksheet – QRA Visit, Hurley Drug Company, undated (On file with Committee).

14. Other Pharmaceutical Distributors (Noted Changes in Last year): HD Smith, Cardinal Health, Harvard, Masters, Top Rx. Currently HD Smith primary, Cardinal secondary

15. % of Prescription Sales = Controlled:    28%

16. New Physicians in Area:    No

17. Proximity/Number of Pain Clinics/Weight Loss/Cancer Clinic:

Pain management clinic in walking distance (2 doors) from above listed pharmacy.

18. Practitioners Involved in Pain Management/Weight Loss or Oncology in the Area:

Mountain Medical, Dr. Hoover (DEA# [REDACTED])  
[REDACTED] and [REDACTED] are also located in the immediate area (2 doors down from pharmacy)

19. Any Suspicious Prescribing of Controlled meds by Area Practitioners:

No

20. Location of Controlled Medications in Pharmacy:

Alphabetical on shelves, mixed with non-controlled

21. Controlled Medications Most Prescribed:

Hydrocodone

22. Projected Increase of Controlled Sales/by Name:

Hydrocodone

A one-page memorandum completed after the site visit concluded that “the pharmacy does not represent a significant risk for diversion.”<sup>777</sup> As discussed above, in the three weeks following the site visit to Hurley, Cardinal increased the pharmacy’s thresholds on five occasions, increasing it from 10,000 doses a month to 155,000 doses a month.

Just three months later, in September 2008, Cardinal learned of derogatory information about Dr. Hoover, specifically that two nearby Kentucky pharmacies would not fill prescriptions

<sup>777</sup> Cardinal Health Inc., Memorandum on Hurley Drug Company (June 3, 2008) (On file with Committee).

from her based on concerns about her practice.<sup>778</sup> A memorandum included in the customer files for both Hurley Drug Company and Family Discount Pharmacy stated:

[Pharmacist] stated that he has ridden by the office of Dr. Hoover and there are lines of people standing outside, waiting to get in the office. He stated that he was not comfortable accepting prescriptions from her and has turned customers away.<sup>779</sup>

Cardinal investigators subsequently verified that Dr. Hoover's license was valid in West Virginia and researched her practice, finding three prior disciplinary actions, and documented the findings in the same memorandum.<sup>780</sup> Despite learning of this derogatory information, Cardinal did not make any adjustments to Hurley's threshold or undertake an evaluation of the thresholds at this time.

**FINDING: Cardinal did not reevaluate the threshold between June 2008 and March 2011 to determine whether it was accurately set. This includes after learning of derogatory information regarding Dr. Katherine Hoover, a doctor for whom Hurley Drug Company filled prescriptions.**

Cardinal conducted a second site visit at Hurley in June 2009 and a pharmacy questionnaire was completed within two weeks of the visit.<sup>781</sup> Neither the memorandum documenting the June 10, 2009, site visit nor the questionnaire make mention of Hurley's drug thresholds or indicate that any thresholds were reevaluated in connection with the site visit.

The memorandum indicates Cardinal requested a drug utilization report, which it received and forwarded to Cardinal's QRA-Anti-Diversion division.<sup>782</sup> Presumably, Cardinal could have discerned from the drug utilization report that the hydrocodone threshold was far in excess of the amount actually dispensed by the pharmacy. Cardinal also checked the status of prescribers' medical licenses, though the memorandum does not name the doctors whose licenses were checked or reference the September 2008 discovery regarding Dr. Hoover.<sup>783</sup> The site visit memorandum concludes that the visit and findings "support the determination at this time that the pharmacy does not represent a significant risk for diversion."<sup>784</sup>

<sup>778</sup> Cardinal Health Inc., Memorandum (Sept. 12, 2008) (On file with Committee). More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i).

<sup>779</sup> *Id.* A summary of proposed testimony states that a special agent of the HHS Office of Inspector General would testify that in 2010 they observed heavy foot traffic outside Dr. Hoover's clinic, and that the clinic had a hot dog stand and convenience area set up in the lobby to feed the groups of people waiting to be seen. *In re Miami-Luken*, U.S. Drug Enforcement Admin., No. 16-13 (Jan. 15, 2016) (Government's Prehearing Statement) (On file with Committee).

<sup>780</sup> Cardinal Health Inc., Memorandum (Sept. 12, 2008) (On file with Committee). More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i).

<sup>781</sup> See E-Mail from Staff, Cardinal Health Inc., to Response for SCS-P Retail Independent Pharmacy Questionnaire, Cardinal Health, Inc. (June 23, 2009 10:39 am) (On file with Committee); see also Cardinal Health Inc., Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).

<sup>782</sup> Cardinal Health, Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).

<sup>783</sup> *Id.*

<sup>784</sup> *Id.*

When asked by the Committee about the decision to increase Hurley's hydrocodone threshold from 10,000 dosage units to 155,000 dosage units within a period of three weeks, Cardinal stated:

Like all customers at that time, Hurley Drug. Co. was subject to Cardinal Health's controlled substance anti-diversion program. Thresholds were adjusted by anti-diversion professionals following a review of the totality of the circumstances, including an analysis of whether the information available to Cardinal Health suggested the pharmacy presented an unreasonable risk of diversion.<sup>785</sup>

*ii. Cardinal's Documentation of Threshold Reductions*

While Hurley's 155,000-dose threshold was in place, Cardinal was the secondary supplier for the pharmacy. It was not until March 2011, as Cardinal prepared to switch the pharmacy from a secondary to primary customer, that the distributor reduced Hurley's threshold level from 155,000 doses to 66,501 doses.<sup>786</sup>

Cardinal employees initially believed Hurley's drug thresholds would need to be increased to accommodate the change to primary supplier for the pharmacy. Yet after an assessment of the pharmacy's drug usage was completed, Cardinal instead cut Hurley's hydrocodone threshold by more than half—an indication that the prior threshold was higher than appropriate.

For example, in discussing Cardinal's change from being a secondary to the primary supplier for Hurley, one Cardinal employee wrote that they liked to know when the status of a pharmacy is changing so as to "better accommodate the growth factor."<sup>787</sup> This e-mail is reproduced below:

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<sup>785</sup> Letter from Counsel to Cardinal Health Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>786</sup> Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>787</sup> E-Mail from Pharmacy Business Consultant, Cardinal Health, Inc., to Staff, Cardinal Health, Inc. (Mar. 7, 2011, 12:12 pm) (On file with Committee).

**From:** [REDACTED]  
**Sent:** Monday, March 07, 2011 12:12 PM  
**To:** [REDACTED]; [REDACTED]  
**Cc:** [REDACTED] (PD)  
**Subject:** RE: Hurley Drug #80850 DEA [REDACTED]

[REDACTED]

I have received the data but have yet to analyze it – from a QRA standpoint we don't make the customers status (ie primary, secondary) – this may be something you want to bring to CCDB's attention – since this is already an existing customer there is no need for QRA approval.

We just like to know when the status of a pharmacy is changing from Secondary to Primary so we can better accommodate that growth factor and that is why you sending us usage is very helpful.

Thank you,

[REDACTED]

When Cardinal analyzed Hurley's dispensing data for controlled substances, it found that Hurley's total monthly hydrocodone purchases and/or dispensing<sup>788</sup> for the past year averaged 50,953 doses a month.<sup>789</sup> As a result of the usage analysis, Cardinal reduced the threshold limits for eight drugs, including hydrocodone, which was cut by more than half. The following chart, which refers to hydrocodone by its DEA base code 9193 and oxycodone by its DEA base code 9143, shows the threshold adjustments made.<sup>790</sup>

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<sup>788</sup> Cardinal was unable to clarify whether the information was related to the pharmacy's purchases or dispensing of controlled substances. *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>789</sup> Cardinal Health, Inc., Hurley Drug dispensing analysis, Mar. 1, 2010 to Feb. 28, 2011 (On file with Committee).

<sup>790</sup> *Id.*

Hurley Drug - ██████████ - DC 8						
Date Range - 12 Months - 3/1/2010-2/28/2011						
Comments - This customer is moving to Primary Status with CAH						
Base	Quantity	Avg	Limit	Limit-Avg/Avg	Changes	
1640	43056	3588	2000	-44%	6001	
2737	87990	7333	5000	-32%	9501	
9050	77721	6477	5500	-15%	8001	
2782	52720	4393	3800	-14%	5001	
2783	46220	3852	3700	-4%	5001	
9273	47884	3990	4200	5%	500	off the market
2765	50434	4203	5200	24%	5501	
2925	18579	1548	2500	61%	N/C	
9064	14608	1217	2100	73%	1801	
2885	39924	3327	6000	80%	4001	
2882	231413	19284	44000	128%	25501	
9143	58958	4913	12000	144%	6501	
9193	611434	50953	155000	204%	66501	
9300	9901	825	6000	627%	1501	
9801	1535	128	1000	682%	175	
5000	22978	1915	16000	736%	3001	

The hydrocodone threshold was reduced to 65,001 doses on March 8, 2011, the day after the previously referenced e-mail. This was due to “usage analyzed and TH adjusted,” according to comments included in a threshold adjustment chart that Cardinal provided the Committee.<sup>791</sup>

**FINDING:** Cardinal reviewed Hurley Drug Company’s account before the pharmacy’s switch from a secondary to primary customer, initially anticipating that thresholds would need to be increased to accommodate growth. However, as a result of the review, Cardinal cut Hurley’s hydrocodone threshold from 155,000 to 66,501 dosage units.

As discussed previously, Cardinal reached a settlement with the DEA in May 2012 that required it to make changes to its anti-diversion policies and to establish the LV-TAC to review high volume customers. After the settlement, the frequency of Cardinal’s site visits to Hurley increased and it lowered the pharmacy’s hydrocodone threshold again. On December 12, 2012, Hurley’s hydrocodone threshold was reduced from 66,501 dosage units to 55,005 dosage units.<sup>792</sup> Cardinal’s threshold change documentation states the adjustment was made “per LV-TAC review.”<sup>793</sup> While Cardinal conducted only two site visits to Hurley between 2008 and August 2012, the company conducted nine site visits to the pharmacy between September 2012

<sup>791</sup> Cardinal Health, Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>792</sup> *Id.*

<sup>793</sup> *Id.*

and October 2014.<sup>794</sup> For reasons the Committee could not determine, Hurley stopped purchasing hydrocodone and oxycodone from Cardinal after 2014. However, the company continued to supply other controlled substances to the pharmacy and conducted additional site visits.<sup>795</sup>

As demonstrated by this case study, for thresholds to detect suspicious orders, they must be able to flag orders that are out of the ordinary for a pharmacy. If thresholds are set so high that a pharmacy could purchase between three to 14 times their typical ordering volumes without hitting a threshold, the threshold cannot be expected to effectively flag suspicious orders. Similarly, if thresholds are set and then not independently evaluated for an extended period of time to ensure that they appropriately match the dispensing patterns of a pharmacy, they cannot be expected to effectively flag suspicious orders.

*c. Case Study on Cardinal Health: Vetting Threshold Increases*

Once thresholds are appropriately set, distributors must document their subsequent justifications for increasing and decreasing thresholds, and investigate the justifications provided by customers who seek to increase their thresholds. Thorough documentation and investigation makes it more likely that a distributor will identify “bad actor” pharmacies, and less likely that diversion of drugs supplied by the distributor will occur.

Between 2006 and 2017, Cardinal Health’s top purchaser of hydrocodone and oxycodone products in West Virginia was Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779.<sup>796</sup> Cardinal distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount between 2006 and 2012.<sup>797</sup>

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<sup>794</sup> Cardinal Health, Inc., KYC site visit survey detail for Family Discount Pharmacy and Hurley Drug Company, undated (On file with Committee).

<sup>795</sup> *Id.*

<sup>796</sup> Cardinal Health, Inc., Top 10 oxycodone and hydrocodone customers (On file with Committee).

<sup>797</sup> U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

<b>Cardinal's Distribution to Family Discount Pharmacy<sup>798</sup></b>	
<b>2006</b>	
<b>Drug</b>	<b>Dosage Units</b>
Hydrocodone	151,600
Oxycodone	0
<b>2007</b>	
Hydrocodone	161,400
Oxycodone	16,600
<b>2008</b>	
Hydrocodone	705,600
Oxycodone	129,000
<b>2009</b>	
Hydrocodone	1,361,700
Oxycodone	170,200
<b>2010</b>	
Hydrocodone	1,358,800
Oxycodone	164,500
<b>2011</b>	
Hydrocodone	1,321,300
Oxycodone	183,800
<b>2012</b>	
Hydrocodone	975,380
Oxycodone	129,800
<b>Total</b>	<b>6,829,680</b>

**FINDING:** Between 2006 and 2012, Cardinal Health distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, population 1,779. This amount made the pharmacy Cardinal Health's top purchaser of hydrocodone and oxycodone products in West Virginia between 2006 and 2017.

The Committee requested Cardinal provide information related to threshold changes as well as all documents related to the company's due diligence files for Family Discount's Mount Gay-Shamrock location.<sup>799</sup> According to the records provided and as documented in the chart below, Cardinal adjusted Family Discount's hydrocodone threshold limits a total of 19 times between May 2008 and April 2013.<sup>800</sup>

<sup>798</sup> *Id.*

<sup>799</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec. Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, available at <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf>.

<sup>800</sup> Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).



<b>Hydrocodone Threshold Adjustments for Family Discount Pharmacy Mount Gay-Shamrock<sup>801</sup></b>		
<b>Date of Change</b>	<b>Initial Monthly Dosage Threshold</b>	<b>New Monthly Dosage Threshold</b>
June 13, 2008	27,000	40,000
June 19, 2008	40,000	66,000
June 25, 2008	66,000	70,000
June 27, 2008	70,000	75,000
July 30, 2008	75,000	90,000
October 31, 2008	90,000	35,000
November 13, 2008	35,000	65,000
November 19, 2008	65,000	75,000
December 3, 2008	75,000	80,000
December 18, 2008	80,000	85,000
December 29, 2008	85,000	110,000
May 22, 2009	110,000	110,005
August 25, 2009	110,005	115,005
August 28, 2009	115,005	110,005
January 21, 2010	110,005	150,005
June 14, 2012	154,500 <sup>802</sup>	100,005
July 17, 2012	100,005	75,005
November 12, 2012	75,005	5,005
April 24, 2013	5,005	1

As previously discussed, Cardinal did not issue its first formal standard operating procedures, which included threshold policies, until December 22, 2008.<sup>803</sup> Before those SOPs were adopted, Cardinal complied with its suspicious order monitoring obligations by having

<sup>801</sup> *Id.*

<sup>802</sup> Documents provided by Cardinal Health do not indicate when the hydrocodone threshold was adjusted from 150,005 doses to 154,500 doses. When asked, Cardinal Health was unable to confirm when the threshold was changed. *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>803</sup> Letter from Counsel to Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

distribution center employees “identify any orders that appeared excessive in relation to what other customers were buying and/or the customer’s purchase history.”<sup>804</sup> The new SOPs included policies through which Cardinal established custom thresholds for all customers.<sup>805</sup> The thresholds were established “based on the customer’s size and class of trade, using historical controlled substance ordering data for all customers.”<sup>806</sup> The policies laid out a process by which Cardinal held orders that surpassed the threshold, collected information from customers, and determined whether the orders should be reported as suspicious.<sup>807</sup>

However, based on documents Cardinal provided the Committee, Cardinal did not consistently document the reason for each threshold adjustment nor does it appear to have applied the same level of scrutiny to each threshold increase. In some but not all cases, Cardinal provided threshold event reports that precipitated threshold adjustments as well as accompanying threshold surveys in which pharmacy personnel answered questions about Family Discount’s business. At times, Cardinal also included comments in a threshold adjustment chart provided to the Committee or provided emails or other correspondence that references the pharmacy’s thresholds. Because the same level of documentation was not kept for all threshold adjustments, it is unclear what factors were taken into consideration prior to some hydrocodone threshold increases for Family Discount. It is also unclear, at times, whether Cardinal verified explanations provided by Family Discount regarding its increased hydrocodone dispensing.

*i. Cardinal’s investigation of Dr. Katherine Hoover*

Cardinal adjusted Family Discount Pharmacy’s hydrocodone threshold 19 times between June 13, 2008, and April 24, 2013, with the pharmacy offering various explanations during this time regarding why it requested a higher threshold limit. Among the explanations provided by Family Discount Pharmacy was that the pharmacy was experiencing an increased need for controlled substances based on an increase in prescriptions written by Dr. Katherine Hoover. Yet, Cardinal did not provide documents to the Committee indicating that it inquired further regarding the reason why a single doctor’s prescribing was driving up controlled substance orders, nor did Cardinal reevaluate Family Discount’s thresholds after it learned other customer pharmacies refused to fill Dr. Hoover’s prescriptions.

Before increasing Family Discount’s hydrocodone threshold for the first time, Cardinal conducted a site visit on June 3, 2008. A one-page memorandum detailing the site visit stated Family Discount drew clients from a 35-mile radius and that two hospitals and doctors’ offices were located within two miles of the property.<sup>808</sup> The memorandum also stated the pharmacy had significant business dispensing non-controlled drugs, as well as a moderate amount of

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<sup>804</sup> See Letter from Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., April 25, 2018 (On file with Committee); see also Cardinal Health, Inc., Process to Establish SOM Threshold Limits, Dec. 22, 2008 (On file with Committee).

<sup>805</sup> Cardinal Health, Inc., Process to Establish SOM Threshold Limits, Dec. 22, 2008 (On file with Committee).

<sup>806</sup> Letter from Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., April 25, 2018 (On file with Committee).

<sup>807</sup> Cardinal Health, Inc. Standard Operating Procedures, Sales – threshold event, Dec. 22, 2008 (On file with Committee).

<sup>808</sup> Cardinal Health, Inc., Memorandum, (June 13, 2008) (On file with Committee).

walk-in traffic, and concluded that “the pharmacy does not represent a significant risk for diversion.”<sup>809</sup>

Family Discount hit its hydrocodone threshold four times in June 2008 following the site visit. Each time, Cardinal increased its threshold for hydrocodone. Below is an example of a threshold event dated June 24, 2008. According to the document, Cardinal released the hydrocodone order and increased Family Discount’s threshold from 66,000 to 70,000 dosage units.<sup>810</sup>

### Anti-Diversion Customer Profile

QRA Site Visit   Sales Site Visit

**FAMILY DISCOUNT PHARMACY INC**

<p>DEA Activity Code   A   0   RETAIL PHARMACY</p> <p>DEA Schedules   22N 33N 4 5</p> <p>Expiration Date   2008/09/30</p> <p>First Cardinal Account Created   9/5/2006</p> <p><b>Customer Information</b></p> <p>FAMILY DISCOUNT PHARMACY INC</p> <p>OLD ROUTE 119</p> <p>MOUNT GAY   WV   25637</p> <p>(304) 752-1445</p> <p><b>Customer Type   Accounting Class   Designated Size</b></p> <p>Retail   10   Large</p> <p>Customer Visited   Yes</p> <p>QRA Decision   Decision Pending</p> <p>CIM Customer   No</p> <p>Total Rx Sales   \$4,055,654.06</p> <p>Control Sales   \$334,631.35</p> <p>% Controlled Substance Purchases   16.65%</p> <p>% AHOP Control Purchases   59.28%</p> <p>Account Restricted   No</p> <p>Total # of Events   9</p>	<p><b>Drug Family</b>   9193   HYDROCODONE BITARTRATE</p> <p># Events   4</p> <p>Overage Date   6/24/2008</p> <p>Total Accrual   66,100</p> <p>Monthly Limit   66,000</p> <p>Order #   3170608</p> <p>Item #   3320688</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td>May 07   16,100</td> <td>Nov 07   22,260</td> </tr> <tr> <td>Jun 07   9,690</td> <td>Dec 07   52,545</td> </tr> <tr> <td>Jul 07   10,400</td> <td>Jan 08   10,529</td> </tr> <tr> <td>Aug 07   13,785</td> <td>Feb 08   4,961</td> </tr> <tr> <td>Sep 07   8,673</td> <td>Mar 08   2,724</td> </tr> <tr> <td>Oct 07   11,550</td> <td>Apr 08   980</td> </tr> </table> <p>Average Units Per Month   13,855</p> <p><b>Distrack Information</b></p> <p>Dublin 6   WH   60829</p> <p>8   BFC0660565   9193</p> <p>Report Order to DEA   <input type="checkbox"/></p> <p>Reviewed By:   <span style="background-color: black; color: black;">[REDACTED]</span>   Executed By:   <span style="background-color: black; color: black;">[REDACTED]</span></p> <p style="text-align: right; margin-top: 10px;"> <input checked="" type="checkbox"/> Increase Limits   <input checked="" type="checkbox"/> Release Order   <input checked="" type="checkbox"/> Cut Order  <input checked="" type="checkbox"/> 70,000 </p>	May 07   16,100	Nov 07   22,260	Jun 07   9,690	Dec 07   52,545	Jul 07   10,400	Jan 08   10,529	Aug 07   13,785	Feb 08   4,961	Sep 07   8,673	Mar 08   2,724	Oct 07   11,550	Apr 08   980
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Sep 07   8,673	Mar 08   2,724												
Oct 07   11,550	Apr 08   980												

Wednesday, June 25, 2008

The day after the June 24, 2008, threshold event, Family Discount’s pharmacist in charge faxed documentation to Cardinal explaining the pharmacy’s increasing need for controlled substances. He wrote that the pharmacy had “experienced a recent increase in the number of prescriptions written by dr. k. hoover”<sup>811</sup> a reference to Dr. Katherine Hoover of Williamson, West Virginia.<sup>812</sup> Based on documents provided to the Committee, this is the

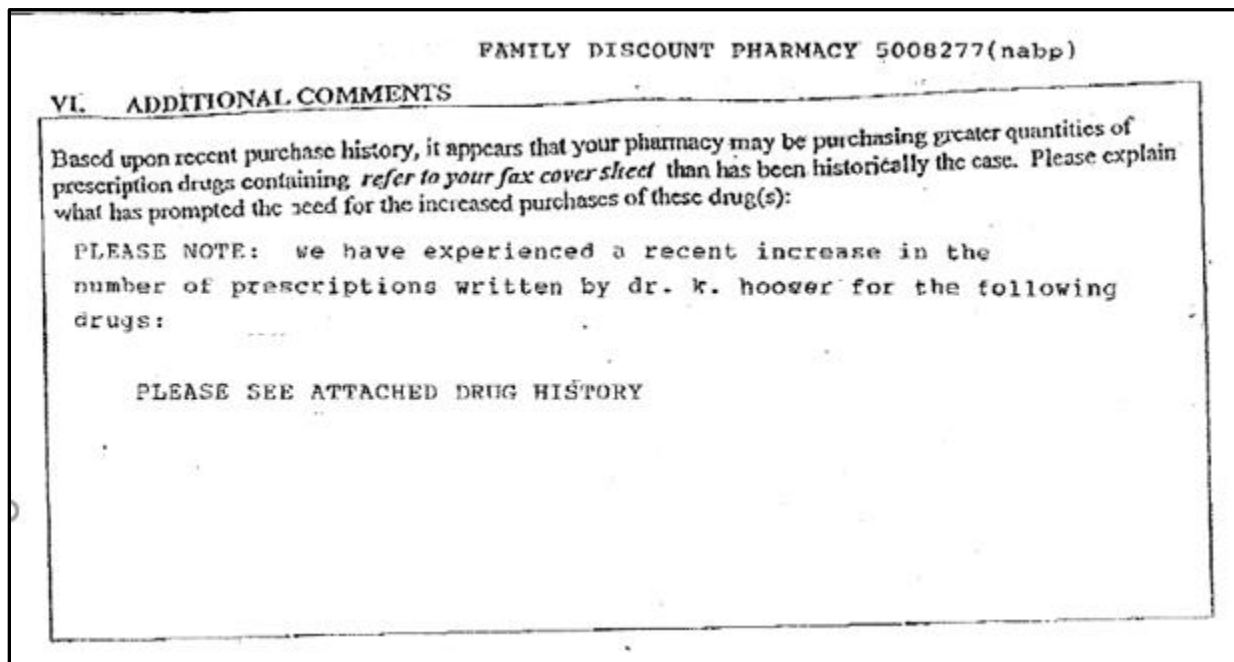
<sup>809</sup> *Id.*

<sup>810</sup> Cardinal Health, Inc., Anti-Diversion Customer Profile for Family Discount (June 25, 2008) (On file with Committee).

<sup>811</sup> Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (June 25, 2008) (On file with Committee).

<sup>812</sup> Dr. Hoover worked at Mountain Medical Care Center in Williamson, West Virginia, which was raided by federal authorities in 2010 as part of an investigation into pill mill pharmacies. Between December 2002 and 2010, Dr.

earliest explanation Family Discount provided to Cardinal after the June 3, 2008 site visit about the reason for its increased hydrocodone dispensing:<sup>813</sup>



In support of the threshold increase request, the pharmacy attached historical drug sales data for six various strengths and formulations of hydrocodone.<sup>814</sup> Despite the pharmacy's reference to an increase in hydrocodone prescriptions written by a single doctor in justifying the request for a controlled substance increase, Cardinal does not appear to have inquired further about Dr. Hoover's prescribing at that time. The documents provided to the Committee do not show any attempt by Cardinal to further investigate Dr. Hoover's prescribing after this disclosure. Cardinal increased Family Discount's hydrocodone threshold to 70,000 dosage

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Hoover was responsible for writing 355,132 controlled substance prescriptions in West Virginia, more than any other prescriber in the state. See Memorandum Opinion and Order, *United States v. \$88,029.08, More or Less, in United States Currency*, No. 2:10-cv-1087 (S.D. W.Va. Sept. 28, 2012). While she fled to the Bahamas shortly after the raid, federal authorities seized \$88,000 from her, and other physicians who worked at the clinic were criminally charged and received prison sentences. See Lawrence Messina, Associated Press, *Doctor seeks \$88,000 seized in pill mill probe*, TIMES WEST VIRGINIAN, Dec. 6, 2012, [http://www.timeswv.com/news/doctor-seeks-seized-in-pill-mill-probe/article\\_dac39b98-e59b-5edc-bf5e-c0022b20cb4d.html](http://www.timeswv.com/news/doctor-seeks-seized-in-pill-mill-probe/article_dac39b98-e59b-5edc-bf5e-c0022b20cb4d.html). Dr. Hoover had a disciplinary history in other states that included two years' probation by the Florida medical board following allegations of inappropriately and excessively prescribing controlled substances, a \$1 million payment in a malpractice settlement, and suspension and eventual restoration of her license in West Virginia over a matter not related to controlled substance prescribing. Cardinal Health, Inc., Memorandum (Sept. 12, 2008) (On file with Committee). At least one other distributor viewed her controlled substance prescriptions with concern. H.D. Smith reported its concerns regarding Dr. Hoover's prescribing habits to DEA in April 2008. See Letter from Counsel to H.D. Smith Wholesale Drug Co. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>813</sup> Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (June 25, 2008) (On file with Committee).

<sup>814</sup> *Id.*

units on June 25, 2008, and 75,000 dosage units two days later on June 27, 2008.<sup>815</sup>

**FINDING: In June 2008, Family Discount Pharmacy cited an increase in hydrocodone prescriptions written by a single doctor—Dr. Katherine Hoover—in requesting an increase to its thresholds. Based on documents provided to the Committee, Cardinal did not inquire further about Dr. Hoover’s prescribing at that time and raised the hydrocodone thresholds for the pharmacy.**

As was referenced in the case study for Hurley Drug Company, Cardinal learned in September 2008 that two Kentucky pharmacists would not fill prescriptions for Dr. Hoover based on their concerns regarding her practice.<sup>816</sup> One of the Kentucky pharmacists described “lines of people standing outside, waiting to get in the office.”<sup>817</sup> Cardinal conducted an investigation into Dr. Hoover’s background and documented the findings in a memorandum included in case files for both Hurley and Family Discount.<sup>818</sup> However, Cardinal does not appear to have inquired about or calculated the percentage of Family Discount’s controlled substance prescriptions written by Dr. Hoover. When asked by the Committee, Cardinal said it was “unable to reconstruct the specific information surrounding conversations with either Family Discount Pharmacy or Hurley Drug Company regarding prescriptions by Dr. Hoover.”<sup>819</sup> Cardinal did not produce any documentation showing that it reevaluated the threshold limits for Family Discount upon learning about the prescribing practices of Dr. Hoover.

**FINDING: In September 2008, Cardinal learned of derogatory information regarding Dr. Hoover, specifically, that two pharmacists in Kentucky would not fill prescriptions for Dr. Hoover based on concerns about her practice. Documents provided by Cardinal do not indicate the company reevaluated Family Discount Pharmacy’s hydrocodone thresholds after learning of this information.**

In December 2008, Cardinal adopted policies that highlighted “alert signals” for possible diversion, including “practitioners writing a disproportionate share of the prescriptions for controlled substances being filled.”<sup>820</sup> The policy demonstrates that Cardinal considered it a red flag if a doctor prescribed a disproportionate amount of a pharmacy’s controlled substances. Due diligence documentation provided to the Committee, however, does not indicate that Cardinal undertook a sufficient review of Family Discount’s prescribing physicians before raising thresholds. For example, the documents do not give any indication that Cardinal requested or determined the percentage of controlled substance prescriptions written by Dr.

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<sup>815</sup> Cardinal Health, Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>816</sup> Cardinal Health, Inc., Memorandum (Sept. 12, 2008) (On file with Committee).

<sup>817</sup> *Id.*

<sup>818</sup> *Id.* More information regarding Dr. Hoover can be found at *supra* Section VI (B)(2)(c)(i).

<sup>819</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018, (On file with Committee).

<sup>820</sup> Cardinal Health, Inc., Sales – Anti-Diversion Alert Signals, Dec. 22, 2008 (On file with Committee).

Hoover or any other doctors identified by the pharmacy as top-prescribing physicians. In contrast, H.D. Smith found after requesting and reviewing dispensing data that at one point in 2009 Dr. Hoover wrote 51 percent of Family Discount's hydrocodone prescriptions.<sup>821</sup>

*ii. Cardinal's Investigation of Pharmacy Closures*

On multiple occasions, Family Discount cited the closure of or difficulties with another pharmacy as reasons why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims. While it is entirely plausible and legitimate that the closure of or difficulties with a nearby pharmacy could increase controlled substance sales at another pharmacy, a distributor should at a minimum, verify such a justification before approving a threshold increase.

A threshold survey completed by Family Discount on October 20, 2008 cited the closure of a pharmacy in Chapmanville, West Virginia, approximately 12 miles from the Family Discount location in Mount Gay-Shamrock, to justify its increased hydrocodone quantities.<sup>822</sup> The threshold survey is reproduced in relevant part below:

```
Please explain your need for increased quantities of the drug family:
{Enter answer in paragraph form}
[ we have had an increase in the number of prescriptions filled a local
pharmacy (health rite) located in chapmanville wv 25508 has recently closed
for business i have faxed the drug utilizaiton ]

Name of Drug Family held per Regulatory Review:
{Enter text answer}
[ HYDROCODONE 10/650 ]
```

A second threshold event survey submitted two days later on October 22, 2008 for another strength of hydrocodone provided nearly identical information.<sup>823</sup> No documentation provided by Cardinal indicates if the company took steps to verify whether the Chapmanville pharmacy closed or whether its customers were transferring prescriptions to Family Discount. The Committee was unable to determine whether a Health Rite pharmacy in Chapmanville, West Virginia, closed in the October 2008 time period. There is not currently a Health Rite pharmacy in Chapmanville.

On October 31, 2008, Cardinal reduced Family Discount's hydrocodone threshold from 90,000-dosage units to 35,000 dosage units. Documentation provided by Cardinal does not indicate why the threshold was reduced. Cardinal told the Committee that, given the passage of

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<sup>821</sup> H.D. Smith Wholesale Drug Co., Account Notes – Family Discount Pharmacy (Mount Gay-Shamrock) Apr. 14, 2009 to May 14, 2009 (On file with Committee).

<sup>822</sup> E-Mail from Staff, Cardinal Health, Inc., to Response for HSCS-P Threshold Event, Cardinal Health, Inc. (Oct. 20, 2008, 12:21pm) (On file with Committee).

<sup>823</sup> E-Mail from Staff, Cardinal Health, Inc., to Response for HSCS-P Threshold Event, Cardinal Health, Inc. (Oct. 22, 2008, 9:27 am) (On file with Committee).

time, it is “unable to reconstruct the specific information surrounding the threshold change for Family Discount Pharmacy on or about October 31, 2008.”<sup>824</sup>

This decrease, however, was immediately followed by five increases in Family Discount’s hydrocodone threshold that brought the monthly allowable distribution above the previous 90,000-dosage threshold.<sup>825</sup> Between November 13, 2008 and December 18, 2008, Family Discount’s threshold was increased four times to 85,000 dosage units. Family Discount hit its hydrocodone thresholds on December 17, 2008 and again on December 19, 2008.<sup>826</sup> On December 23, 2008, Family Discount completed another threshold event survey which again cited the closure of the Chapmanville pharmacy.<sup>827</sup> There is no indication in Cardinal’s due diligence files for the pharmacy that it validated this explanation. Nevertheless, on December 29, 2008—seven days after Cardinal’s SOP was implemented—Cardinal increased the pharmacy’s hydrocodone threshold from 85,000 dosage units to 110,000 dosage units. Documentation provided by Cardinal about this threshold increase states only that “data supports quantity.”<sup>828</sup>

The closure of the Health Rite Pharmacy in Chapmanville was not the only one cited by Family Discount Pharmacy to Cardinal as a justification for a threshold increase. In October 2009, Family Discount e-mailed Cardinal and asked for a hydrocodone threshold review, writing, “[w]e are in the middle of this month and our quantities continue to increase, therefore I needed some advise [sic] on how to submit a review for our threshold. i [sic] did send a threshold event survey at the end of September 2009.”<sup>829</sup> Family Discount also explained that it needed a threshold increase because it received additional customers due to issues with nearby pharmacies.<sup>830</sup> This e-mail is reproduced below:

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<sup>824</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>825</sup> Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>826</sup> Cardinal Health, Inc., Anti-Diversion Customer Profile for Family Discount, Dec. 17, 2009 and Dec. 19, 2009 (On file with Committee).

<sup>827</sup> Facsimile from Family Discount Pharmacy to Cardinal Health, Inc., Threshold Event Survey, Dec. 23, 2008 (On file with Committee).

<sup>828</sup> Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>829</sup> E-Mail from Staff, Family Discount Pharmacy, to QRA Anti-Diversion, Cardinal Health, Inc., (Oct. 14, 2009, 12:15 pm) (On file with Committee).

<sup>830</sup> *Id.*

**From:** [REDACTED]  
**Sent:** Wednesday, October 14, 2009 12:15 PM  
**To:** GMB-QRA-Anti-Diversion  
**Subject:** regulatory review

dear [REDACTED]

we currently do not have a hold on any drugs, however, at the end of sept 2009, we did receive a hold on hydrocodone, we have several factors that did increase our quantities for the month of september 2009. we are in the middle of this month and our quantites continue to increase, therefore i needed some advise on how to submitt a review for our threshold. i did send a threshold event survey at the end of September 2009. there is two main reasons for our increased units, there is a kroger pharmacy within walking distance (aprox 500 feet) from our pharmacy location. kroger pharmacy has recently purchased a new computer system, they have experienced much longer wait times due to problems with their new system, and they are also offering the flu shots, which have also increased pharmacy wait times, we have received numerous customers from krogers( kroger pharmacy at holden wv phone [REDACTED] also wal mart pharmacy located at the fountain place mall at logan wv 25601, was undergoing remodeling and we received customers from walmart as well. please let me know what i need to do to update our threshold to avoid any regulatory holds for the end of this month.

please advise

sincerely

[REDACTED]  
family discount pharmacy  
[REDACTED]

In response to Family Discount's request, Cardinal appears to have sought drug usage data from the pharmacy;<sup>831</sup> Cardinal did not increase the pharmacy's thresholds at that time.

Several months later, in January 2010, Family Discount Pharmacy renewed its request for a hydrocodone increase and provided hydrocodone dispensing data, citing the same customer service problems at the Kroger pharmacy.<sup>832</sup> There is no indication in the documents produced to the Committee that Cardinal attempted to verify Family Discount's claim regarding the Kroger pharmacy, or its previous claim about the Walmart pharmacy, by visiting the sites or otherwise. Cardinal raised the pharmacy's hydrocodone threshold from 110,005 dosages to 150,005 dosages in January 2010.<sup>833</sup>

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<sup>831</sup> E-Mail from QRA Anti-Diversion, Cardinal Health to Employee of Cardinal Health, Inc., (Oct. 14, 2009, 12:22 pm) (On file with Committee).

<sup>832</sup> Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (Jan. 18, 2010) (On file with Committee).

<sup>833</sup> Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).



**FINDING:** On at least three occasions, Family Discount Pharmacy cited the closure of another pharmacy as a reason why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims.

*iii. Family Discount Pharmacy's Frustration with Thresholds*

Cardinal also appeared to be under internal pressure from its own sales employees to increase thresholds. Concerns regarding the pharmacy's frustration with thresholds were raised after Family Discount hit its threshold for alprazolam on April 29, 2009. In a May 1, 2009 e-mail discussing the suspicious order monitoring check for the threshold event, a Cardinal sales manager wrote that the customer "has become frustrated with the repeated SOMs and feels he has provided detailed information to justify his orders."<sup>834</sup> This e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Friday, May 01, 2009 8:59 AM  
**To:** GMB-QRA-Anti-Diversion  
**Cc:** [REDACTED]; [REDACTED]  
**Subject:** FW: [SOMStatus] Status Change Notification

We have submitted utilization reports and questionnaires are filled out, a site visit has been made previously, however, thresholds are not adjusted to coincide with monthly usage. This account has become very frustrated with the repeated SOM's and feels he has provided detailed information to justify his orders.

Thanks,  
[REDACTED]

In April 2010, a Cardinal pharmacy business consultant e-mailed other Cardinal employees indicating the company had concerns about losing Family Discount's business to a competitor due to delays caused by its threshold system.<sup>835</sup> Referencing two threshold events that occurred in December 2009, a month before the company raised the hydrocodone threshold to 150,005 dosages, the Cardinal employee wrote, "we were at risk of losing Family Discount as a customer because of this interruption in service."<sup>836</sup> This e-mail is reproduced below:

<sup>834</sup> E-Mail from Sales Manager, Cardinal Health, Inc., to Sales QRA Anti-Diversion Team, Cardinal Health, Inc. (May 1, 2009, 8:59 am) (On file with Committee).

<sup>835</sup> E-Mail from Pharmacy Business Consultant, Cardinal Health, Inc., to Staff, Cardinal Health, Inc. (Apr. 12, 2010, 10:09 am) (On file with Committee).

<sup>836</sup> *Id.*

**From:** [REDACTED]  
**Sent:** Monday, April 12, 2010 10:09 AM  
**To:** [REDACTED]; [REDACTED]; [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Family Discount Pharmacy  
**Importance:** High

FYI

[REDACTED]

Here is my info too and I also wanted to provide some background info about why we have set up QRA personal attention to paid to Family Drug Mt Gay, WV. First Family Drug is a very large Independent pharmacy that hit two thresholds in December carrying over into January. The first threshold occurred on a Wednesday which was a day before the holiday and so we didn't deliver on Friday or Saturday and their next normal day was on a Monday. The second blocked order occurred on the exact same day the next week which caused their order to be blocked again and not released then had to be ordered on Monday for Tuesday since everything was reset do to a being a new month they could then get their Meds do to things being reset. These thresholds occurred do to Kroger pharmacy ( Avg 350 to 400 RX 's a day) that is across the street installed new pharmacy software which was causing their customers to wait up to 24 hrs to get a prescriptions filled. We were at risk of losing Family Pharmacy as a customer because of this interruption on service and McKesson' s says they are now offering a proactive program to prevent QRA thresholds. I hope this helps to give you some additional info. We have also had a couple of on site visits by [REDACTED] & [REDACTED] from QRA team previously. Please let me as we go through this if I can help in anyway.

Thanks,

[REDACTED]

**CARDINAL HEALTH**  
**PHARMACY BUSINESS CONSULTANT**

*iv. Cardinal's Evaluation and Reduction of Family Discount's Thresholds*

As was the case with Hurley, Cardinal began to reduce Family Discount's hydrocodone threshold after the 2012 establishment of the LV-TAC. The LV-TAC was responsible for the "periodic review and scrutiny of large volume purchasers of commonly diverted Controlled Substances or other drugs of interest (ODI) based on existing information in the QRA [Quality and Regulatory Affairs] documents and current purchase patterns."<sup>837</sup> The LV-TAC review procedures took effect on April 12, 2012.<sup>838</sup> Cardinal reduced Family Discount's hydrocodone threshold two months later from 154,500 dosage units to 100,005 dosage units as the result of an LV-TAC decision.<sup>839</sup> Cardinal reduced the pharmacy's hydrocodone threshold again in July 2012 from 100,005 doses to 75,005 doses as a result of another LV-TAC decision, which noted the reductions were "aligned to size of pharmacy."<sup>840</sup> In 2012, Cardinal reported 10 suspicious orders to the DEA regarding Family Discount's orders—all 10 were for hydrocodone and were

<sup>837</sup> Cardinal Health, Inc., Large Volume – Tactical and Analytical Committee Periodic Review Process (Apr. 12, 2012) (On file with Committee).

<sup>838</sup> *Id.*

<sup>839</sup> Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

<sup>840</sup> *Id.*

reported after the July threshold reduction.<sup>841</sup> By the end of 2012, Cardinal stopped distributing hydrocodone and oxycodone to Family Discount.<sup>842</sup>

**FINDING: After Cardinal formed a Large Volume – Tactical and Analytical Committee, it reviewed and reduced Family Discount Pharmacy’s hydrocodone threshold limit from 154,500 dosage units to 75,005 dosage units.**

The Committee asked Cardinal whether it performed any independent due diligence in the years prior to these reductions to substantiate the justifications Family Discount provided regarding its requests for threshold increases.<sup>843</sup> Cardinal responded:

As a retail independent customer of Cardinal Health, Family Discount Pharmacy was subject to Cardinal Health’s controlled substance anti-diversion program. From time to time, Family Discount Pharmacy made certain representations to Cardinal Health about changes to its business. In some instances, Cardinal Health would take steps to verify information, for example, by checking records made available on the Board of Pharmacy or DEA website.<sup>844</sup>

Cardinal’s due diligence files for Family Discount includes multiple examples of queries through the West Virginia Board of Pharmacy on pharmacy employees as well as DEA registrant profiles.<sup>845</sup> Cardinal also told the Committee it requested dispensing data from customers “from time to time” and would ask pharmacies to identify their top prescribers of controlled substances.<sup>846</sup> When asked by the Committee whether it requested or analyzed dispensing data that identified the corresponding prescribing doctor, Cardinal stated it “does not request for anti-diversion purposes prescription level information revealing the prescriber and patient as that information is protected from disclosure by HIPAA.”<sup>847</sup>

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<sup>841</sup> Cardinal Health has maintained that it has been unable to locate documentation for suspicious orders submitted to the DEA regarding West Virginia pharmacies prior to 2012. Before that time, the company indicated that it reported excessive purchases and concerning customers rather than individual suspicious orders to the DEA. *See* Cardinal Health Inc., Suspicious Orders, 2012 (On file with Committee).

<sup>842</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>843</sup> *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Cardinal Health, Inc. (Aug. 6, 2018, 3:58 pm) (On file with Committee).

<sup>844</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>845</sup> *See* Cardinal Health, Inc., West Virginia Board of Pharmacy Business Details, Jan. 20, 2008 (On file with Committee); Cardinal Health, Inc., Drug Enforcement Administration registrant profile for Family Discount Pharmacy Inc., Jan. 20, 2008 (On file with Committee).

<sup>846</sup> *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

<sup>847</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

However, in multiple instances Cardinal does not appear to have attempted to validate easily discernable information provided by the pharmacy to justify its request for a threshold increase, such as whether a pharmacy had closed. Moreover, as mentioned above, at least one other distributor requesting dispensing data with prescribers identified, and analyzed the data to identify the percentage of prescriptions written by individual doctors to identify possible red flags. Cardinal's own policies highlight that a high percentage of controlled substances prescriptions written by a single or small group of doctors can be a possible indicator of diversion.<sup>848</sup>

At the Subcommittee's May 8, 2018 hearing, Cardinal's Executive Chairman of the Board, George Barrett, was asked about the degree to which the company vetted threshold increase requests and whether it sought to verify the veracity of justifications provided. He testified:

Q. When a pharmacy goes over its monthly drug threshold, does Cardinal inquire about the reason for the higher drug order?

A. Thank you, Congresswoman. Today, if an order reaches its threshold, it simply stops. So the process is the threshold is set, and the threshold is set based on a number of factors, the size of the community it serves, not just the population but the community it serves. Other factors. Does it serve a hospice center, a surgical center, et cetera. If an order reaches that threshold, that limit, it simply stops.

Q. But in the past, did it question it, before today?

A. So as I look back at some of the historical documents, I think the thresholds probably should have been set with a different set of eyes. I've mentioned this notion of asking different questions. And I think today we'd probably set those quite differently. But I think at the time of those pharmacies you referred to, thresholds probably should have been adjusted down more quickly.

Q. Did they -- did Cardinal make an assessment as to whether the explanation for increasing its threshold made sense and verified it in any way?

A. It's hard for me to answer that fully. Again, this is part of the history. I have no reason to question the good intent of those doing that kind of assessment. They were professionals. I think they were looking at the incoming order of prescribing. I think now we know some of that prescribing was driven by some behavior that we would have liked to have caught in the physician world. And today that simply

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<sup>848</sup> Cardinal Health, Inc., Sales – Anti-Diversion Alert Signals, Dec. 22, 2008 (On file with Committee).

could not happen.<sup>849</sup>

It is critical that distributors maintain records on threshold increases and decreases, and verify justifications provided by a pharmacy to support a threshold increase. If a pharmacy cites a specific doctor as the reason for an increase in controlled substances, the distributor should be able to verify, or at least attempt to verify, the percentage of the pharmacy's prescriptions written by that doctor. Likewise, if a pharmacy cites the closure of another pharmacy as the cause of increased business, the distributor should investigate and document the veracity of that statement. Cardinal's due diligence files for Family Discount included the pharmacy's justifications for why its thresholds should be increased. Based on documents provided to the Committee, however, Cardinal did not clearly document its investigation of those justifications, if any, or its reasons why the thresholds increased or decreased.

*d. Case Study on McKesson: Enforcing Thresholds*

Even after thresholds are set, vetted, and any subsequent changes are documented and investigated, where necessary, they must be enforced. A failure to do so makes the thresholds essentially meaningless.

In 2006 and 2007, McKesson distributed more than 5.54 million dosages of hydrocodone and more than 204,000 dosages of oxycodone to Sav-Rite No. 1,<sup>850</sup> population 406, in Kermit, West Virginia.<sup>851</sup> The hydrocodone and oxycodone distributions McKesson made in 2006 and 2007 alone were enough that Sav-Rite No. 1 ranked as the company's third largest West Virginia purchaser of those two drugs between all of 2006 and 2017.<sup>852</sup> In 2006, Sav-Rite No. 1 was ranked 22nd in the nation in regard to the overall number of hydrocodone pills it received.<sup>853</sup>

As previously discussed, McKesson launched its "Lifestyle Drug Monitoring Program" (LDMP) in May 2007. This was the first monitoring program implemented by McKesson that utilized thresholds. The purpose of the program was to help identify potential excessive orders and enable the company to work more closely with the DEA, and the program set initial thresholds for all McKesson customers at 8,000 dosages per month for four controlled substance drug families including oxycodone and hydrocodone.<sup>854</sup>

On June 12, 2007, McKesson's counsel wrote to the DEA, confirming that the lifestyle drug monitoring program had been implemented nationwide, stating:

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<sup>849</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong at 108 (2018), available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>850</sup> McKesson Corp., 2006-2017 Sales Data (On file with Committee).

<sup>851</sup> American FactFinder, *Kermit town, West Virginia*, Census 2010 Total Population, available at [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml)

<sup>852</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee). The largest and second largest customers did business with McKesson for six and twelve years, respectively.

<sup>853</sup> Curtis Johnson, *Big Pill Network Exposed*, HERALD-DISPATCH, Apr. 1, 2009, [http://www.herald-dispatch.com/news/recent\\_news/big-pill-network-exposed/article\\_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html](http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html).

<sup>854</sup> McKesson Corp., Lifestyle Drug Monitoring Program, May 15, 2007 (On file with Committee).

McKesson **has already conducted a level 1 inquiry of all customers** (other than VA hospitals and chain pharmacies) about their distribution practices. These contacts have been documented at each DC. . . . McKesson is in the process of conducting a level 2 inquiry with those customers who have placed orders above the expected norm based on the customer’s profile and threshold amounts.<sup>855</sup>

The letter appended a copy of McKesson’s lifestyle drug monitoring operations manual which showed that a level 1 review would include, among other things, a review of a pharmacy’s purchases over a three-month period, an evaluation of whether the purchases were reasonable, and additional investigation if the initial evaluation yielded inconclusive results with respect to the order’s reasonableness.<sup>856</sup> The program also required documentation of these evaluations.<sup>857</sup> The Committee infers from McKesson’s representation to the DEA that it did, in fact, conduct a level 1 inquiry of all customers, including Sav-Rite No. 1, before June 12, 2007.

However, documentation provided by McKesson indicates that the company continued to ship massive quantities of opioids to Sav-Rite No. 1 even after the implementation of these guidelines and the representation to the DEA that it had completed an initial review of all its customers. In 2007—the very year the lifestyle drug monitoring program was implemented—McKesson sent more than 3 million doses of hydrocodone to the pharmacy.<sup>858</sup> Moreover, this total represents shipments for only a partial year as McKesson terminated Sav-Rite No. 1 as a customer after conducting a site visit on November 14, 2007.<sup>859</sup> The amount of hydrocodone pills McKesson sent to Sav-Rite No. 1 in 2007 equates to an average of 9,650 pills a day, or 289,500 pills a month, which is more than 36 times the threshold amount set that year by the LDMP. Given the volume of hydrocodone pills shipped during this time, it is unclear why it took five months after McKesson’s representation to the DEA that a level 1 inquiry of all customers had been completed to conduct a site visit and terminate this pharmacy as a customer.

**FINDING: In 2007, McKesson shipped an average of 9,650 hydrocodone pills a day to the Sav-Rite No. 1 pharmacy in Kermit, West Virginia. This was 36 times the threshold amount set by the Lifestyle Drug Monitoring Program.**

Notably, and as discussed previously, the entirety of the due diligence file that McKesson produced to the Committee on Sav-Rite No. 1 contained only a single, two-page document—a November 2007 affidavit of James Wooley.<sup>860</sup> The due diligence file did not include any documents regarding the level 1 review or the 8,000 dosage per month threshold imposed by the

<sup>855</sup> Letter from Counsel to McKesson Corp., to Linden Barber, Chief, Regulatory Section, Office of Chief Counsel, U.S. Drug Enforcement Admin., June 12, 2007 (emphasis added) (On file with Committee).

<sup>856</sup> McKesson Corp., Lifestyle Drug Monitoring Program, May 15, 2007 (On file with Committee).

<sup>857</sup> *Id.*

<sup>858</sup> McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).

<sup>859</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee). McKesson did not produce any documents to the Committee referring to or otherwise discussing this site visit.

<sup>860</sup> This document is produced in its entirety in Section VI(D)(2)(b)(ii) of this report.

LDMP.<sup>861</sup> The due diligence file also did not include any threshold event documentation indicating that Sav-Rite No. 1 surpassed the threshold, or any documents indicating that the threshold was raised above the 8,000 dosage per month threshold. Based on the documents provided, the Committee also cannot confirm the November 14, 2007, site visit by McKesson to Sav-Rite No. 1, or the reasons for the termination of the pharmacy by McKesson in November 2007.

**FINDING: McKesson continued to supply Sav-Rite No. 1 with massive quantities of opioids for five months after representing to the DEA that it had reviewed all customers pursuant to the Lifestyle Drug Monitoring Program.**

At the Subcommittee's May 8, 2018 hearing, McKesson President, CEO, and Board Chairman John Hammergren was asked about McKesson's continued shipments to Sav-Rite No. 1 after implementation of the LDMP:

Q. Now, McKesson started a program in 2007, I think you called it the Lifestyle Drug Monitoring Program, under which McKesson reviewed every single customer for high-volume orders for certain drugs. Is that correct?

A. That's correct.

Q. Including hydrocodone and oxycodone. I think we referenced that in tab 1 in the binder. So the initial threshold, as I understand it, set by McKesson was 8,000 pills a month. The document indicates that you picked that number as a reasonable monthly threshold, correct?

A. That's correct.

Q. And so do you know the average number of hydrocodone dosage units or pills McKesson distributed to that Sav-Rite pharmacy that you terminated a relationship with back in 2007?

A. I do not.

Q. So, we did some research. It appears it's 9,650 pills a day, which averages to 289,500 hydrocodone pills in a 30-day month, which is more than 36 times the initial monthly threshold set by the program.

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<sup>861</sup> McKesson later produced a May 2007 e-mail that indicates Sav-Rite No. 1 stood out due to its dispensing volume. This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Sav-Rite No. 1. See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, available at <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>. Rather, McKesson's production of the May 2007 e-mail was in response to a supplemental question posed by the Committee on July 31, 2018 regarding a representation McKesson made to the Committee on June 11, 2018. See E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

The program required distribution centers to review any order in excess of the threshold and document why orders above the threshold were shipped.

Now, according to a document produced by McKesson, all customers had been reviewed by June 12, 2007. This clearly should have identified Sav-Rite, considering your own distribution was 36 times higher than the threshold you set. I think that document's in tab 2. So, did this program identify the Sav-Rite pharmacy?

A. It did not, sir. It should have been terminated sooner.

Q. And if so, on what basis did McKesson decide to continue supplying hydrocodone far above your own threshold? This is what we're trying to figure out.

A. Our systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough.

Q. So, are there any documents justifying the continued distribution to Sav-Rite?

A: I don't know, sir. But, as I've testified, we terminated that relationship as soon as we became aware that the purchases were as you described.<sup>862</sup>

Following the hearing, the Committee requested clarification on Mr. Hammergren's answer.<sup>863</sup> In an e-mail to Committee staff, McKesson stated:

McKesson has not, at this point, been able to identify complete records related to the level 1 review described in its outside counsel's letter to DEA. Nonetheless, McKesson does not currently have information suggesting that Sav-Rite was flagged for further inquiry as part of the level 1 review described in that letter. McKesson personnel did, in May of 2007 (around the same time that the level 1 review was conducted), review data that caused them to flag the pharmacy for follow up.<sup>864</sup>

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<sup>862</sup> *Combating the Opioid Epidemic: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115<sup>th</sup> Cong. 60-62 (2018) (testimony of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.*

<sup>863</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (May 23, 2018 1:38 pm) (On file with Committee).

<sup>864</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (June 11, 2018 7:02 pm) (On file with Committee).



In response to follow-up questions posed by the Committee, McKesson subsequently produced the following e-mails in support of its statement that Sav-Rite No. 1 was flagged by McKesson for follow up:<sup>865</sup>

**From:** [REDACTED]  
**Sent:** 5/9/2007 11:34:59 PM  
**To:** [REDACTED]; [REDACTED]@mckesson.com]  
**Subject:** FW: Daily Dosage

Today I sat down and went through DC by DC. These two along with Garden in Lakeland really stick out. You and can connect by phone later this week or early next week, I have some thoughts on analysis.

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Wednesday, May 09, 2007 4:14 PM  
**To:** [REDACTED]; [REDACTED] (Washington Court House)  
**Cc:** [REDACTED]  
**Subject:** Daily Dosage

[REDACTED]: I have been going through the April Daily Dosage for all DC's. Two of your customers really jumped out at me

Family Discount Phcy  
Sav-Rite Phcy

We need to document those ASAP and I would like to understand their business that would drive the numbers

[REDACTED]

McKesson did not produce additional documents demonstrating what due diligence, if any, McKesson conducted to examine the pharmacy "ASAP," as described in the e-mail. At a minimum, the e-mails indicate that McKesson was aware that Sav-Rite No. 1 was a cause for concern as early as May 2007, yet did not perform a site visit or suspend distribution to the pharmacy until November 2007.

Based on the daily average, between May 2007, when McKesson identified the pharmacy as requiring additional review, and November 2007, when it conducted a site visit, McKesson distributed approximately 2.02 million doses of hydrocodone to the pharmacy. During this entire time, McKesson's threshold for Sav-Rite No. 1 was set at 8,000 dosages of hydrocodone a month.

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While many wholesale distributors have established threshold systems to identify and block customers' suspicious controlled substance orders, the Committee's investigation demonstrates that the formation of threshold guidelines alone does not necessarily prevent overdistribution and diversion. Distributors must ensure thresholds are enforced and conduct

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<sup>865</sup> E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 11:34 pm) (On file with Committee); E-mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 4:14 pm) On file with Committee).

proper oversight of threshold increase requests and approvals. As shown by H.D. Smith, when distributors do not implement formal threshold systems, they may not detect and investigate rapid increases in controlled substances purchases. McKesson established an 8,000-dosage unit a month threshold for certain highly abusable controlled substances but did not adequately enforce the threshold against a West Virginia pharmacy for months, continuing to ship the equivalent of 9,650 hydrocodone pills a day to the pharmacy. Finally, as demonstrated by Cardinal's handling of two West Virginia pharmacies, distributors need to accurately set threshold limits, as well as document the justifications for increasing or decreasing the thresholds. Distributors should also investigate the justifications provided by customers who seek to increase their drug thresholds. The documentation Cardinal provided to the Committee regarding these two customers does not justify the hydrocodone threshold increases the company approved—a conclusion the company appears to have reached itself years later when it established a task force to review large volume purchasers and subsequently lowered the thresholds of these pharmacies and others.

While the adoption, and implementation, of a threshold system certainly enhances a distributor's ability to know its customer and potentially identify suspicious orders in a more efficient manner, such systems should not be exclusively relied upon to effectively fulfill a distributor's legal obligations to maintain effective controls against diversion and to report suspicious orders when discovered. For example, if a distributor were to exclusively rely on its threshold system to identify suspicious orders, it risks not discovering suspicious activity that may be present, but potentially undetected, if a pharmacy's monthly orders for certain controlled substances do not reach the established threshold levels. As such, a distributor should incorporate its use of thresholds into its overall approach of conducting ongoing, and comprehensive due diligence of its customers that takes into account a variety of different factors, such as the prevalence of drug abuse in a particular area. Such efforts will better enable distributors to identify and report suspicious orders to the DEA, in accordance with their legal obligations.

## C. Suspicious Order Reporting by Distributors

### 1. The Legal Framework Regarding Suspicious Order Reporting

DEA regulations implementing the CSA's closed distribution system require registrants to, among other things, report suspicious orders of controlled substances to the DEA when they are discovered.<sup>866</sup> The Committee's review of suspicious order monitoring programs found the various iterations of these programs distributors had in place in West Virginia did not always result in the required reporting to DEA.

The CSA requires distributors to, among other things, "[maintain] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."<sup>867</sup> In furtherance of this statutory requirement, the CSA's implementing regulations mandate:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.<sup>868</sup>

With respect to the regulation to report suspicious orders, however, in September 2006 and February 2007, the DEA told registrants, "[it] bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion."<sup>869</sup>

To address concerns regarding controlled substance diversion, the DEA established the Distributor Initiative Program in 2005. This initiative recognized the role distributors play in the CSA's closed system of distribution and was meant to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."<sup>870</sup> As

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<sup>866</sup> See 21 C.F.R. 1301.74(b).

<sup>867</sup> 21 U.S.C. § 823(b)(1) and 21 U.S.C. § 823(e)(1).

<sup>868</sup> 21 C.F.R. § 1301.74(b). The definition of "suspicious" is not limited to orders of unusual size, frequency, or those that deviate substantially from typical ordering patterns. Pursuant to a 2015 order issued by the DEA's Acting Administrator, which has been upheld by the United States Court of Appeals for the District of Columbia Circuit, a pharmacy could have characteristics that "might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency." See 80 Fed. Reg. 55,418, 55,473-4, Sept. 15, 2015. See also *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).

<sup>869</sup> 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 Committee); 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 Committee).

<sup>870</sup> *Improving Predictability and Transparency in DEA and FDA Regulation, Hearing Before Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. Serial No. 113-137, 5 (2014) (statement of Joseph T.

part of the initiative, DEA headquarters officials conducted individual, in-person meetings with some wholesale distributors. The Committee received copies of memorandums regarding the meetings that the agency held with four of the five distributors discussed in this report: AmerisourceBergen, Cardinal, H.D. Smith, and McKesson. Miami-Luken did not have a similar meeting with the DEA. At the meetings, DEA officials reviewed the distributor's legal responsibilities and provided specific examples of the distributor's own customers whose ordering habits and characteristics were suggestive of diversion.<sup>871</sup>

Following the individual distributor initiative meetings, the DEA sent a series of three letters in 2006 and 2007 to every DEA-registered distributor, reiterating distributors' legal obligations to conduct due diligence and report suspicious orders. The initial two letters sent by the DEA in September 2006 and February 2007 provided the same guidance on circumstances which may be indicative of controlled substance diversion. Both letters stated:

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs

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Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin) *available at* <https://docs.house.gov/meetings/IF/IF14/20140407/102093/HHRG-113-IF14-Wstate-RannazzisiJ-20140407.pdf>.

<sup>871</sup> See 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=.af8d3f2847ba](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=.af8d3f2847ba). See also Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee); and Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee).

4. Ordering the same controlled substance from multiple distributors.<sup>872</sup>

The two letters also provided a suggested list of questions that distributors could use as they try to determine whether a suspicious order is indicative of diversion. An excerpt of the letters is reproduced below:<sup>873</sup>

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

Further, the letters emphasized distributors' legal responsibilities as well as the integral role they play in the CSA's closed distribution system.<sup>874</sup>

The third letter, sent on December 20, 2007, addressed suspicious order reporting in a more pointed manner. The DEA explicitly emphasized that the regulations required registrants

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<sup>872</sup> See 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 Committee); 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 Committee).

<sup>873</sup> *Id.*

<sup>874</sup> *Id.*

to inform the local DEA Division Office of suspicious orders when they are discovered and underlined this reporting requirement in the letter.<sup>875</sup> The letter stated:<sup>876</sup>

**The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unit purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.**

The DEA warned registrants that monthly reports, submitted after orders were already filled and sent to customers, would not meet the regulatory requirements, nor would such requirements be met by providing the DEA with daily, weekly, or monthly “excessive purchases” reports.<sup>877</sup> Distributors were urged to take a proactive posture for identifying suspicious orders and were cautioned against relying on rigid formulas.<sup>878</sup> The DEA also informed registrants that it would not endorse a specific system for reporting suspicious orders and that distributors should no longer rely on explicit or implicit approval they may have received from the DEA in the past.<sup>879</sup> The letter stated:

The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.<sup>880</sup>

DEA’s December 2007 letter also referenced an order issued by the DEA’s Deputy Administrator in July 2007 that revoked the DEA registration of Southwood Pharmaceuticals, Inc. for failing to meet its obligations under the CSA.<sup>881</sup> Underlying the Deputy Administrator’s decision was Southwood’s failure to identify and report suspicious orders as well as the company’s failure to conduct adequate due diligence.<sup>882</sup> In the order, the Deputy Administrator

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<sup>875</sup> 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 Committee).

<sup>876</sup> *Id.* Section 3292 of the SUPPORT for Patients and Communities Act codified the requirement of suspicious order reporting but not the other requirements upheld in *Masters* on registrants if the suspicious order is shipped. See SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

<sup>877</sup> 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 Committee).

<sup>878</sup> *Id.*

<sup>879</sup> *Id.*

<sup>880</sup> *Id.*

<sup>881</sup> See 72 Fed. Reg. 36,504, July 3, 2007.

<sup>882</sup> See *Id.* at 36,487.

rejected Southwood’s argument that its submission of ARCOS data was an acceptable substitute for submitting timely suspicious order reports, stating:

The ARCOS reporting requirement and the suspicious orders reporting requirement serve two different purposes. While ARCOS provides the Agency with information regarding trends in the diversion of controlled substances, the reports need not be submitted until fifteen days after the end of the reporting period. In contrast, as explained above, a suspicious order must be reported “when discovered by the registrant.” 21 CFR 1301.74(b). The suspicious order reporting requirements exists to provide investigators in the field with information potential illegal activity in an expeditious manner. Respondent’s compliance with the ARCOS reporting requirement is thus not a substitute for its failure to report suspicious orders.<sup>883</sup>

The Deputy Administrator also made clear the company’s disclosure of its largest controlled substance purchasers to the DEA was also not an acceptable substitute for submitting timely suspicious order reports, stating:

Even if [Respondent] had no intent to mislead by submitting these negative reports, Respondent still violated the regulation by failing to report suspicious orders. That some of the pharmacies were identified on the two reports Respondent submitted listing its largest purchasers of controlled substances (which Respondent submitted in February and July 2006), does not excuse its failure to comply with the regulation.<sup>884</sup>

Distributors were also apprised of their responsibility to report suspicious orders at a pharmaceutical industry conference held in September 2007. At the conference, the Chief of DEA’s Regulatory Section and AmerisourceBergen’s Vice President of Corporate Security and Regulatory Affairs gave a joint presentation on distributors’ legal obligations to maintain effective controls against diversion and report suspicious orders when they are discovered.<sup>885</sup> According to a summary of the conference published by DEA, AmerisourceBergen “stressed the importance of knowing your customer, and providing due diligence investigations on all new retail and wholesale accounts, with the exception of retail chain pharmacies.”<sup>886</sup>

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<sup>883</sup> *Id.* at 36,501.

<sup>884</sup> *Id.*

<sup>885</sup> U.S. Drug Enforcement Admin., *Pharmaceutical Industry Conference – September 11 & 12, 2007 – Houston, Texas* (last visited July 10, 2018) available at [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_industry/13th\\_pharm/index.html](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html). AmerisourceBergen’s presentation at the industry conference came shortly after the company reached a settlement with the federal government on June 22, 2007 to resolve allegations that it failed to meet its obligations and maintain effective controls to prevent controlled substance diversion. As will be discussed in this section, notwithstanding the company’s participation in the September 2007 industry conference, the Committee has concerns with respect to AmerisourceBergen’s recent suspicious order reporting efforts. See *infra*, Section VI(C)(4).

<sup>886</sup> U.S. Drug Enforcement Admin., *Pharmaceutical Industry Conference – September 11 & 12, 2007 – Houston, Texas* (last visited July 10, 2018) available at [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_industry/13th\\_pharm/index.html](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html).

In order to understand the processes by which distributors monitor and report suspicious orders, the Committee requested that AmerisourceBergen, Cardinal, McKesson, H.D. Smith, and Miami-Luken provide copies of any manuals outlining suspicious order monitoring programs or written protocols regarding the identification of suspicious orders.<sup>887</sup> The Committee also requested the companies provide suspicious order reports submitted to the DEA.

The information distributors provided to the Committee demonstrates a variety of interpretations regarding companies' suspicious order report submissions to DEA. McKesson, for example, reported suspicious customers, which it defined as customers it stopped selling controlled substances to, rather than individual suspicious orders to DEA. As a result, McKesson did not submit its first suspicious order report regarding West Virginia pharmacies until 2013. Others like Cardinal Health were unable to provide a comprehensive accounting of suspicious orders reported to DEA, raising questions about the thoroughness of Cardinal's suspicious order monitoring program. AmerisourceBergen began blocking and reporting suspicious orders in 2008 in West Virginia, but after reporting an annual high of 792 suspicious orders in 2013, the company reported just five in 2017. Miami-Luken was found to have no suspicious order monitoring program in place at all and instead allowed employees to make subjective assessments regarding which orders to block and report. H.D. Smith blocked hundreds of hydrocodone and oxycodone orders made by West Virginia pharmacies, but did not report those orders as suspicious because it was instead focused on reporting to DEA customers it terminated. Despite the long-standing legal requirement to report suspicious orders and the supplemental guidance provided by the DEA and a fellow distributor, the documents indicate in West Virginia, that distributors largely failed to meet their legal responsibilities under the CSA.

## **2. McKesson's Suspicious Order Reporting for West Virginia Pharmacies**

From April 2006 through 2016, McKesson supplied more than 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies.<sup>888</sup> The Committee requested McKesson provide all suspicious order reports it made to the DEA regarding orders placed by

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<sup>887</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President and Chief Exec. Officer, AmerisourceBergen Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215AmerisourceBergen.pdf>; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf>; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammargren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to J. Christopher Smith, President and Chief Exec. Officer, H.D. Smith., Jan. 26, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126HDSmith.pdf>; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Jan. 26, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126Miami-Luken.pdf>.

<sup>888</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee).



West Virginia pharmacies from 2006 to 2017.<sup>889</sup> During this period, and as discussed in greater detail below, McKesson entered into two settlements with the DEA in 2008 and 2017 that required changes to its suspicious order monitoring policies. As a result of changes McKesson made to its policies and procedures during this time, the company did not continuously report the same information to the DEA and could not produce the requested information for the full 11-year period.

**FINDING: McKesson Corporation supplied just under 300 million doses of hydrocodone and oxycodone to West Virginia pharmacies between April 2006 and 2016.**

DEA met one-on-one with McKesson twice in 2005 and 2006 as part of the agency's Distributor Initiative to discuss drug diversion concerns. A DEA memorandum describes a September 2005 meeting and indicates that DEA briefed McKesson about sales of controlled substances to illicit internet pharmacies, and specifically identified a pharmacy that McKesson was supplying.<sup>890</sup> The memorandum stated:

During this briefing, McKesson Corporation was provided with information to identify potential illicit Internet pharmacies, advised that hydrocodone, Alprazolam, and Phentermine were the preferred controlled substances in this illicit market, and actions which McKesson Corporation could implement to prevent sales to illicit internet pharmacies.<sup>891</sup>

In January 2006, DEA discussed with McKesson concerns regarding the company's shipment of more than 2 million doses of hydrocodone to six alleged Internet pharmacies over a twelve-day period despite the prior meeting regarding diversion warning signs.<sup>892</sup> DEA officials indicated at the meeting that McKesson might be asked to surrender the registration for its Lakeland, Florida Distribution Center or the DEA would pursue an Order to Show Cause.<sup>893</sup> Amid the backdrop of these interactions with DEA, McKesson began to alter its suspicious order reporting practices.

Prior to 2008, McKesson complied with its suspicious order reporting requirements by submitting "excessive order" reports to the DEA, which were orders that exceeded certain thresholds set by the company.<sup>894</sup> McKesson described these reports as "large hard copy

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<sup>889</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>.

<sup>890</sup> See Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee).

<sup>891</sup> *Id.*

<sup>892</sup> See Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee).

<sup>893</sup> *Id.*

<sup>894</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp., to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

printouts of individual orders” that were compiled by distribution centers and sent to local DEA offices on a monthly basis.<sup>895</sup> It was not until April 2008 that McKesson began to block suspicious orders that exceeded monthly thresholds.<sup>896</sup> As stated above, the DEA’s letters to McKesson and other distributors made clear that filing excessive order reports does not satisfy a distributor’s legal obligation to report suspicious orders.<sup>897</sup>

McKesson entered into a \$13.25 million settlement and an administrative memorandum of agreement with the DEA in May 2008 to resolve allegations that several of its distribution centers violated their legal obligations by failing to report suspicious orders, as required by 21 C.F.R. § 1301.74(b).<sup>898</sup> When the Department of Justice announced DEA’s 2008 settlement with McKesson regarding its alleged failure to report suspicious orders, authorities noted McKesson’s continued shipment of controlled substances to illicit internet pharmacies despite the Distributor Initiative warnings:

Three McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They did so even after a Sept. 1, 2005, meeting at which DEA officials met with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions. The pharmacies filled purported online “prescriptions” for hydrocodone (contained in drugs such as Vicodin), but the prescriptions were issued outside the normal course of professional practice and not for a legitimate medical purpose.<sup>899</sup>

McKesson told the Committee that, while this settlement was being finalized, “certain local DEA offices communicated to McKesson that it should stop sending ‘excessive order’ reports because they were inundating the local DEA office fax machines and were not useful.”<sup>900</sup> Instead of sending reports of excessive orders, McKesson said it understood the DEA wanted the company “to identify problematic pharmacies and report those pharmacies to DEA.”<sup>901</sup> However, the administrative memorandum of agreement subsequently filed in the settlement states that, among other things, McKesson would maintain a compliance program that included

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<sup>895</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>896</sup> Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

<sup>897</sup> See 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 Committee).

<sup>898</sup> *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).

<sup>899</sup> U.S. Dept. of Justice, *McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, May 2, 2008, available at <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

<sup>900</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>901</sup> *Id.*

procedures to review orders for controlled substances and report suspicious orders to the DEA. According to the memorandum of agreement:

Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels.<sup>902</sup>

The agreement further stipulated that McKesson should inform DEA headquarters of suspicious orders rather than the local DEA field divisions.<sup>903</sup>

In 2008, McKesson substantially revised its Controlled Substance Monitoring Program (CSMP), including the adoption of a new policy to report suspicious customers to the DEA instead of reporting individual orders.<sup>904</sup> McKesson defined suspicious customers as being those that it had terminated.<sup>905</sup> Documents McKesson identified as its 2008 CSMP operations manual, however, do not explicitly state that only terminated customers will be reported. Rather, the policy is broader and included suspicious orders, transactions, and customers.<sup>906</sup> The policy is reproduced below:

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<sup>902</sup> *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).

<sup>903</sup> *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).

<sup>904</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

<sup>905</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

<sup>906</sup> See McKesson, Controlled Substance Monitoring Program, First version drafted Feb. 11, 2008, (On file with Committee). The Committee asked McKesson to produce copies of the CSMP operating manual used in each year between 2006 through 2017. McKesson identified this document as its 2008 CSMP, though the document incorporates 43 revisions made through Sept. 24, 2013. The revisions are noted in a log at the end of the document, and indicate what section was changed and when.

## 6. DEA Reporting Requirements

As per the McKesson/DEA agreement, McKesson will provide the following information to the DEA:

- On a daily basis, McKesson will report any controlled substance transactions/customer that is deemed "suspicious". This process will be performed centrally by the Directors of Regulatory Affairs.
- On a monthly basis, McKesson will provide reports of all non-reportable controlled substance transactions.

### 6.1 Suspicious Order / Customer Reporting

If at any time a customer or customer transaction is discovered and deemed to be "suspicious", that customer shall be reported to the appropriate Director of Regulatory Affairs. The Regulatory Affairs department will notify the appropriate DEA offices and provide to them any required information.

Distribution centers will be directed to contact their local DEA field offices to report the suspicious customer/transaction as needed by their regional DRA.

Suspicious orders/transactions/customers can be discovered by way of the Level 1, 2, 3 process, DC partner input and/or sales interaction.

Though the CSMP states the company will, on a daily basis, "report any controlled substance transactions/customer that is deemed 'suspicious,'" <sup>907</sup> McKesson said it was not the company's practice at that time to report suspicious orders to the DEA. McKesson told the Committee that "[w]hile orders that exceeded monthly thresholds were blocked under the program, those blocked orders were not reported to DEA as 'suspicious.'" <sup>908</sup> The chart below details the number of hydrocodone and oxycodone orders from West Virginia pharmacies that McKesson blocked but did not report to DEA between May 19, 2008 and July 30, 2013. <sup>909</sup> McKesson began reporting suspicious orders to the DEA on August 1, 2013, so the chart only reflects orders blocked before that time.

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<sup>907</sup> See McKesson, Controlled Substance Monitoring Program, First version drafted Feb. 11, 2008 (On file with Committee).

<sup>908</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>909</sup> McKesson Corp., West Virginia pharmacy hydrocodone and oxycodone orders McKesson did not ship (On file with Committee).

West Virginia Hydrocodone and Oxycodone Orders Blocked by McKesson <sup>910</sup>							
2006	2007	2008 <sup>911</sup>	2009	2010	2011	2012	2013 <sup>912</sup>
0	0	300	322	234	221	541	316

McKesson told the Committee that, after the 2008 settlement, it reviewed its revised CSMP with DEA, including its plan to focus on reporting suspicious customers instead of suspicious orders.<sup>913</sup> According to McKesson, “DEA does not appear to have raised concerns about the program’s design or its focus on suspicious customers at that time.”<sup>914</sup> The Committee was not able to verify this statement through documents produced by McKesson.

However, McKesson’s plan to report suspicious customers instead of suspicious orders ran counter to the plain and unambiguous text of the regulation which requires distributors to report suspicious orders when they are discovered.<sup>915</sup> In addition, McKesson’s plan to focus on reporting suspicious customers was proposed just a few months after the company received the December 2007 letter from the DEA wherein the agency highlighted the legal requirement to report suspicious orders “when discovered” – a phrase underlined for emphasis in the letter.<sup>916</sup> The DEA letter also advised distributors that the agency would not approve or endorse a particular system for reporting suspicious orders and that it was incumbent upon the distributors to satisfy their legal obligations.<sup>917</sup> McKesson’s plan to satisfy its legal requirements by reporting suspicious customers was also contrary to DEA precedent, as stated in the July 3, 2007 Deputy Administrator Order, which expressly rejected alternate types of reporting other than the timely reporting of individual suspicious orders.<sup>918</sup>

From 2008 through July 2013, McKesson did not submit any suspicious order reports to the DEA with respect to orders placed by West Virginia pharmacies. In documents provided to the Committee, the earliest suspicious order McKesson reported to the DEA regarding a West Virginia pharmacy was made on August 1, 2013.<sup>919</sup>

<sup>910</sup> *Id.*

<sup>911</sup> McKesson Corp. began blocking orders on May 19, 2008, so this represents a partial year.

<sup>912</sup> McKesson began reporting orders to the DEA on August 1, 2013, so this represents a partial year.

<sup>913</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>914</sup> *Id.*

<sup>915</sup> See 21 C.F.R. 1301.74(b).

<sup>916</sup> See 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 Committee).

<sup>917</sup> *Id.*

<sup>918</sup> See 72 Fed. Reg. 36,487, July 3, 2007.

<sup>919</sup> McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee). The Committee’s review of material obtained during its investigation indicates that McKesson’s failure to report suspicious orders to the DEA was not limited to West Virginia. The Committee requested that McKesson provide

**FINDING: McKesson did not submit suspicious order reports to the DEA regarding orders placed by West Virginia pharmacies until August 1, 2013.**

Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.<sup>920</sup> Between 2006 and 2012, the years in which McKesson did not submit any suspicious order reports to the DEA, the company shipped more than 162.6 million doses of hydrocodone and oxycodone to pharmacies in West Virginia.<sup>921</sup> The chart below details the number of suspicious order reports submitted to DEA regarding West Virginia pharmacies as well as the amount of oxycodone and hydrocodone doses shipped to the state each year.

Suspicious Order Reports Submitted by McKesson to the DEA <sup>922</sup>											
2006	2007	2008	2009	2010	2011	2012	2013*	2014	2015	2016	2017**
0	0	0	0	0	0	0	992	3,346	2,603	1,954	1,148
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia <sup>923</sup>											
17.07	25.63	23.67	22.76	22.16	24.94	26.42	27.92	32.03	40.71	36.53	---

\* Documents provided to the Committee indicate that McKesson submitted its first suspicious order report to DEA regarding a West Virginia pharmacy on Aug. 1, 2013, thus, the number of reports in 2013 represents a partial year.  
 \*\* McKesson provided suspicious order reports through December 18, 2017; thus, the number of suspicious orders reported in 2017 represents a partial year.

**FINDING: Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.**

the five states with the highest number of suspicious orders that McKesson reported to the DEA for each year between 2006 and 2017. *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, available at <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf>. McKesson failed to provide the Committee with any statistics for suspicious orders reported between 2006 and 2010, suggesting that no suspicious orders were reported in that timeframe. In 2011 and 2012, McKesson reported a very low number of suspicious orders to the DEA. *See* McKesson Corp., States with the Highest Number of Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>920</sup> *See* McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

<sup>921</sup> *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee).

<sup>922</sup> McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

<sup>923</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee). McKesson produced shipment data from April 2006 through the end of 2016.

McKesson began reporting suspicious orders and revised its suspicious order monitoring system after the company came under investigation by the DEA, suggesting to the Committee that the change was prompted by this enforcement action. Documents obtained by the Committee show that the DEA was actively investigating McKesson in early 2013,<sup>924</sup> and the agency served McKesson with an Administrative Inspection Warrant and an Administrative Subpoena on March 12, 2013 in order to obtain records from the company's Aurora, Colorado distribution facility, in furtherance of a possible ISO.<sup>925</sup> That same year McKesson began reporting suspicious orders to the DEA in West Virginia and also "devoted substantial resources to enhance and revise its CSMP."<sup>926</sup> In a letter to the Committee, McKesson described six subject areas in which it has made improvements to its CSMP since 2013. Those areas include: an expansion of its compliance team, additional customer due diligence, advanced threshold analytics and suspicious order reporting, ongoing oversight, customer education, and collaboration with federal and state authorities.<sup>927</sup>

**FINDING: McKesson devoted "substantial resources to enhance and revise" its Controlled Substance Monitoring Program in 2013, the same year the DEA served the distributor an Administrative Inspection Warrant and an Administrative Subpoena to obtain records from its Aurora, Colorado distribution facility.**

McKesson has continued to update its policies in conjunction with enforcement activities from the DEA. In January 2017, McKesson entered into another administrative memorandum of agreement with the DEA and agreed to pay a record-setting \$150 million civil penalty. As part of the settlement, the company accepted responsibility for failure to abide by the terms of the 2008 settlement agreement, including by failing to report suspicious orders to the DEA that should have been identified as suspicious "at various times" between January 1, 2009 and January 17, 2017.<sup>928</sup>

The settlement again required McKesson to send daily suspicious order reports to DEA headquarters rather than division offices and obligated McKesson to "maintain a compliance program intended to detect and prevent diversion of controlled substances."<sup>929</sup> A 36-page compliance addendum attached to the settlement includes other requirements, such as

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<sup>924</sup> E-Mail from Legal Assistant, U.S. Drug Enforcement Admin., to Section Chief, Pharmaceutical Investigations Section, U.S. Drug Enforcement Admin., et al. (Feb. 5, 2013 1:53 pm) (On file with Committee).

<sup>925</sup> U.S. Drug Enforcement Admin., *Significant Enforcement Activity Report (SEAR Number: SEAR-2013-00643)*, Mar. 15, 2013 (On file with Committee).

<sup>926</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>927</sup> *See Id.*

<sup>928</sup> *In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928471/download>.

<sup>929</sup> *Id.*

maintaining documentation regarding the onboarding of new customers and threshold change requests, and it required McKesson to block and not ship the orders it identifies as suspicious.<sup>930</sup>

Updates were also made to McKesson's CSMP manual in May 2017. The most recent version of the CSMP manual regarding independent and small-to-medium chain retail pharmacies that McKesson provided to the Committee states that all controlled substance orders that exceed a customer's monthly threshold cap are blocked and flagged.<sup>931</sup> At the end of each business day, all flagged orders are compiled in a suspicious order report that is transmitted to DEA headquarters.<sup>932</sup>

McKesson did not report suspicious orders for West Virginia customers until 2013. Since it began doing so, the company submitted upwards of 10,000 suspicious order reports to the DEA. By not reporting suspicious orders when they were discovered, McKesson failed to meet its responsibilities under the CSA. In addition, the failure to report suspicious orders deprived the DEA of timely information that could have alerted the agency to potential controlled substance diversion, which the agency could have used to act against registrants that were illegally diverting controlled substances.

### **3. Cardinal Health's Suspicious Order Reporting for West Virginia Pharmacies**

Cardinal Health distributed approximately 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016, making it the state's largest supplier of controlled substances out of the companies examined as part of the Committee's investigation.<sup>933</sup> The Committee requested that Cardinal provide all suspicious order reports it made to the DEA regarding orders placed by West Virginia pharmacies between 2006 and 2017, as well as policies and procedures related to suspicious order monitoring.<sup>934</sup>

**FINDING: Cardinal was West Virginia's largest supplier of oxycodone and hydrocodone between 2005 and 2016, distributing approximately 366 million doses during that time.**

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<sup>930</sup> *In re McKesson*, Compliance Addendum, Jan. 17, 2017, available at <https://www.justice.gov/opa/press-release/file/928481/download>.

<sup>931</sup> McKesson, ISMC Controlled Substance Monitoring Program Operating Manual, May 17, 2017 (On file with Committee).

<sup>932</sup> *Id.*

<sup>933</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).

<sup>934</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec. Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, available at <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf>.



In response to the Committee’s request, Cardinal produced spreadsheets detailing suspicious order reports made to the DEA from January 2012 through September 2017.<sup>935</sup> Cardinal told the Committee that, prior to 2012, the company “reported to DEA concerning customers to whom it had ceased distribution of controlled substances based on concerns about potential diversion.”<sup>936</sup> Cardinal also told the Committee that it consolidated its suspicious order reporting into one system in 2012 and therefore could not produce comprehensive suspicious order reporting data prior to that time.<sup>937</sup> From 2006 to 2011, the time period for which Cardinal was unable to provide comprehensive data regarding suspicious order reporting in West Virginia, the company distributed approximately 174 million doses of hydrocodone and oxycodone to the state.<sup>938</sup> The below chart details the suspicious orders Cardinal could confirm it submitted to the DEA regarding West Virginia pharmacies from January 2012 through September 16, 2017. During this time, Cardinal submitted more than 2,000 suspicious order reports regarding purchases of all controlled substances.

<b>Suspicious Order Reports Submitted by Cardinal to the DEA<sup>939</sup></b>											
2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017**
0	0	1*	0	0	0	245	542	557	285	260	181
<b>Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia<sup>940</sup></b>											
23	24	27	28	36	36	36	31	32	40	34	---

\* This suspicious order report was identified by the Committee during its review.

\*\* Cardinal provided suspicious order reports through September 16, 2017; thus, the number of suspicious orders reported in 2017 represents a partial year.

The Committee identified a small number of suspicious order reports submitted by Cardinal to the DEA prior to 2012 in the due diligence files the Committee requested for specific West Virginia pharmacies. For example, Cardinal produced a suspicious order report it submitted to DEA regarding Hurley Drug Company’s attempted purchase of 8,000 doses of alprazolam in November 2008.<sup>941</sup> The report sent to DEA indicated the pharmacy’s alprazolam threshold was set at 5,000 doses at that time and the entire order was blocked. Another

<sup>935</sup> Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>936</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).

<sup>937</sup> See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).

<sup>938</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).

<sup>939</sup> Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>940</sup> Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).

<sup>941</sup> Facsimile from Cardinal Health, Inc. to Drug Enforcement Admin., Charleston Resident Office, Dec. 3, 2008 (On file with Committee)

suspicious order report was submitted to the West Virginia Board of Pharmacy regarding Family Discount Pharmacy's attempted purchase of 18,600 doses of hydrocodone in December 2008.<sup>942</sup> The report indicates that the entire order was blocked.<sup>943</sup>

**FINDING: Cardinal did not have a consolidated suspicious order reporting system in place until 2012 and was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012.**

Gaps in Cardinal's suspicious order monitoring program came despite guidance from the DEA on suspicious order reporting obligations. DEA met one-on-one with representatives of Cardinal Health in August 2005 as part of the agency's Distributor Initiative. At the meeting, DEA discussed the characteristics of pharmacies involved in illicit internet sales and provided Cardinal with an example of a Miami, Florida customer to whom the distributor had supplied more than 100,000 doses of hydrocodone a month for three months.<sup>944</sup> After the presentation, Cardinal representatives advised "they would do some research on that account."<sup>945</sup> Cardinal also requested DEA "provide them with as much information as possible concerning the drugs involved, the states that seem to have more Internet pharmacies than others, and anything else that could help them narrow the scope of their review for suspicious orders."<sup>946</sup>

Despite the DEA meeting, Cardinal Health apparently struggled to meet its legal requirements to prevent diversion. Cardinal Health entered into settlement agreements with the federal government on multiple occasions to resolve allegations that it failed to maintain effective controls against diversion and report suspicious orders to the DEA. In 2008, Cardinal agreed to pay a \$34 million fine to resolve allegations that several of its distribution centers failed to maintain effective controls and to report suspicious orders to the DEA.<sup>947</sup> The agreement stipulates that Cardinal employees would review orders that hit established thresholds and determine whether they should be blocked and reported to DEA or allowed to be filled.<sup>948</sup> Under the terms of the settlement agreement, Cardinal was required to report suspicious orders to DEA in the following manner:

Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose

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<sup>942</sup> Facsimile from Cardinal Health, Inc. to West Virginia Board of Pharmacy, Jan. 16, 2009 (On file with Committee).

<sup>943</sup> *Id.*

<sup>944</sup> Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee).

<sup>945</sup> *Id.*

<sup>946</sup> *Id.*

<sup>947</sup> *In re Cardinal Health*, Settlement Agreement, Oct. 2, 2008 (On file with Committee).

<sup>948</sup> *In re Cardinal Health*, Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008 (On file with Committee).

and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels.<sup>949</sup>

Cardinal's agreement also described how the company was required it to report suspicious orders to DEA headquarters rather than DEA field offices.<sup>950</sup> The settlement agreement stated, in part:

Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters.<sup>951</sup>

Cardinal implemented its first formal standard operating procedures (SOP) in 2008. As previously discussed, among the policies implemented in 2008, Cardinal began using an electronic order monitoring system, which established "custom thresholds for controlled substance distribution for all customers based on the customer's size and class of trade, using historical controlled substance ordering data for all customers."<sup>952</sup> Cardinal's SOP also outlined requirements for, among other things, reporting suspicious orders to DEA and other regulatory bodies, conducting on-site investigations, interactions between the sales team and pharmacy customers, and responding to "highlight reports" that flag customer pharmacies for investigation based on changes in controlled substance sales.<sup>953</sup> The 2008 policy regarding the regulatory notification of suspicious orders required "communication to the DEA about suspicious controlled substances ordering and suspension of controlled substances sales to customers whose orders CAH has deemed suspicious."<sup>954</sup>

Although Cardinal's policies dating back to 2008 required it to notify DEA of suspicious orders, the Committee was unable to determine the frequency with which this occurred in West Virginia prior to 2012 because Cardinal was unable to provide consolidated data regarding suspicious order reporting. The company told the Committee it terminated or suspended shipments of controlled substances to approximately 330 customers across the United States between December 1, 2007 and February 2, 2012.<sup>955</sup>

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<sup>949</sup> *Id.*

<sup>950</sup> *Id.*

<sup>951</sup> *Id.*

<sup>952</sup> Letter from Counsel to Cardinal Health, Inc. to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee). Cardinal's threshold policies are discussed in further detail in section VI(B)(1)(b).

<sup>953</sup> See Cardinal Health, Inc., Sales – Highlight Report, Dec. 22, 2008 (On file with Committee); see also Cardinal Health, Inc., Sales - Investigation, Dec. 22, 2008 and Cardinal Health, Inc., Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled/List 1 Substances, Dec. 22, 2008 (On file with Committee). **3**

<sup>954</sup> Cardinal Health, Inc., Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled/List 1 Substances, Dec. 22, 2008 (On file with Committee).

<sup>955</sup> See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

**FINDING: Since 2008, Cardinal’s policies have required notification of DEA regarding suspicious orders. The company was unable to provide comprehensive data prior to 2012 demonstrating compliance with these reporting policies in West Virginia.**

Despite the adjustments made to Cardinal’s suspicious order monitoring system, the company’s suspicious order monitoring program came under scrutiny by DEA again. In May 2012, Cardinal entered into another settlement with DEA to resolve allegations that its Lakeland, Florida distribution facility did not abide by the terms of the 2008 settlement agreement and that it continued to fail to report suspicious orders to the DEA.<sup>956</sup> As part of the agreement, Cardinal admitted that between the time the 2008 memorandum of agreement took effect and May 14, 2012, it failed to detect and report suspicious orders and failed to conduct due diligence to ensure controlled substances were not diverted.<sup>957</sup> Among the terms and conditions of the settlement, Cardinal was required to maintain a compliance program that would detect and prevent controlled substance diversion, to implement procedures ensuring the company inspected pharmacies where diversion was suspected, and to enhance its procedures for establishing thresholds and its processes for conducting due diligence reviews.<sup>958</sup>

With respect to reporting suspicious orders to the DEA, the settlement again required Cardinal to report suspicious orders to DEA headquarters rather than DEA field offices.<sup>959</sup> The Administrative Memorandum of Agreement stated, in part:

f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.

Cardinal issued a “complete rewrite” of its policies related to detecting and reporting suspicious orders and responding to threshold events in April 2012.<sup>960</sup> In an explanation of the changes, Cardinal’s policy states the rewrite was done “to properly define the process for detecting and reporting suspicious order and responding to threshold events.”<sup>961</sup>

<sup>956</sup> *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012 (On file with Committee).

<sup>957</sup> *Id.*

<sup>958</sup> *Id.*

<sup>959</sup> *Id.*

<sup>960</sup> Cardinal Health, Inc., Detecting and Reporting Suspicious Orders and Responding to Threshold Events, Apr. 12, 2012 (On file with Committee).

<sup>961</sup> *Id.*

**FINDING: Cardinal issued a “complete rewrite” of its Detecting and Reporting Suspicious Orders and Responding to Threshold Events policy in April 2012. This was done a month before it entered into a settlement agreement with DEA to resolve allegations the company failed to report suspicious orders.**

The policy described orders as suspicious if they were of unusual size, frequency or deviated substantially from a normal pattern for the customer.<sup>962</sup> Cardinal’s 2012 policy provided detailed guidance on how to respond to each circumstance and required that any order deemed suspicious must be held and reported to the DEA.<sup>963</sup>

The civil penalties component of the 2012 settlement was resolved in 2016 when Cardinal agreed to pay a \$34 million fine as well as another \$10 million fine to resolve allegations brought against one of its subsidiaries, Kinray, Inc.<sup>964</sup> Policy updates continued in 2016. While a version of the policy issued in October 2016 included much of the same language describing the initial review of customer orders, it additionally required that a held order be reviewed by Corporate Quality and Regulatory Affairs (QRA) personnel and incorporates the DEA-mandated requirement that threshold adjustments above a certain level require two-person concurrence.<sup>965</sup>

Prior to 2012, Cardinal focused on reporting to DEA customers it suspended rather than individual suspicious orders. According to Cardinal, the company terminated or suspended shipments of controlled substances to approximately 330 customers across the United States between December 1, 2007 and February 2, 2012.<sup>966</sup> The company appears to have been submitting individual suspicious order reports prior to 2012, as demonstrated by documentation included in Family Discount Pharmacy’s due diligence files, as discussed earlier. As the 2012 settlement agreement between the DEA and Cardinal made clear, however, the DEA was not satisfied by the level of suspicious order reporting that occurred between 2008 and 2012. Cardinal was unable to provide consolidated report data to the Committee regarding suspicious orders prior to 2012, so it is unclear how frequently such reports were submitted. Cardinal issued revised suspicious order policies in 2012 and between 2012 and 2017, Cardinal submitted more than 2,000 suspicious order reports to DEA regarding West Virginia pharmacies.<sup>967</sup>

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<sup>962</sup> *Id.*

<sup>963</sup> *Id.*

<sup>964</sup> Press Release, U.S. Dep’t of Justice, M.D. Fla., United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under the Controlled Substances Act (Dec. 23, 2016), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

<sup>965</sup> Cardinal Health, Inc., Detecting and Reporting Suspicious Orders and Responding to Threshold Events, Oct. 17, 2016 (On file with Committee).

<sup>966</sup> See Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

<sup>967</sup> Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

#### **4. AmerisourceBergen’s Suspicious Order Reporting for West Virginia Pharmacies**

AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.<sup>968</sup> The Committee requested AmerisourceBergen provide all suspicious order reports submitted to the DEA regarding orders placed by West Virginia pharmacies from 2006 and 2017 as well as policies and procedures related to suspicious order monitoring during that period.<sup>969</sup> AmerisourceBergen told the Committee it had a program in place to monitor and report suspicious orders since at least the 1980s.<sup>970</sup> Contrary to McKesson and Cardinal, AmerisourceBergen began blocking and reporting suspicious orders to the DEA in 2007.

**FINDING: AmerisourceBergen distributed nearly 250 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.**

Two years before AmerisourceBergen began reporting suspicious orders to the DEA, the agency provided guidance to the company on how to comply with its legal obligations. The DEA met one-on-one with AmerisourceBergen in 2005 as part of the Distributor Initiative to discuss characteristics and warning signs of illicit internet pharmacies. A DEA memorandum regarding the August 2005 meeting states that DEA officials discussed distributors’ legal responsibilities to report suspicious orders when they are discovered and provided AmerisourceBergen with two examples of internet pharmacies to highlight “the brazenness of activity to which Internet pharmacies will go to.”<sup>971</sup>

Prior to July 2007, AmerisourceBergen mailed copies of reports to the DEA on a monthly basis identifying pharmacies that placed orders for controlled substances in excess of thresholds set by the company.<sup>972</sup> Although AmerisourceBergen reported these orders to the DEA, it did not block suspicious orders received from customers prior to July 17, 2007.<sup>973</sup>

Less than a month before AmerisourceBergen began blocking orders, the company reached a settlement with the federal government on June 22, 2007 that resolved allegations that it previously failed to meet its obligations and maintain effective controls to prevent controlled substance diversion.<sup>974</sup> Once AmerisourceBergen began blocking suspicious orders, it also

<sup>968</sup> Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>969</sup> See Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President and Chief Executive Officer for AmerisourceBergen Corp., Feb. 15, 2018, *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf>.

<sup>970</sup> See Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>971</sup> Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee).

<sup>972</sup> Briefing by Staff, AmerisourceBergen Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

<sup>973</sup> *Id.*

<sup>974</sup> *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with Committee).



started submitting suspicious order reports to the DEA when the orders were deemed suspicious, instead of doing so on a monthly basis, including those for orders placed by West Virginia pharmacies.<sup>975</sup>

AmerisourceBergen told the Committee that, in 2007, it created an “enhanced order monitoring program” in “consultation with DEA.”<sup>976</sup> According to policies and procedures AmerisourceBergen provided the Committee, the company issued numerous revised policies in June 2007– the same month it reached a settlement with DEA. In testimony at the Subcommittee’s May 8, 2018 hearing, AmerisourceBergen Chairman Steven Collis described the interaction the company had with DEA at the time:

Q. [Has DEA] ever given you any kind of directions or guidelines? You know, I get it if they’re outside the rim, you know, and obviously there’s something going on. But, I mean, aside from that. Mr. Collis.

A. Well in 2007, we had a lot of discussion with them, and we developed our current controlled substance order monitoring program and with the understanding that this was where they wanted the industry to go.<sup>977</sup>

The order monitoring program developed in 2007 “consisted of policies and procedures dedicated to diversion control; a team of full-time diversion control employees; Know Your Customer Due Diligence; an Order Monitoring Program; ongoing monitoring and investigations; and training.”<sup>978</sup> As part of that program, the company “began to compare orders placed by customers to thresholds” and then block orders determined to be suspicious.<sup>979</sup>

**FINDING: In June 2007, AmerisourceBergen reached a settlement with the government to resolve allegations it failed to maintain effective controls to prevent controlled substance diversion. A month later, the company began to block suspicious orders and submit suspicious order reports to the DEA. Prior to July 2007, AmerisourceBergen mailed copies of suspicious order reports to the DEA on a monthly basis but did not block any orders deemed suspicious.**

An “excessive/suspicious order investigation program” policy revised in June 2007 states that AmerisourceBergen’s Corporate Security and Regulatory Affairs division would review

<sup>975</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>976</sup> Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>977</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the S. Comm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 115 (2018) (testimony of Steven H. Collis, Chairman, President, and CEO, AmerisourceBergen Corp.), available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.

<sup>978</sup> Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>979</sup> Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Mar. 19, 2018 (On file with Committee).

controlled substance orders daily to determine which orders exceeded thresholds.<sup>980</sup> The policy required that orders which exceeded thresholds be held and that orders determined to be possibly suspicious were then investigated further, reported to DEA, and not shipped<sup>981</sup>

AmerisourceBergen also issued a new policy in June 2007 on its controlled substance and listed chemical order monitoring program. The policy stated that distribution center managers or compliance coordinators had autonomy to conduct an initial review of orders based on “know your customer guidelines” and were required to understand “how, when and where their DC [distribution center] is reporting suspicious orders to DEA.”<sup>982</sup> The policy indicates that the Corporate Security and Regulatory Affairs (CSRA) division would conduct an investigation of an order if it was flagged by the distribution center.<sup>983</sup> Under the policy, all orders identified as suspicious by CSRA would be logged, investigated, and reported to the DEA as suspicious and any subsequent orders for controlled substances from the same drug family would be rejected pending the result of the CSRA investigation<sup>984</sup>

As indicated by the chart below, AmerisourceBergen began to report and block suspicious orders after the OMP took effect in June 2007. The number of suspicious orders reported from West Virginia pharmacies for all controlled substances varied dramatically from year to year. AmerisourceBergen reported 792 orders as suspicious in 2013. However, the company only provided the DEA with three suspicious order reports for West Virginia pharmacies in 2016, all of which related to orders placed by the same pharmacy on a single day.<sup>985</sup> Similarly, AmerisourceBergen only submitted five suspicious order reports to the DEA in 2017 for orders placed by West Virginia pharmacies.<sup>986</sup> Indicating that AmerisourceBergen’s suspicious order reporting may have decreased nationwide, in 2017, on a per-capita basis, West Virginia had the second highest number of suspicious orders reported to the DEA by AmerisourceBergen of all states.<sup>987</sup>

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<sup>980</sup> AmerisourceBergen, Corp., Excessive/Suspicious Order Investigation Program, June 29, 2007 (On file with Committee).

<sup>981</sup> *Id.*

<sup>982</sup> AmerisourceBergen, Corp., Controlled Substance and Listed Chemical Order Monitoring Program, June 30, 2007 (On file with Committee).

<sup>983</sup> *Id.*

<sup>984</sup> *Id.*

<sup>985</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

<sup>986</sup> *Id.*

<sup>987</sup> *See* Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., May 2, 2018 (On file with Committee). Given that West Virginia accounted for only five suspicious orders in 2017, the Committee asked AmerisourceBergen if the representation made in the Company’s May 2, 2018 letter was correct. *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) In response, the Company told the Committee that the representations made in its May 2, 2018 letter were accurate. *See* E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm).



Suspicious Order Reports Submitted by AmerisourceBergen to the DEA <sup>988</sup>											
2006	2007*	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
0	6	18	60	47	178	311	792	545	53	3	5
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia <sup>989</sup>											
18.02	20.34	22.34	24.03	16.8	19.94	21.8	20.16	19.89	15.85	11.51	---

\* AmerisourceBergen began to report and block suspicious orders in July 2007, thus, the number of suspicious orders reported in 2007 represents a partial year.

**FINDING: The number of suspicious order reports regarding West Virginia pharmacies that AmerisourceBergen submitted to DEA and blocked from shipment ranged from a high of 792 orders in 2013 to a low of three orders in 2016.**

At times, AmerisourceBergen stopped doing business with a pharmacy following a series of suspicious order reports. For example, 36 of the 60 suspicious order reports made by AmerisourceBergen in 2009 were for orders placed by Tug Valley Pharmacy.<sup>990</sup> The 36 suspicious orders were reported to DEA within a one-month period between September 18, 2009 and October 8, 2009. AmerisourceBergen provided the Committee with documentation showing Tug Valley ordered 108,700 doses of hydrocodone in September 2009, up from 12,500 doses ordered the prior month.<sup>991</sup> A Corporate Security and Regulatory Affairs review was undertaken and determined “that a high percentage of the prescriptions written were from two physicians, both with extensive disciplinary records and prior revocations in other states.”<sup>992</sup> AmerisourceBergen stopped doing business with Tug Valley Pharmacy on October 19, 2009 as a result of a Corporate Security and Regulatory Affairs review.<sup>993</sup>

However, in at least two other instances, the number of suspicious orders reported did not cause AmerisourceBergen to take such prompt action. AmerisourceBergen submitted approximately 400 suspicious orders for a single pharmacy, Beckley Pharmacy between 2012 and 2015.<sup>994</sup> Of those suspicious order reports, 199 were reported between November 2013 and

<sup>988</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

<sup>989</sup> Letter from Counsel to AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).

<sup>990</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

<sup>991</sup> AmerisourceBergen Corp., OMP Activity – Tug Valley Pharmacy – Columbus, Feb. 23, 2010 (On file with Committee).

<sup>992</sup> *Id.*

<sup>993</sup> AmerisourceBergen Corp., Controlled Substances “Do Not Ship” List, last updated Oct. 17, 2017 (On file with Committee).

<sup>994</sup> AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

March of 2014.<sup>995</sup> Documents provided to the Committee indicate that AmerisourceBergen did not investigate the pharmacy until February 2015, however, at which point the company found numerous red flags of diversion and opted to stop doing business with Beckley.<sup>996</sup>

In another instance, AmerisourceBergen submitted 103 suspicious order reports regarding City Pharmacy in Martinsburg, West Virginia between January 2012 and March 2014. Yet AmerisourceBergen continued doing business with City Pharmacy until April 2014, when the owner, David Wasanyi, was arrested.<sup>997</sup> A second pharmacy, City Pharmacy of Charles Town, was also owned by the same individual but not placed on AmerisourceBergen’s “Do Not Ship” list until January 2016.<sup>998</sup> According to a complaint filed in 2016 by the U.S. Attorney’s Office for the Northern District of West Virginia, between January 2010 and November 2015, the two pharmacies “filled more than 1,100 prescriptions written by medical providers located in Florida, Georgia, Virginia and Tennessee for individuals residing in Alabama, Florida, Georgia, Kentucky, Maryland, Ohio, Pennsylvania, Tennessee and Virginia.”<sup>999</sup>

In a briefing with Committee staff, AmerisourceBergen representatives said there is no rule or policy regarding the number of suspicious order reports that would trigger an investigation of a pharmacy customer.<sup>1000</sup> The company would consider it a problem, however, if a pharmacy continued to get repeated suspicious order reports.<sup>1001</sup>

**FINDING: AmerisourceBergen responded inconsistently when pharmacies triggered repeated suspicious orders. In 2009, the company investigated and terminated its relationship with Tug Valley Pharmacy after reporting 36 suspicious orders in one month. However, AmerisourceBergen continued to supply Beckley Pharmacy for nearly a year after reporting 109 suspicious orders in five months from 2013 to 2014.**

<sup>995</sup> *Id.*

<sup>996</sup> Pharma Compliance Group, Observations and Recommendations Report – Beckley Pharmacy, Feb. 15, 2015 (On file with Committee). AmerisourceBergen reinstated Beckley Pharmacy as a customer in 2016 after a subsequent review determined that several of the concerns leading to its termination had been alleviated and the risk of diversion was reduced. *See, Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (responses to questions for the record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).

<sup>997</sup> AmerisourceBergen Corp., Controlled Substances “Do Not Ship” List, last updated Oct. 17, 2017 (On file with Committee). . Wasanyi was arrested in April 2014 and later convicted on a series of state charges related to the dispensing of controlled substance prescriptions at his two pharmacies. *In re City Pharmacy, LLC, et al*, U.S. Justice Dept., N.D.W.Va. No. 16-cv-24 (Feb. 29, 2016) (Order on Motion to Dismiss, Motion to Strike Expert Testimony, and Motion on Summary Judgement) (On file with Committee).

<sup>998</sup> AmerisourceBergen Corp., Controlled Substances “Do Not Ship” List, last updated Oct. 17, 2017 (On file with Committee).

<sup>999</sup> *In re City Pharmacy, LLC, et al*, U.S. Justice Dept., N.D.W.Va. No. 16-cv-24 (Feb. 29, 2016) (Complaint) (On file with Committee). In the complaint, prosecutors said Mr. Wasanyi and his co-defendants “should have known that prescriptions for controlled substances, written by medical providers located in distant states, presented by a large number of individuals who traveled together from distant locations were not written for legitimate medical purposes.” *Id.*

<sup>1000</sup> Briefing by Staff, AmerisourceBergen Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

<sup>1001</sup> *Id.*

AmerisourceBergen has continued to update its suspicious order monitoring policies in recent years. The most recent diversion control program policies and procedures manual AmerisourceBergen produced to the Committee was issued in January 2017. The Order Monitoring Program policy requires that AmerisourceBergen reject and report all orders designated as suspicious to the DEA and state authorities, as well as that the company “establish mechanisms to continually monitor drug product trends and customer trends and ordering patterns in order to prevent the diversion of Controlled Substances into other than legitimate medical, scientific, and industrial channels.”<sup>1002</sup>

Under the 2017 policies, members of AmerisourceBergen’s Diversion Control Team assess whether an order of interest is suspicious based on factors including product information, customer data, and customer ordering history.<sup>1003</sup> The employee will make a determination “based on the totality of the information that is reviewed during investigation of the *Order of Interest*” and, if the order is deemed suspicious, “the order will be rejected and reported to DEA and state authorities, as appropriate.”<sup>1004</sup>

As mentioned previously, the number of suspicious order reports AmerisourceBergen submitted to DEA varied widely from year to year. The company told the Committee the variation is due to numerous factors, including a recent decrease in the overall number of opioid prescriptions written, more precise identification of suspicious orders by the company, and efforts to stop selling controlled substances to pharmacy customers that raise concern.<sup>1005</sup> AmerisourceBergen described its efforts to enhance its order monitoring system:

Over time, as technology has evolved, ABDC has refined the algorithms it uses to identify orders that should be held for additional scrutiny. Additionally, ABDC has worked hard to more precisely identify suspicious orders which it reports to DEA. ABDC developed additional data monitoring and compilation tools, the dashboards referenced in correspondence to the Committee, which allow for greater insight into customer purchasing patterns and history, enabling ABDC to more precisely identify suspicious orders.<sup>1006</sup>

Additionally, AmerisourceBergen told the Committee that it aims to work with trusted customers who share the company’s commitment to diversion control and that the company “believes its due diligence and monitoring efforts help eliminate problematic orders from the start, with ABDC ultimately refusing to contract with certain customers, terminating customers,

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<sup>1002</sup> AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Order Monitoring Program, Jan. 1, 2017 (On file with Committee).

<sup>1003</sup> AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Identifying and Reporting Suspicious Orders, Jan. 1, 2017 (On file with Committee).

<sup>1004</sup> AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Identifying and Reporting Suspicious Orders, Jan. 1, 2017 (Emphasis in original) (On file with Committee).

<sup>1005</sup> See E-Mail from Counsel for AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 p.m.) (On file with Committee).

<sup>1006</sup> *Id.*

and limiting customers' ordering – thereby resulting in fewer suspicious orders to be reported.”<sup>1007</sup>

AmerisourceBergen's current policies indicate the company will investigate orders that hit thresholds to determine whether they are in fact suspicious and report any such orders to the DEA. Since 2007, the company has actively blocked suspicious orders from West Virginia, but the number of suspicious orders reported to DEA has dropped significantly since 2013. In 2016, the company reported a total of three suspicious orders regarding West Virginia pharmacies yet shipped more than 11 million doses of hydrocodone and oxycodone to the state. While the amount of hydrocodone and oxycodone shipments has also dropped, the decrease has not been proportional to the drop in suspicious orders. The company also indicated that repeated suspicious order reports for a single customer would be considered a problem, yet the Committee identified two instances in which AmerisourceBergen reported more than 100 suspicious orders but continued to supply the pharmacies for an extended period of time. AmerisourceBergen eventually cut off both customers, in one case because an investigation found red flags of diversion, and in another case because the pharmacy owner was arrested.

## **5. Miami Luken's Suspicious Order Reporting for West Virginia Pharmacies**

Miami-Luken was a regional distributor based in Springboro, Ohio that serviced customers in the Midwest and Appalachia. An OTSC the DEA filed against Miami-Luken in 2015 noted the high volume of opioid pills the company sent to pharmacies in West Virginia, including: 683,300 doses of hydrocodone to Sav-Rite Pharmacy No. 1 during July, August and September of 2008; 118,900 doses of hydrocodone to Westside Pharmacy in December 2013; and 95,400 doses of hydrocodone to Family Discount Pharmacy in April 2014.<sup>1008</sup> The Committee requested Miami-Luken provide copies of all suspicious order reports for hydrocodone or oxycodone that were submitted to DEA since 2008.<sup>1009</sup> The company was unable to produce documentation from the full timeframe because it did not have a suspicious order monitoring system until 2015, and did not consistently submit suspicious order reports to the DEA.

Miami-Luken received the three letters issued by DEA in 2006 and 2007 advising distributors of their obligation to report suspicious orders.<sup>1010</sup> According to court documents,

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<sup>1007</sup> *Id.*

<sup>1008</sup> U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

<sup>1009</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Sept. 25, 2017, available at [https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami\\_Luken.pdf](https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf).

<sup>1010</sup> See 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 Committee); 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 Committee) and Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r,

DEA also met with representatives from Miami-Luken in 2008 to discuss distributors' responsibility to inform DEA about suspicious orders, as outlined in the December 2007 letter.<sup>1011</sup> DEA officials also interviewed Miami-Luken employees about the company's distribution practices in 2012, 2013 and 2015, as outlined in a filing related to the OTSC.<sup>1012</sup>

Miami-Luken told the Committee that before its suspicious order monitoring program was implemented in 2015, suspicious order monitoring was done based on "one's feeling" about whether an order was suspicious.<sup>1013</sup> Documents Miami-Luken produced to the Committee regarding suspicious order reports included e-mails the company sent to DEA. Those documents show that as early as October 2012, the company e-mailed DEA authorities to inform them that Miami-Luken stopped selling controlled substances to specific customers based on concerns about their business practices.<sup>1014</sup> Based on the documents provided to the Committee, it appears the first time Miami-Luken sent an e-mail to DEA regarding an order-specific suspicious order report was in May 2014, when Miami-Luken reported that it rejected a pharmacy's orders for oxycodone after the pharmacy hit its threshold for that month.<sup>1015</sup> This e-mail is reproduced below:

**From:** [REDACTED]  
**Sent:** Wednesday, May 14, 2014 1:25 PM  
**To:** [REDACTED]@usdoj.gov; [REDACTED]@usdoj.gov;  
[REDACTED]@usdoj.gov  
**Cc:** Anthony Rattini  
**Subject:** [REDACTED] Pharmacy license [REDACTED]

The above pharmacy is not a primary customer of ours, for which we have certain thresholds we have established, for the purchases of controlled drugs. Recently this customer has reached this threshold for Oxycodone purchases. Therefore, we have rejected recent orders received, and notified the customer we will no longer be processing his orders, for Oxycodone, this month.

I do not have a DEA agent contact for the state of Tennessee, would you please pass along this information.

Regards,  
[REDACTED]  
Compliance Mgr.  
Miami Luken, Inc.

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Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Dec. 20, 2007 (On file with Committee).

<sup>1011</sup> *In re Miami-Luken*, U.S. Drug Enforcement Admin., No. 16-13 (Jan. 15, 2016) (Government's Prehearing Statement) (On file with Committee).

<sup>1012</sup> *Id.*

<sup>1013</sup> Transcribed Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, at 11 (On file with Committee).

<sup>1014</sup> The first e-mail demonstrative of this communication with DEA was provided in reference to a Columbus, Ohio pharmacy. Miami-Luken provided suspicious order reports for all states, not just for West Virginia pharmacies. *See* E-Mail from Compliance Manager, Miami-Luken, Inc., to Staff, U.S. Dep't of Justice (Oct. 16, 2012 12:24 pm) (On file with Committee).

<sup>1015</sup> E-Mail from Compliance Manager, Miami-Luken, Inc., to Staff, U.S. Dep't of Justice (May 14, 2014 1:25 pm) (On file with Committee).

**FINDING:** Before providing DEA with order-specific suspicious order reports, Miami-Luken previously reported customers it stopped doing business with. Documents provided to the Committee appear to indicate the first customer termination report was made to DEA in October 2012.

**FINDING:** Based on documents produced to the Committee, the first order-specific suspicious order report Miami-Luken made because a pharmacy hit a monthly threshold was submitted to DEA on May 14, 2014.

Documents provided to the Committee show that since 2015, the order-specific reports Miami-Luken provided to DEA identify individual suspicious orders.<sup>1016</sup> For example, the e-mails sometimes state that pharmacies' orders are being held through Miami-Luken suspicious order monitoring (SOM) system or indicate that orders have been cut and include corresponding DEA order forms. The following is an example of a suspicious order report submitted to DEA in 2015 that references the SOM<sup>1017</sup> as well as supporting documentation:<sup>1018</sup>

**From:** [REDACTED]  
**Sent:** Tuesday, September 22, 2015 1:41 PM  
**To:** [REDACTED]@usdoj.gov; [REDACTED]@usdoj.gov  
**Cc:** [REDACTED]  
**Subject:** [REDACTED] order # 2474875  
**Attachments:** [REDACTED].PNG

[REDACTED]

Order #2474875 was pended as suspicious by our SOM software on 09-22-2015. As a result, we ceased shipment of the items. Please see the attached document for more detail.

If you have questions or concerns please let me know. Thanks.

[REDACTED]  
Compliance Agent  
Miami-Luken Inc.

<sup>1016</sup> Miami-Luken, Suspicious Orders for Hydrocodone and Oxycodone Reported to the DEA 2008 – 2017 (On file with Committee).

<sup>1017</sup> E-Mail from Compliance Agent, Miami-Luken, Inc., to Staff, U.S. Dep't of Justice (Sept. 22, 2015 1:41 pm) (On file with Committee).

<sup>1018</sup> E-Mail from Compliance Agent, Miami-Luken, Inc., to Staff, U.S. Dep't of Justice (Sept. 22, 2015 1:41 pm) (Attachment) (On file with Committee).

<b>Order Number:</b>	2474875	<b>Company Name:</b>	[REDACTED]
<b>Order Date:</b>	2015-09-22 08:57:00	<b>Customer Number:</b>	[REDACTED] (History/All/Dosage History)
<b>Active Ingredient Group:</b>	Oxycodone - CII	<b>DEA Number:</b>	[REDACTED] (History/All/Dosage History)
<b>Doses this order:</b>	1,500 (27,500mg total)	<b>Address:</b>	[REDACTED]
<b>Doses 30 day:</b>	7,600 (138,500mg total)		
<b>Doses this month:</b>	6,100 (111,000mg total)		
<b>Status:</b>	Pended		

Based on the documents Miami-Luken provided the Committee, the company appears to have provided two order-specific suspicious order reports to the DEA in 2014, 10 reports in 2015, 33 reports in 2016, and one report in 2017.<sup>1019</sup> At least 20 other e-mails were provided to the Committee in response to its request for suspicious orders that identify instances in which Miami-Luken stopped selling controlled substances to a pharmacy.

**FINDING: Miami-Luken provided DEA with at least two suspicious order reports in 2014, 10 in 2015, 33 in 2016, and one in 2017. The distributor also stopped selling controlled substances to at least 20 pharmacies.**

In a transcribed interview with Committee staff, Miami-Luken’s Chairman of the Board, Dr. Joseph Mastandrea, stated that prior to 2013, the company made “rudimentary efforts” to comply with its legal responsibility to report suspicious orders.<sup>1020</sup> Dr. Mastandrea stated:

Q. So what steps did you take to address these concerns that were now raised that you were seeing this information?

A. Again, we engaged the services of [redacted], who outlined steps that we needed to take, one of which was to institute a more robust suspicious order monitoring system. We had made rudimentary efforts to engage in suspicious order monitoring as early as 1995. Unfortunately, these efforts were primarily based on one's feeling about what constituted a suspicious order.

Q. What do you mean by that?

A. It was one individual's feeling about whether or not this order represented an unusual quantity, frequency, or whatever the other Controlled Substance Act says that we should consider as a

<sup>1019</sup> Miami-Luken, Suspicious Orders for Hydrocodone and Oxycodone Reported to the DEA 2008 – 2017 (On file with Committee). These totals do not include e-mails in which Miami-Luken communicated to DEA that it would stop selling controlled substances to a customer pharmacy and only includes those in which the company said it had blocked drug orders.

<sup>1020</sup> Transcribed Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, at 11 (On file with Committee). According to Dr. Mastandrea, Miami-Luken began receiving subpoenas from the DEA in early 2013.

suspicious order. The president was instructed to obtain a suspicious order monitoring system, and the only one I was familiar with on a commercial basis -- because we couldn't develop it in-house, we had tried -- was a system manufactured, developed by Buzzeo. We purchased the Buzzeo system sometime in December of 2013.<sup>1021</sup>

**FINDING: According to Miami-Luken's Chairman of the Board, prior to 2013, the company made "rudimentary efforts" to monitor suspicious orders and decisions on what constituted a suspicious order were made based on "one's feeling."**

Miami-Luken's then- Chief Executive Officer, Anthony Rattini, described new efforts the company was purportedly undertaking in January 2013 in an e-mail to Miami-Luken employees. In the e-mail he said the system would set a maximum number of dosage units a customer would be able to purchase per month:<sup>1022</sup>

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<sup>1021</sup> Transcribed Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, at 10, (On file with Committee).

<sup>1022</sup> E-Mail from Chief Exec. Officer, Miami-Luken, Inc. to Staff, Miami-Luken, Inc. (Jan. 15, 2013 4:47 pm) (On file with Committee).



**From:** Anthony Rattini <[REDACTED]@miamiluken.com> .  
**Sent:** Tuesday, January 15, 2013 4:47 PM  
**To:** [REDACTED]; [REDACTED]  
[REDACTED]; [REDACTED]@miamiluken.com; [REDACTED]@miamiluken.com  
**Cc:** [REDACTED]  
**Subject:** Excessive or suspicious control drug monitoring  
**Attachments:** DOC.PDF; DOC.PDF

Hello Everyone,

I would like to send examples of the new controlled drug monitoring system we installed in our customer order processing system. We only have one customer on it currently to see how we can make it efficient and effective. It will be a great help to [REDACTED] and me. All units are by the pill not bottles.

The first 7 page document shows purchases by product family, the family includes brand and generics no matter how the manufacturer is, listed under the **Class** column on the spreadsheet. The report you see is for a three month period of time and sorts by product class.

The second attachment, one page, shows a grid that has been placed on the customer's file. The first column shows the product family, **Med Fam**, and the fourth column show the maximum units the system will allow this customer to purchase in a month. Once the **Max Units** are achieved for that month the customer will not receive that family of product until the next month.

[REDACTED] will make every attempt to contact the sales rep when the customer is reaching that cut off number. I have not seen an invoice but I believe that if the customer attempts to purchase an item from the product family where he maxed for the month a message will appear on the invoice stating the item was not shipped because maximum limit was reached, or something to that affect.

I hope this helps everyone understand how the system works. We can make it a sales meeting discussion.

Tony Rattini

The order monitoring system was not, however, put to use at this time as described in the e-mail. Dr. Mastandrea described the problems the company encountered in trying to get the new system up and running:

- Q. Did you direct Mr. Rattini to engage a vendor and purchase such a program?
- A. Absolutely.
- Q. Do you know about when you would have given him such a direction?
- A. 2013.
- Q. And when you gave him the direction, did you have him report back to you, or how did you do the follow up to make sure he was carrying out your direction?

A. After they had purchased the Buzzeo system and it arrived and it sat on the desk of our compliance officer, I was shown the system. Unfortunately, I didn't know what I was looking at, and even more unfortunately, neither did our compliance officer.

Q. And who was that at the time?

A. His name is [redacted]. The Buzzeo system sat unutilized for a period of time. Suspicious orders were not flagged. The reason that they were not flagged and reported to the DEA was because of there were an inordinate number of false positives. We could have, in fact, pended or held every order on some days. In [redacted's] defense, I don't think he received support from the vendor.<sup>1023</sup>

Dr. Mastandrea further described the problems with the Buzzeo system, stating that unless proper data was entered into the system beforehand, every order would flag as suspicious because it had no prior order history to compare.<sup>1024</sup> He stated, "we had the Buzzeo system. We purchased it in 2013. I don't know when it was actually delivered, but it was ineffectual until 2015."<sup>1025</sup>

**FINDING: Miami-Luken did not implement a functional suspicious order monitoring system until 2015.**

Miami-Luken also provided the Committee with documentation regarding policies for suspicious order monitoring in place as of 2016. Those policies state that once an order is identified as suspicious it will be held and the following investigative steps will take place:<sup>1026</sup>

- Pended order customer details are reviewed (Customer Name, Address, DEA#)
  - The item ordered, quantity ordered, and the doses ordered this month are reviewed
- 
- The NDC#'s are checked in the Medi-Span drug database (for accuracy)
  - The twelve (12) month dosage history is reviewed
  - The active ingredient history is reviewed
  - If the order cannot be justified in the data, the reviewer may choose to speak with customer service representative to ensure that the item has not been short stocked (which could explain a back to back order causing the "pend")
  - If the order is not justifiable to the reviewers satisfaction through these methods, the pharmacist in charge or the owner is contacted via telephone

<sup>1023</sup> Transcribed Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, at 17-18 (On file with Committee).

<sup>1024</sup> *Id.* at 55.

<sup>1025</sup> *Id.* at 56 (On file with Committee).

<sup>1026</sup> Miami-Luken, Inc., Inventory Controls, Apr. 8, 2016 (On file with Committee).

- If the order is not justifiable to the reviewers satisfaction through these methods, the pharmacist in charge or the owner is contacted via telephone
  - -if the explanation from the pharmacist appears to be valid & reasonable (i.e. the pharmacist in charge is going on vacation for two (2) weeks and he/she is the only pharmacist authorized to order) the order can be released with the pharmacist name & explanation in the release comments
- If the compliance agent is unable to justify the order based on the information available, the compliance agent cannot reach the pharmacist, or the compliance agent does not conclude that the justification provided by the pharmacist is valid, the order is pulled and will not be shipped
  - -In addition, upon making the determination that an order is suspicious, the order is reported to the DEA and respective state board of pharmacy via email

On November 23, 2015, the DEA issued an OTSC to Miami-Luken, informing the company that the DEA was taking action to revoke the company's DEA registration, and alleging that the company failed to maintain effective controls against diversion of controlled substances between 2007 and 2015.<sup>1027</sup> Among the allegations made by DEA was that Miami-Luken failed to maintain a system to report suspicious orders to the DEA.<sup>1028</sup>

In the OTSC, the DEA alleged that Miami-Luken shipped more than 3.48 million doses of hydrocodone to Sav-Rite No. 1 in Kermit, West Virginia between February 2008 and November 2011, but failed to report any orders placed by the pharmacy during this time as being suspicious.<sup>1029</sup> Miami-Luken's alleged failure to report suspicious orders was despite the fact that the company raised concerns about Sav-Rite No. 1's hydrocodone purchases to the DEA in February 2008 and notwithstanding the fact that Sav-Rite No. 2., which Miami-Luken also supplied controlled substances to, was shut down following a federal raid in March 2009.<sup>1030</sup>

The DEA also alleged that Miami-Luken provided Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia with controlled substances between September 2012 and March 2015, but failed to report any orders placed by the pharmacy during this time as being suspicious.<sup>1031</sup> In the OTSC, the DEA cited numerous examples of orders that were placed by Family Discount Pharmacy that should have been considered suspicious by Miami-Luken,

<sup>1027</sup> U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

<sup>1028</sup> *Id.*

<sup>1029</sup> *Id.* In total, Miami-Luken shipped more than 6.34 million doses of hydrocodone and oxycodone to both Sav-Rite locations between 2006 and 2011. As mentioned, Sav-Rite No. 2 was only in operation from October 2008 until March 2009 when it was forced to close following a federal raid. *See* Miami-Luken, Inc., Sales Data (On file with Committee); *see also* Curtis Johnson, *Big pill network exposed*, HERALD DISPATCH, Apr. 1, 2009, [http://www.herald-dispatch.com/news/recent\\_news/big-pill-network-exposed/article\\_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html](http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcd3ec9.html).

<sup>1030</sup> U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

<sup>1031</sup> Miami-Luken stopped selling controlled substances to Family Discount Pharmacy on March 4, 2015. *See* U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

including hydrocodone orders, placed in April 2014, that when aggregated, resulted in a 1,574 percent increase in volume from the month prior.<sup>1032</sup>

Miami-Luken's insufficient compliance occurred even though the company had received three letters from the DEA regarding suspicious order reporting obligations, in addition to having several meetings with the agency where suspicious order reporting obligations were reviewed or the agency inquired about the company's distribution practices.<sup>1033</sup> When asked what he considered Miami-Luken's past failings to be, Dr. Mastandrea cited the company's failure to adopt a suspicious order monitoring system and noted, "[h]ad we done so, I'm not sure we would be here today."<sup>1034</sup> In 2018, Miami-Luken stated that it was going out of business "as a result of the ongoing DEA administrative proceeding and multiple lawsuits that have been filed against the Company."<sup>1035</sup>

Miami-Luken did not have a fully functional suspicious order monitoring system in place until 2015 and as a result it was not submitting suspicious order reports to the DEA, as required by law. Based on information provided to the Committee, it appears Miami-Luken did tell DEA it was terminating customers based on compliance concerns as early as October 2012 but the date of the first instance in which Miami-Luken's submitted a suspicious order report to DEA was May 2014.

## **6. H.D. Smith's Suspicious Order Reporting for West Virginia Pharmacies**

H.D. Smith shipped more than 15.49 million doses of hydrocodone and 5.38 million doses of oxycodone to West Virginia between 2006 and 2017.<sup>1036</sup> The Committee requested that H.D. Smith provide all suspicious order reports it submitted to DEA related to orders placed by West Virginia pharmacies between 2006 and 2017.<sup>1037</sup> The earliest such report H.D. Smith produced to the Committee for this period appears to be from May 1, 2008, which also coincides with the date that H.D. Smith's controlled substance ordering monitoring program was launched.<sup>1038</sup> In addition, the Committee's review of the documents provided to it by H.D. Smith shows that during the requested time period, there were a total of six years where H.D.

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<sup>1032</sup> U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

<sup>1033</sup> *Id.*

<sup>1034</sup> Transcribed Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, at 24 (On file with Committee).

<sup>1035</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>1036</sup> H.D. Smith Wholesale Drug Co., Hydrocodone and Oxycodone pills sold by H.D. Smith to purchasers in West Virginia from 2006 through 2017 (On file with Committee).

<sup>1037</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to J. Christopher Smith, President and CEO, H.D. Smith Wholesale Drug Co., Jan. 26, 2018 *available at* <https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126HDSmith.pdf>.

<sup>1038</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee). *See also* Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

Smith does not appear to have submitted any suspicious order reports to the DEA for orders placed by West Virginia pharmacies.<sup>1039</sup>

The Committee’s review shows H.D. Smith provided DEA with order-specific suspicious order reports only in 2008 and 2009. H.D. Smith submitted 356 suspicious order reports in 2008 and 37 reports in 2009.<sup>1040</sup> H.D. Smith changed its suspicious order reporting practice in 2009 after consultation with DEA and began to instead send e-mails to DEA, informing the agency that it had either terminated certain West Virginia pharmacies or blocked their ability to purchase controlled substances due to compliance concerns.<sup>1041</sup> H.D. Smith also provided e-mails it sent to DEA between 2010 and 2017 regarding six West Virginia pharmacies to which it stopped selling controlled substances.<sup>1042</sup> The following chart details both the order-specific suspicious order reports H.D. Smith made in 2008 and 2009, as well as the reports made to DEA regarding the six pharmacies:

<b>Suspicious Order Reports H.D. Smith Submitted to DEA<sup>1043</sup></b>											
2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
0	0	356	37	0	1	3	0	0	0	1	1
<b>Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia<sup>1044</sup></b>											
---	2.67	6.09	4.11	2.95	1.58	0.67	0.17	0.36	0.45	0.97	0.82

Based on data and documents H.D. Smith provided to the Committee, the company reported no suspicious orders in 2007, 2010, 2013, 2014, and 2015. The company shipped approximately 6.6 million doses of hydrocodone and oxycodone to West Virginia during these years.<sup>1045</sup> The frequency of H.D. Smith’s suspicious order reports to the DEA decreased significantly after the company stopped reporting order-specific suspicious orders. Documentation provided to the Committee shows H.D. Smith continued to block shipments of

<sup>1039</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee). The years in which H.D. Smith did not provide any suspicious order reports to the DEA for orders placed by West Virginia pharmacies include: 2006, 2007, 2010, 2013, 2014, and 2015.

<sup>1040</sup> *Id.*

<sup>1041</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018, 7:35 pm) (On file with Committee).

<sup>1042</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2010 – 2017 (On file with Committee).

<sup>1043</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>1044</sup> H.D. Smith Wholesale Drug Co., Hydrocodone and Oxycodone pills sold to West Virginia purchases from 2006 to 2017 (On file with Committee). H.D. Smith supplied 5,100 hydrocodone pills to West Virginia purchasers in 2006.

<sup>1045</sup> *Id.*

hydrocodone and oxycodone orders but apparently did not report those orders to DEA.<sup>1046</sup> Further, it does not appear that H.D. Smith informed the DEA each time it terminated a business relationship with a pharmacy regarding compliance concerns.<sup>1047</sup> H.D. Smith produced documentation of 228 blocked orders between 2008 and 2017, including 115 orders placed by Family Discount Pharmacy.<sup>1048</sup> As discussed in further detail in this section, H.D. Smith's policies regarding suspicious order reporting indicated that orders deemed suspicious should be reported to DEA.

Like all distributors, H.D. Smith received three letters from the DEA wherein the agency discussed suspicious order monitoring and emphasized the legal requirement to report suspicious orders when they are discovered.<sup>1049</sup> Further, on January 10, 2006, H.D. Smith's Director of Corporate Security met with officials from DEA's Office of Diversion Control; among the issues covered at the meeting was a "[r]eview of the suspicious order requirements Title 21, Code of Federal Regulations."<sup>1050</sup> According to a DEA memorandum describing the meeting, the DEA reviewed hydrocodone purchases made by three current or former H.D. Smith customers and told the company that the ordering patterns had similar characteristics to that of internet pharmacies.<sup>1051</sup> H.D. Smith also provided DEA with a list of four pharmacies it had recently terminated based on excessive purchases of controlled substances and highlighted another six pharmacies the company was in the process of reviewing.<sup>1052</sup>

H.D. Smith implemented its Controlled Substance Ordering Monitoring Program (CSOMP) in 2008. Under the policy, orders that hit an assigned unit reporting level would be held for review. If upon review the order was determined to be suspicious, "it was cancelled and reported to the DEA."<sup>1053</sup> The section of H.D. Smith's initial CSOMP related to suspended and

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<sup>1046</sup> H.D. Smith Wholesale Drug Co., Hydrocodone and oxycodone orders placed by West Virginia pharmacies that were not shipped 2006-2017 (On file with Committee). The list of orders that H.D. Smith said it did not ship includes orders from 2008 to 2012, while individual orders that H.D. Smith said it reported to DEA includes orders from 2008 and 2009.

<sup>1047</sup> H.D. Smith provided the Committee a list of 15 West Virginia customers it prevented from purchasing controlled substances based on compliance concerns. Corresponding emails alerting DEA that the company had stopped selling to the customer were not provided for each of the 15 customers.

<sup>1048</sup> H.D. Smith Wholesale Drug Co., Blocked hydrocodone and oxycodone orders 2006 – 2017 (On file with Committee).

<sup>1049</sup> See 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 Committee); 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 Committee); 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 Committee).

<sup>1050</sup> Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin., to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee).

<sup>1051</sup> *Id.*

<sup>1052</sup> *Id.*

<sup>1053</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

suspicious orders, delineates the steps corporate diversion investigators should take to review orders.<sup>1054</sup> The CSOMP is reproduced in relevant part below:

<p>Standard Operating Procedures CSOMP</p> <p style="text-align: right;">March 22, 2008</p> <p><b>III. <u>Suspended Orders</u></b></p> <p>Each morning, Corporate Diversion Investigators or others designated by the Corporate Director of Compliance and Security, shall access records of all suspended orders, and suspended and then released orders, from the day prior.</p> <p>A review of suspended and then released orders will be made to determine:</p> <ul style="list-style-type: none"><li>• Have orders been released according to guidelines set by the Director of Compliance and Security.</li><li>• Do any of the account's URLs need to be adjusted.</li><li>• Should division management be contacted reference any released orders.</li><li>• Is further investigation required.</li><li>• Should the released order be identified as suspicious and be reported to DEA.</li></ul> <p>A review of suspended orders will be made and contact with division management will be initiated. During discussions with division management the Diversion Investigator, with the assistance of the Director of Corporate Compliance and Security shall attempt to determine:</p> <ul style="list-style-type: none"><li>• Was there adequate reason to suspend the order.</li><li>• Is there a Customer Profile on file for the account.</li><li>• Is there dispensing information available.</li><li>• Is further investigation required.</li><li>• Do any of the account's URLs need to be adjusted.</li><li>• Are there any extenuating circumstances.</li><li>• Has division management contacted the account reference the suspended order.</li><li>• Should all or any part of the order be released.</li><li>• Should the order be cancelled.</li><li>• Should the order be identified as suspicious and reported to DEA.</li><li>• Do we continue to service the controlled substance needs of this account.</li><li>• Do we continue to service this account at all.</li></ul> <p><b>IV. <u>Suspicious Orders</u></b></p> <p>From the Suspended Order Editor screen, an authorized corporate user may mark a suspended order as suspicious. In doing so, user must enter option 7. A comment will be expected to be written to confirm the basis of the action, see Figure IV.1.1.</p>
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In 2009, H.D. Smith changed the scope of information it reported to DEA, which led to the decrease in the number of reports it submitted to DEA in the following years. In a letter to

<sup>1054</sup> H.D. Smith Wholesale Drug Co., Controlled Substance Order Monitoring Program Corporate Security Procedures, Mar. 22, 2008 (On file with Committee).



the Committee, H.D. Smith described why it stopped submitting order-specific suspicious order reports:

As reflected in the records produced by the Company, H.D. Smith's practice after 2009 was to inform the DEA via email whenever it identified suspicious activity or blocked a customer's ability to purchase controlled substances. These changes were made pursuant to its discussions with the DEA. In late 2009, [redacted], DEA Staff Investigator, had a discussion with [H.D. Smith staff] and explained that an order is not "suspicious" and does not need to be reported to the DEA simply because it triggers H.D. Smith's Controlled Substance Order Monitoring Program ("CSOMP") system. Thus, from that point forward, while H. D. Smith did stop automatically submitting as suspicious every order that triggered H.D. Smith's CSOMP, it continued to report activity it identified as suspicious to the DEA in accord with the information it received from DEA.<sup>1055</sup>

**FINDING: In 2008 and 2009, H.D. Smith submitted individual suspicious order reports to DEA for every transaction that triggered its Controlled Substance Order Monitoring Program. The company altered its practices in subsequent years, and instead of reporting individual orders to DEA, it alerted DEA when it stopped selling controlled substances to a pharmacy or identified other suspicious customer activity.**

H.D. Smith reported 393 suspicious orders to the DEA in 2008 and 2009. All but one of the suspicious order reports involved pharmacies discussed in this report. Of the 393 order-specific reports that H.D. Smith reported to DEA in 2008 and 2009, the company reported 110 for Family Discount Pharmacy, 86 for Hurley Drug Company, 109 for Sav-Rite Pharmacy No. 1, and 87 for Tug Valley Pharmacy.<sup>1056</sup> While H.D. Smith stopped doing business with or stopped selling hydrocodone and oxycodone to all four of these pharmacies,<sup>1057</sup> the company did not provide documentation to the Committee that indicates it informed the DEA of these terminations. H.D. Smith provided the Committee with the names of fifteen West Virginia pharmacies that it prevented from purchasing controlled substances due to compliance concerns or a pharmacy's refusal to cooperate with due diligence requests since 2006.<sup>1058</sup> Documents produced to the Committee, however, indicate that only six of the pharmacies were named in suspicious order report e-mails that H.D. Smith sent to DEA relaying that it had stopped supplying controlled substances. Those pharmacies include others cited in the Committee's investigation, including Westside Pharmacy and Colony Drug.<sup>1059</sup>

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<sup>1055</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018, 7:35 pm) (On file with Committee).

<sup>1056</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee)

<sup>1057</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1058</sup> H.D. Smith Wholesale Drug co., Terminated West Virginia Pharmacies 2006 – 2017 (On file with Committee).

<sup>1059</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee)



**FINDING: All but one of the 393 suspicious order reports H.D. Smith submitted to the DEA in 2008 and 2009 related to orders placed by Family Discount Pharmacy, Hurley Drug Company, Sav-Rite No. 1, and Tug Valley Pharmacy.**

**FINDING: H.D. Smith terminated business relationships with 15 West Virginia pharmacies over compliance concerns or failure to cooperate with due diligence efforts, but provided documentation indicating it informed DEA about six of the terminations.**

Despite its failure to either report or document action taken to stop selling controlled substances to eight of the fifteen pharmacies, H.D. Smith discussed concerns regarding some of those pharmacies with the DEA. The company told the Committee it provided dispensing data analysis regarding Tug Valley, Hurley and Sav-Rite No. 1 to DEA on May 12, 2008.<sup>1060</sup> The company also produced a May 2008 e-mail, a recipient of which was a DEA diversion investigator, which indicates the company discussed concerns regarding Hurley, Sav-Rite and Family Discount with the DEA.<sup>1061</sup>

Though H.D. Smith told the Committee its practices regarding suspicious order reporting changed in 2009 after consultation with DEA, the company's CSOMP policies issued in November 2009 do not appear to reflect those changes. For example, the November 2009 CSOMP stated, in part:

Orders marked as suspicious will be automatically cancelled from the system and the order will not be shipped. The suspicious order information will be sent via email to DEA Headquarters by Corporate Compliance personnel. Email notification of a suspicious order will be sent to the divisional Designated Representative so that it may be forwarded to the division's local DEA Field Office.<sup>1062</sup>

**FINDING: H.D. Smith's 2009 policy states that suspicious order information will be sent to DEA Headquarters and DEA field offices. The policy does not indicate the company changed its reporting procedures to focus on suspicious activity and customers rather than order-specific suspicious order reports.**

The most recent version of H.D. Smith's CSOMP corporate policy provided to the Committee, revised in October 2013, contains largely the same guidance as the 2009 policy

<sup>1060</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1061</sup> E-Mail from [Name Redacted] to Dir., Corporate Security, H.D. Smith (May 8, 2008, 9:28 am) (On file with Committee).

<sup>1062</sup> H.D. Smith Wholesale Drug Co., 809-V HDS SOP Controlled Substance Order Monitoring Program Corporate Policy, Nov. 8, 2009 (On file with Committee).

regarding suspicious orders, except that it no longer directs employees to report suspicious orders to DEA Headquarters.<sup>1063</sup>

H.D. Smith initially began reporting order-specific suspicious orders to DEA in 2008 but later stopped reporting suspicious orders and instead began reporting customers deemed suspicious after it suspended sales to a pharmacy. H.D. Smith's policies in place at the time, however, appeared to continue requiring reporting of suspicious orders, not suspicious customers. The company continued to block orders it deemed suspicious through at least 2012 but did not report these orders to DEA. The company also did not always appear to report to DEA when it suspended sales to a pharmacy. H.D. Smith's failure to report this information to DEA potentially limited the agency's insight to problem pharmacies.

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The DEA began to educate distributors on their responsibility to report suspicious orders in 2005—including through one-on-one meetings with four of the five distributors involved in the Committee's investigation and a series of three letters sent to all DEA registrants. DEA emphasized that distributors were required to report suspicious orders when discovered and advised registrants that monthly reports, submitted after orders were already filled and sent to customers, would not meet the regulatory requirements. As documented in this section, however, distributors failed to report individual suspicious orders when discovered. Instead, they reported a wide variety of other information to DEA over the years in an effort to meet suspicious order reporting requirements. This included monthly excessive order reports, and reports on customer terminations.

Despite the DEA's education efforts, distributors still did not implement suspicious order monitoring systems that appeased the agency. Four of the five distributors whose practices were reviewed by the Committee revised their suspicious order monitoring systems only after the DEA initiated an enforcement action. This emphasizes the importance of DEA's oversight of distributors as a means to ensure distributors design and implement adequate suspicious order monitoring systems. However, it also raises questions about DEA's ability to clearly communicate its expectations regarding suspicious order reporting.

When distributors do not have suspicious order monitoring systems in place, they are unable to appropriately identify suspicious orders that should be blocked and investigated. Likewise, if distributors block shipments but do not report that information to DEA, they leave the federal government in the dark. It is not enough that distributors have suspicious order monitoring policies on paper, they must also take appropriate action to enforce those policies. But as demonstrated over the years through various iterations of these distributors suspicious order monitoring systems, adequate oversight by both the distributors and DEA is key. Without it, distributors' systems may not properly vet controlled substance orders and drug diversion can occur unabated. In addition, by adequately discharging its legal obligations to report suspicious orders, a distributor may be more attuned to potential red flags associated with a pharmacy, including those of which that may not be statistically-based. Identifying, and analyzing any such

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<sup>1063</sup> H.D. Smith Wholesale Drug Co., 809-V HDS SOP Controlled Substance Order Monitoring Program Corporate Policy, Oct. 22, 2013 (On file with Committee).

red flags is essential for a distributor if it intends to properly fulfill its obligation to conduct adequate, and ongoing due diligence of its customers.

## **D. Distributors Continued to Ship Opioids to Pharmacies in West Virginia Despite Red Flags of Diversion**

### **1. Obligations of Distributors to Conduct Ongoing Due Diligence and Investigate Suspicious Orders**

As part of the CSA's overall mandate to maintain effective controls against diversion,<sup>1064</sup> federal regulations require wholesale distributors to identify and report suspicious orders to the DEA when they are discovered.<sup>1065</sup> However, reporting suspicious orders to the DEA does not, on its own, satisfy distributors' legal obligations to maintain effective controls against diversion and to know their customers. As discussed in greater detail in section VI(A)(1), distributors also have an obligation to conduct meaningful, ongoing due diligence of both their prospective and existing customers in furtherance of section 823 of the CSA's overall mandate to maintain effective controls against diversion. This includes proper investigation of potentially suspicious orders that are shipped to the customer instead of being reported to the DEA as suspicious.

In the July 2007 order revoking the DEA registration of Southwood Pharmaceuticals, the DEA's Deputy Administrator cited the company's continued shipments to pharmacies despite having ample information indicating that diversion was likely as being among the reasons why the company's DEA registration should be revoked, stating, "it is especially appalling that notwithstanding the information Respondent received from both this agency and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies."<sup>1066</sup>

Later that year, in a December 20, 2007 letter to all distributors, the DEA informed distributors that, if a distributor intends to ship an order it determines to be suspicious, reporting any such order to the DEA, on its own, will not absolve the distributor of their responsibility to maintain effective controls against diversion, stating:

Registrant must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.<sup>1067</sup>

In the letter, the DEA also warned distributors that they risked having their registration revoked if they reported orders as suspicious but elected to fill them without making a determination that the orders were not being diverted, stating:

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<sup>1064</sup> See 21 U.S.C. § 823(b)(1) and 21 U.S.C. § 823(e)(1).

<sup>1065</sup> See C.F.R. § 1301.74(b).

<sup>1066</sup> 72 Fed. Reg. 36,487; 36,500, July 3, 2007.

<sup>1067</sup> 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 Committee).

**[R]egistrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion.** Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.<sup>1068</sup>

In the September 2015 order revoking the DEA registration of Masters Pharmaceutical, subsequently upheld by the United States Court of Appeals for the District of Columbia Circuit, DEA’s Acting Administrator found that the company failed to report suspicious orders to the DEA despite having information that created a strong suspicion that pharmacies it provided controlled substances to were engaged in diversion.<sup>1069</sup> Significantly, the Acting Administrator rejected the company’s argument that suspicious orders are limited only to those that are of unusual size, deviate from a normal pattern, or are of unusual frequency, stating:

[L]imiting the scope of suspicious orders to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency would have ill-served the CSA’s purpose of preventing the “illegal . . . distribution, . . . possession and improper use of controlled substances.” 21 U.S.C. 801(2). Under Respondent’s view, even if it had acquired actual knowledge (let alone developed a suspicion) that a customer was ordering controlled substances from it for the purpose of diverting them, it would have no obligation to report the order as long as the order was of a usual size, did not deviate substantially from the customer’s normal ordering pattern, or was consistent with the usual frequency of the customer’s orders. **But even orders that do not fall within the three categories set forth in 21 CFR 1301.74(b) can be diverted. Thus, I agree with the ALJ’s reasoning “that a pharmacy’s business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency.”**<sup>1070</sup>

To this point, the D.C. Circuit stated, “[r]eading section 1301.74(b)’s listed characteristics as exemplary rather than exhaustive, DEA reasonably concluded that other indicia may also raise suspicions about an order for controlled substances. That conclusion was entirely consistent with the text of the regulation as well as agency precedent.”<sup>1071</sup>

Later in the order, the Acting Administrator stated the relevancy of a customer’s business practices was not limited to the definition of what constitutes a suspicious order. Rather,

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<sup>1068</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (emphasis added) (On file with Committee).

<sup>1069</sup> See 80 Fed. Reg. 55,501, Sept. 15, 2015; see also *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).

<sup>1070</sup> 80 Fed. Reg. 55,473-4, Sept. 15, 2015 (ellipsis in original) (emphasis added).

<sup>1071</sup> *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335, 21 (D.C. Cir. 2017).

according to the Acting Administrator, information regarding the scope of drug abuse in a particular area, is also relevant to the question of when a distributor discovers that an order is suspicious, stating:

[C]onsistent with the ALJ’s earlier statement that a violation can be proved “by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious order monitoring program,” I hold that an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order. Moreover, a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer’s business practices. **Nor, in assessing whether a pharmacy’s orders are suspicious can it ignore information it has obtained as to the scope of drug abuse in a particular area.** Certainly, a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious order monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer’s dispensing practices.<sup>1072</sup>

With respect to the scope of drug abuse in the relevant geographic area at issue in this investigation, and as discussed in section IV(B) of this report, the deleterious impacts of drug abuse, and in particular opioid abuse, have been particularly profound in West Virginia. Between 1999 and 2004, the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent, giving West Virginia the highest unintentional drug overdose death rate in the United States at the time.<sup>1073</sup> According to the Centers for Disease Control and Prevention, in 2017, West Virginia continued to have the highest overdose death rate in the country.<sup>1074</sup>

The Acting Administrator also addressed whether a distributor’s obligation to report suspicious orders could be discharged through its own investigation, stating:

[A] distributor’s investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor inform the Agency about the order.<sup>1075</sup>

In its opinion, the D.C. Circuit clarified distributors’ obligations to actually investigate individual orders that they chose to ship rather than decline to fill, stating:

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<sup>1072</sup> 80 Fed. Reg. 55,478, Sept. 15, 2015 (internal citations omitted) (emphasis added).

<sup>1073</sup> Memorandum from Aron J. Hall, DVM, Epidemic Intelligence Service Officer, W. Va. Dep’t of Health & Human Res., et al., to Douglas H. Hamilton, M.D., PhD, Dir., Epidemic Intelligence Service, Centers for Disease Control and Prevention (Oct. 12, 2007) (On file with Committee).

<sup>1074</sup> Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999-2017*, NCHS Data Brief (Nov. 2008) available at <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>.

<sup>1075</sup> 80 Fed. Reg. 55,418, Sept. 15, 2015 (internal quotations omitted).

As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like [Masters' Suspicious Order Monitoring System] to guide its efforts, then the distributor must actually undertake the investigation.<sup>1076</sup>

The D.C. Circuit agreed with the Acting Administrator that, among other things, such investigations must dispel all red flags that gave rise to the suspicion and that a distributor's investigation must be documented, saying, "the Administrator recognized that, if investigating employees fail to take such basic steps, [the Suspicious Order Monitoring System] does not function as an effective tool for dispelling suspicion."<sup>1077</sup>

As discussed in section VI (A)(1) of this report, in the final order, the Acting Administrator also reiterated a distributor's obligation to conduct due diligence on prospective and existing customers, noting, "the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer."<sup>1078</sup> In the final order, the Acting Administrator, among other things, referenced that, in certain circumstances, Masters failed to seek further explanation when presented with information that conflicted with what was provided during the due diligence process, leading the Acting Administrator to suggest the company's "purpose in asking these questions was simply to go through the motion of conducting due diligence."<sup>1079</sup>

Through letters sent to all DEA registrants, in-person meetings with distributors, industry conferences, and orders published in the federal register, the DEA has identified and communicated red flags or circumstances that might be indicative of diversion, including, but not limited to:

- One or more physicians are writing a disproportionate share of the prescriptions for controlled substances being filled by a pharmacy;<sup>1080</sup>
- Prescriptions being filled that are written by physicians located a significant distance from a pharmacy;<sup>1081</sup>

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<sup>1076</sup> *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335, 23-24 (D.C. Cir. 2017).

<sup>1077</sup> *Id.* at 24.

<sup>1078</sup> 80 Fed. Reg. 55,477, Sept. 15, 2015.

<sup>1079</sup> *Id.* at 55,488, fn. 179.

<sup>1080</sup> See 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 Committee); 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 Committee).

<sup>1081</sup> See 77 Fed. Reg. 62,321, Oct. 12, 2012.

- A pharmacy orders the same controlled substances from multiple distributors;<sup>1082</sup>
- Large quantities of people paying cash for controlled substance prescriptions;<sup>1083</sup>
- A high percentage of the pharmacy's purchases are for controlled substances;<sup>1084</sup>
- A pharmacy orders an excessive amount of a particular controlled substance in comparison to what is purchased by a typical retail pharmacy;<sup>1085</sup> and
- A pharmacy is located in a geographic area that is known to have problem with controlled substance abuse.<sup>1086</sup>

## **2. Case Studies from the Committee's Investigation**

The Committee's investigation revealed that in several instances, distributors continued to supply questionable West Virginia pharmacies with opioids, the volumes of which on their own should have raised red flags, particularly when viewed in context of what should be considered reasonable to support the legitimate medical needs of the local population. In some of these cases, the shipments to the pharmacies were facilitated with very little corresponding due diligence. In other instances, the due diligence materials and other documents collected by the distributors and produced to the Committee should have raised red flags that required distributors to report suspicious orders more frequently and conduct their own independent investigations. The Committee found, however, that distributors continued to ship opioids to these pharmacies for months and, in some cases, even years.

The case studies below will highlight:

- McKesson continued supplying a pharmacy it had previously terminated, and later reinstated, with controlled substances for approximately five months after discovering additional, serious, red flags associated with the pharmacy;

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<sup>1082</sup> See 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 Committee); 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 Committee).

<sup>1083</sup> See 77 Fed. Reg. 62,326, Oct. 12, 2012.

<sup>1084</sup> See 72 Fed. Reg. 36,492, July 3, 2007. In this order, the DEA Acting Administrator quoted guidance that had been provided by DEA in which it was stated, "in a typical retail pharmacy, controlled substances might amount to between five and twenty percent of the pharmacy's purchases with the other eighty to ninety percent of its purchases being non-controlled drugs." (internal quotation marks omitted) See also 80 Fed. Reg. 55,477, Sept. 15, 2015.

<sup>1085</sup> See 72 Fed. Reg. 36,498, July 3, 2007.

<sup>1086</sup> See Staff Coordinator, Liaison & Policy Section, Office of Diversion Control, U.S. Drug Enforcement Admin., *Distributor Initiative – A National Perspective*, Oct. 22, 2013, available at [https://www.deadiversion.usdoj.gov/mtgs/distributor/conf\\_2013/prevoznik.pdf](https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf); see also 77 Fed. Reg. 62,322, Oct. 12, 2012 and 80 Fed. Reg. 55,479, Sept. 15, 2015.



- After terminating a pharmacy following a site visit, McKesson did not undertake a review of the pharmacy's other location, which was also a McKesson customer and located approximately three miles away, for nearly sixteen months;
- Over a two-year period, H.D. Smith shipped nearly five million doses of hydrocodone and oxycodone to two pharmacies, located approximately four blocks apart in a town of 3,191. Moreover, H.D. Smith obtained dispensing data which demonstrated that a single doctor was responsible for prescribing more than 158,000 doses of hydrocodone dispensed by one of these pharmacies in February 2008;
- Approximately six months after reporting a pharmacy to the DEA, H.D. Smith was presented with information during a site visit suggesting that 90 to 95 percent of this pharmacy's orders were for controlled substances yet the company continued to ship controlled substances to this pharmacy;
- H.D. Smith determined that a single doctor was writing 51 percent of the hydrocodone prescriptions being filled at a particular pharmacy and did not terminate this pharmacy or restrict its ability to purchase controlled substances, despite terminating another pharmacy approximately three months earlier, in part, because the pharmacy continued to fill prescriptions written by this doctor; and
- Miami-Luken continued to supply controlled substances to a pharmacy, even approving a temporary increase to the pharmacy's oxycodone threshold, after the company determined that it had been lied to by the pharmacy's owner regarding a commitment to stop filling prescriptions written by certain doctors.

*a. Case Study on McKesson: Monitoring When Aware of Red Flags*

As discussed earlier in this report, McKesson suspended Tug Valley's ability to purchase controlled substances on January 8, 2016, after the pharmacy was prominently featured in a *CBS News* report concerning the role wholesale distributors may have played in exacerbating the opioid epidemic in West Virginia.<sup>1087</sup> In an affidavit submitted after Tug Valley sued McKesson for suspending its ability to purchase controlled substances, a senior director of regulatory affairs at McKesson stated that the company "had a good-faith belief that continued shipments to Tug Valley Pharmacy put McKesson in jeopardy of being noncompliant with federal and/or state laws and regulations concerning the distribution of controlled substances."<sup>1088</sup> The 2016 cessation of McKesson's and Tug Valley's business relationship would be short-lived, however, as the company quickly reinstated Tug Valley as a customer and continued to supply the pharmacy with controlled substances until it cut the pharmacy off again on February 28, 2018, despite discovering serious red flags regarding the pharmacy approximately five months earlier in October 2017.

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<sup>1087</sup> See *supra* Section VI(A)(2)(c)(i)

<sup>1088</sup> *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee) (internal quotation marks omitted).

On February 26, 2016, the month following the pharmacy's appearance on the *CBS News*, McKesson reinstated Tug Valley as a customer after the pharmacy was purchased by another individual.<sup>1089</sup> Given the allegations against the previous owner, Tug Valley's new owner represented to McKesson that the previous owner no longer had any association with the pharmacy.<sup>1090</sup> This representation appears to have been critical to McKesson's decision to reinstate Tug Valley.

Notwithstanding documents provided by the pharmacy to McKesson indicating that the previous owner provided the financing arrangement to facilitate the sale of the pharmacy while also retaining a security interest in the pharmacy,<sup>1091</sup> McKesson appears to have relied on the statement from the new owner that the previous owner no longer had any association with the pharmacy. However, twenty months later, in October 2017, McKesson learned that the previous owner was, in fact, working at the pharmacy.<sup>1092</sup>

Documents produced to the Committee indicate McKesson conducted due diligence at various points between February 2016 and October 2017 that did not yield evidence that the former owner had any direct association with the pharmacy during this time, meaning that McKesson could not tell from the face of the documents provided by the pharmacy that the previous owner was still involved. For example, the former owner was not listed among the pharmacy's employees on a September 2017 threshold change request form despite the fact that the new owner said he returned to the pharmacy in June 2017.<sup>1093</sup> This suggests that the new owner may have taken deliberate action to conceal the former owner's involvement from McKesson. McKesson, however, does not appear to have attempted to independently confirm that the previous owner was no longer associated with the pharmacy, such as by directly asking the pharmacy or conducting a site visit whereby McKesson could interview pharmacy employees.

McKesson appears to have realized that the previous owner was still associated with the pharmacy somewhat by happenstance. On October 3, 2017, when it was conducting due diligence on Tug Valley's request to increase its buprenorphine threshold, a McKesson investigator called the pharmacy and the previous owner answered the phone.<sup>1094</sup> A Regulatory

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<sup>1089</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee). As discussed earlier, the circumstances attendant to the transfer of ownership and McKesson's ultimate decision to reinstate the pharmacy are highly questionable. *See supra* Section VI(A)(2)(c).

<sup>1090</sup> McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

<sup>1091</sup> *See* McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb. 11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Security Agreement, Feb. 11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Agreement, Feb. 11, 2016 (On file with Committee).

<sup>1092</sup> *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 11, 2017 (On file with Committee).

<sup>1093</sup> *See* McKesson Corp., Threshold Change Request Form – Tug Valley Pharmacy, Sept. 27, 2017 (On file with Committee).

<sup>1094</sup> *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 11, 2017 (On file with Committee).

Investigative Report, authored eight days later documented this phone call.<sup>1095</sup> The report also noted, “[the former owner’s] name does not appear on the [Threshold Change Request (TCR)] form or the McKesson [Controlled Substances Monitoring Program] questionnaire that was included in the TCR package.”<sup>1096</sup> The report also referenced McKesson’s decision to suspend Tug Valley’s ability to purchase controlled substances during the former owner’s tenure as well as the pharmacy being featured on the *CBS News* in relation to the lawsuit concerning its prescribing practices under the former owner.<sup>1097</sup> The portion of the McKesson report that references the litigation and McKesson’s previous decision to suspend the pharmacy is reproduced below:

During an open Internet search, including the OIG Exclusion website, derogatory information was found concerning [REDACTED]. The derogatory information references Tug Valley Pharmacy, under the ownership of [REDACTED] and Tug Valley Pharmacy are mentioned in a civil action (no. 10-c-251) and a circuit court order (no. 14-0144). A CBS News article noted that Tug Valley Pharmacy was being sued for negligently filling prescriptions. (See links below.)  
<http://www.courtsww.gov/supreme-court/calendar/2015/briefs/march15/14-0144order.pdf>  
<http://www.courtsww.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf>  
<http://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/>

It is noted that McKesson suspended Tug Valley Pharmacy’s, under the ownership of [REDACTED] ability to purchase controlled substances on January 8, 2016.

In addition to documenting McKesson’s discovery that the former owner continued to have an affiliation with the pharmacy, the report also noted that the Kentucky State Board of Pharmacy took action against another pharmacist employed by Tug Valley for filling fraudulent hydrocodone prescriptions.<sup>1098</sup> According to the report, McKesson determined that the pharmacist had pleaded guilty to a felony charge and that the pharmacy needed a waiver from the DEA if he were to remain employed by the pharmacy.<sup>1099</sup> Pursuant to the Regulatory Investigative Report, McKesson denied Tug Valley’s request to increase its buprenorphine threshold.<sup>1100</sup>

McKesson drafted a second Regulatory Investigative Report two days later regarding the discoveries made by the company when it was evaluating Tug Valley’s threshold request.<sup>1101</sup> This report referenced the findings from the earlier report, stating, “two current staff pharmacists have pending or finalized litigation or disciplinary actions which needed clarification to

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<sup>1095</sup> *Id.*

<sup>1096</sup> *Id.*

<sup>1097</sup> *Id.*

<sup>1098</sup> *See Id.*

<sup>1099</sup> *Id.* DEA regulations prohibit registrants from employing individuals who have access to controlled substances and have been convicted of a felony related to controlled substances unless a waiver is obtained from the DEA. *See* 21 CFR §1301.76(a) and 56 Fed. Reg. 36,727 (Aug. 1, 1991).

<sup>1101</sup> *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 13, 2017 (On file with Committee).

effectively assess JCL Management & Consulting, LLC., dba: Tug Valley Pharmacy's status as a McKesson customer."<sup>1102</sup> With respect to the former owner of Tug Valley Pharmacy, the report stated:

On October 3, 2017, [the Regulatory Affairs Manager] contacted the pharmacy to inquire about prescribing physicians listed as part of the TCR. She spoke with [Tug Valley's former owner], a relief pharmacist at JCL Management & Consulting, LLC., dba: Tug Valley Pharmacy. [The Regulatory Affairs Manager] recognized that [the former owner] was the former owner of Tug Valley Pharmacy, a customer terminated by McKesson Regulatory Affairs on January 8, 2016. This termination was based on pending civil litigation against [the former owner] which alleged that [the former owner] neglected his pharmacist's corresponding responsibilities when filling prescriptions for controlled substances. Following the termination of this account, [the former owner] sold Tug Valley Pharmacy to [the new owner]. Pursuant to McKesson's Change of Ownership procedures, [the new owner's] ownership was approved and the pharmacy became a McKesson customer on February 26, 2016. When onboarded, it was believed by McKesson Regulatory Affairs personnel that [the former owner] had relinquished any connection to Tug Valley Pharmacy, including employment opportunities.<sup>1103</sup>

McKesson's Director of Regulatory Affairs spoke with Tug Valley's new owner regarding the employment of the former owner as well as the pharmacist with a felony conviction related to controlled substance diversion. With respect to the conversation related to Tug Valley's employment of its former owner, the report stated:

[The Director of Regulatory Affairs] asked [Tug Valley's new owner] about [Tug Valley's former owner's] employment at the pharmacy. [The Director of Regulatory Affairs] prefaced the question by stating that it was McKesson's understanding that when the change of ownership at Tug Valley was approved, [the former owner] would have no affiliation with the pharmacy. [The new owner] stated that when the ownership of the pharmacy transferred to him, [the former owner] had no affiliation with the pharmacy, including employment opportunities. [The new owner] said this status changed in June 2017 when one of the pharmacy's staff pharmacists passed away. [The new owner] stated that he needed to find a pharmacist to fill in occasionally for regular staff. [The new owner] added that because of the pharmacy's rural location it is not easy finding reliable pharmacist's [sic] help. Because of these staffing issues, he asked [the former owner] to

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<sup>1102</sup> *Id.*

<sup>1103</sup> *Id.* McKesson's stated belief that the former owner "relinquished any connection to Tug Valley Pharmacy," seems to conflict with McKesson's knowledge that, pursuant to documents provided to McKesson in February 2016, the former owner retained a security interest in the pharmacy at the time McKesson reinstated Tug Valley as a customer. The circumstances surrounding the sale of Tug Valley Pharmacy in February 2016 are discussed in greater detail in section VI(A)(2)(c)(ii).

fill in until he could find a permanent pharmacist replacement. [The new owner] added that he hired [the former owner] to work part-time hours working approximately 10 – 20 hours weekly at the pharmacy. [The new owner] added that [the former owner] would be excused from this part-time position once a permanent replacement was found.

The report also notes that McKesson’s Director of Regulatory Affairs told Tug Valley’s new owner that if the pharmacy did not find a replacement for the former owner by October 31, 2017, it would suspend Tug Valley’s ability to purchase controlled substances.<sup>1104</sup> The report stated:

[The Director of Regulatory Affairs] reiterated McKesson’s concerns about [the former owner’s] employment because of on-going civil litigation with [the former owner]. [The Director of Regulatory Affairs] told [the new owner] that McKesson could not tell [the new owner] whom to employ, but the company had issues with [the former owner] due to the pending civil litigation. [The Director of Regulatory Affairs] told [the new owner] that McKesson would allow [the new owner] until October 31, 2107 [sic] to find a replacement for [the former owner]. If [the new owner] did not find a replacement for him by October 31, 2017, McKesson would “suspend” JCL Management & consulting, LLC., dba: Tug Valley Pharmacy’s ability to order controlled substances. [The new owner] said that he would need more time due to the problems in finding reliable help.<sup>1105</sup>

Later the same day, the Director of Regulatory of Affairs spoke with Tug Valley Pharmacy’s new owner again, this time, to discuss the need for the pharmacy to obtain a waiver from the DEA related to its employment of a pharmacist with a controlled substance-related felony conviction.<sup>1106</sup> According to the report, the new owner told McKesson that the pharmacist would not work at the pharmacy until the DEA waiver was obtained.<sup>1107</sup>

The report concluded, “McKesson’s Regulatory Affairs will monitor the status of current pharmacy staff until October 31, 2017. On this date, if [Tug Valley’s new owner] has not found adequate staffing resources, the pharmacy’s ability to order controlled substances will be suspended.”<sup>1108</sup>

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<sup>1104</sup> *Id.*

<sup>1105</sup> *Id.*

<sup>1106</sup> *Id.*

<sup>1107</sup> *Id.*

<sup>1108</sup> *Id.*

**FINDING: When McKesson reinstated Tug Valley Pharmacy as a customer in February 2016, the pharmacy’s new owner assured McKesson that its former owner no longer had any association with the pharmacy. However, after learning in October 2017 the former owner was employed by the pharmacy, as was a pharmacist with a felony conviction related to controlled substances, McKesson did not terminate or restrict Tug Valley’s ability to purchase controlled substances.**

A November 1, 2017, Regulatory Investigative Report indicates that McKesson did follow-up with Tug Valley regarding the employment status of the former owner as well as that of the pharmacist with the controlled substance-related felony conviction.<sup>1109</sup> With respect to the former owner, Tug Valley’s new owner told McKesson’s Director of Regulatory Affairs that “he found another pharmacist to replace [the former owner]; however, that pharmacist could not begin working until November 7, 2017.”<sup>1110</sup> The report also documented a conversation the Director of Regulatory Affairs had with the new owner regarding the pharmacist with the controlled-substance felony conviction, noting:

[The new owner] stated that [the pharmacist] was not employed as a pharmacist at the store. [The new owner] added that he had submitted the paperwork required for the waiver consideration to DEA, despite being told by them that [the pharmacist] could continue his employment while the waiver was being reviewed. [The new owner] reiterated that [the individual] would not work at JCL Management & Consulting, LLC dba: Tug Valley Pharmacy until a decision on the waiver was rendered.<sup>1111</sup>

Based upon the representations made by the new owner, the Director of Regulatory Affairs recommended that Tug Valley remain a McKesson customer.<sup>1112</sup> Documents provided to the Committee show no attempt by McKesson to verify the representations made by Tug Valley regarding the employment status of either individual, such as by contacting the pharmacy again after November 7, 2017 to confirm that the new pharmacist hired to replace the former owner had begun work. In fact, McKesson told the Committee that it did not make any additional inquiries with respect to either individual until February 28, 2018.<sup>1113</sup>

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<sup>1109</sup> See McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Nov. 1, 2017 (On file with Committee).

<sup>1110</sup> *Id.*

<sup>1111</sup> *Id.*

<sup>1112</sup> See *Id.*

<sup>1113</sup> See E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

**FINDING: During a November 1, 2017 conversation between McKesson’s Director of Regulatory Affairs and Tug Valley’s new owner, the pharmacy owner made representations about the former owner and the convicted pharmacist that McKesson did not attempt to verify until February 28, 2018.**

McKesson finally suspended Tug Valley Pharmacy’s ability to purchase controlled substances on February 28, 2018, the same day McKesson conducted a site visit to the pharmacy and discovered that the individual with a controlled substance-related felony conviction continued to be employed as a pharmacist at Tug Valley despite not receiving the necessary DEA waiver, and in direct contradiction to the new owner’s pledge that the individual would not be employed by the pharmacy until such a waiver was obtained.<sup>1114</sup>

According to a Regulatory Investigative Report which documented the site visit, the individual was listed among Tug Valley’s pharmacists and worked “on an ‘as needed’ basis[.]”<sup>1115</sup> During the site visit, the Regulatory Affairs Manager also inquired about the employment status of Tug Valley’s former owner and was told by Tug Valley’s Pharmacist in Charge that the former owner no longer worked at the pharmacy, adding that he was unable to recall the last time the former owner worked at the pharmacy.<sup>1116</sup>

On the same day as the site visit, McKesson’s Director of Regulatory Affairs addressed the pharmacy’s continued employment of the individual with a controlled substance-related felony conviction during a conversation with Tug Valley’s new owner. This conversation is documented in a separate Regulatory Investigative Report, which stated:

To gain further insight into [the pharmacist’s] employment, [the Director of Regulatory Affairs] spoke with [the new owner] on February 28, 2018. [The Director of Regulatory Affairs] asked [the new owner] if [the pharmacist] had recently worked at Tug Valley Pharmacy as a pharmacist. [The new owner] stated that [the pharmacist] had worked on one occasion because of scheduling conflicts. [The Director of Regulatory Affairs] asked [the new owner] if the employment waiver from DEA had been finalized allowing [the pharmacist’s] employment. [The new owner] said the waiver had been submitted but no official word had been received. [The new owner] said it could take months before a decision was made.

[The Director of Regulatory Affairs] asked about their previous conversation when [the new owner] committed to not further employ [the pharmacist] until the waiver had been granted. [The new owner] argued with [the Director of Regulatory Affairs] by saying that finding pharmacist

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<sup>1114</sup> McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).

<sup>1115</sup> McKesson Corp., Regulatory Affairs Manager, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).

<sup>1116</sup> *Id.*

staff was difficult in this area of West Virginia and, besides that, the DEA told [the new owner] that [the pharmacist] could work while the waiver was being processed. [The Director of Regulatory Affairs] reiterated that a pharmacist could not work until the waiver was granted and asked [the new owner] for the name of the DEA employee who gave that information to him. [The new owner] could not recall any name or contact information regarding the DEA employee.<sup>1117</sup>

McKesson's ultimate realization of the individual's continued employment at Tug Valley Pharmacy does not appear to have been a product of its own follow-up. As indicated below, two Regulatory Investigative Reports state that McKesson initiated the February 2018 review after the company received an inquiry from a pharmaceutical manufacturer related to Tug Valley pharmacy.<sup>1118</sup>

Pursuant to a manufacturer inquiry from ██████████, RAM ██████████ conducted a triggered event review at JCL Management and Consulting, dba: Tug Valley Pharmacy; hereinafter Tug Valley Pharmacy on February 28, 2018. ██████████

On February 20, 2018, Senior Director of Regulatory Affairs ██████████ informed the Washington Court House Regulatory Affairs team of ██████████'s due diligence request. Tug Valley Pharmacy was identified by ██████████. Senior Director of Regulatory Affairs ██████████ requested an event-triggered due diligence review of the pharmacy.

While McKesson's ultimate decision to restrict the pharmacy's ability to purchase controlled substances is commendable, this action came nearly five months after the company discovered serious red flags with a pharmacy that it terminated in the past for compliance reasons. Moreover, the October 2017 report that began this process came twenty months after McKesson reinstated the pharmacy as a customer almost immediately after terminating it for compliance reasons. Only after receiving a third-party inquiry regarding Tug Valley, did McKesson conduct a site visit in February 2018.

**FINDING: McKesson's February 28, 2018 site visit to Tug Valley, which resulted in the pharmacy's termination, was initiated by a third-party request, not McKesson's own proactive due diligence.**

At the time it terminated Tug Valley's ability to purchase controlled substances in February 2018, McKesson was also supplying controlled substances to three other pharmacies

<sup>1117</sup> See McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).

<sup>1118</sup> See McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee). See also McKesson Corp., Regulatory Affairs Manager, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).



owned by Tug Valley’s new owner, including the former Sav-Rite No. 1 which was operating under a different name.<sup>1119</sup> Given the repeated misrepresentations made by the new owner and the company’s decision to terminate Tug Valley’s ability to purchase controlled substances, the Committee asked McKesson whether it terminated its relationship with or restricted the owner’s other pharmacies from purchasing controlled substances.<sup>1120</sup> In response to the Committee’s question, McKesson indicated that it had not, adding, “[d]ue diligence reviews conducted on the other three pharmacies and their employees have not revealed any areas of concern.”<sup>1121</sup> It is not clear, however, when such due diligence reviews occurred or whether they took the owner’s misrepresentations to McKesson, involving individuals linked to controlled substance diversion, into account had any such reviews occurred following the company’s decision to terminate Tug Valley.

As mentioned, in a 2015 final order revoking the registration of another wholesale distributor, DEA’s then-Acting Administrator noted that “a pharmacy’s business model, dispensing patterns, or other characteristics” may all be factors that a distributor should take into account when assessing whether a controlled substances order placed by a pharmacy is suspicious.<sup>1122</sup> Given the multiple, documented, misrepresentations made by the new owner of Tug Valley Pharmacy, a pharmacy which was purchased under questionable circumstances, in a region of West Virginia that has been severely impacted by the opioid epidemic, McKesson should be particularly vigilant when evaluating controlled substance orders placed by the new owner’s other pharmacies.

***b. Case Study on McKesson: Evaluation of an Owner(s)’s Other Pharmacies***

As previously discussed in this report, McKesson supplied hydrocodone and oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779,<sup>1123</sup> at various times between 2006 and 2014.<sup>1124</sup> In that time, the pharmacy received more than 5.91 million doses of opioids from McKesson alone, making it McKesson’s top purchaser of hydrocodone and oxycodone in West Virginia.<sup>1125</sup> McKesson also supplied Family Discount

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<sup>1119</sup> See E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee); see also Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). As discussed in greater detail in section VI(A)(2)(c)(ii), the circumstances surrounding the new owner’s February 2016 acquisition of Tug Valley Pharmacy are highly questionable. Documents produced to the Committee and the Committee’s own research indicates that Tug Valley’s new owner acquired the other three pharmacies at approximately the same time, during or around April 2017. See McKesson Corp., ISMC Customer Questionnaire – Tug Valley Pharmacy, Apr. 26, 2017 (On file with Committee).

<sup>1120</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

<sup>1121</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

<sup>1122</sup> See 80 Fed. Reg. 55,4734, Sept. 15, 2015.

<sup>1123</sup> American FactFinder, *Mount Gay-Shamrock (CDP), West Virginia* (<https://factfinder.census.gov>).

<sup>1124</sup> See *supra* Section VI(A)(2)(b).

<sup>1125</sup> McKesson Corp., Ten Largest West Virginia Hydrocodone and Oxycodone – 2006 – 2017 (On file with Committee). As discussed in greater detail in Section VI(A)(2)(b), McKesson told the Committee that Family

Pharmacy's second location in Stollings, West Virginia, population 316,<sup>1126</sup> with more than 2.37 million doses of hydrocodone and oxycodone at various times between 2006 and 2015.<sup>1127</sup> Combined, McKesson supplied more than 8.29 million doses of opioids to these two pharmacies, located just three miles apart. As will be discussed below, even after terminating Family Discount Pharmacy in Mount Gay-Shamrock in April 2014 due to red flags related to the pharmacy's dispensing practices, McKesson continued to distribute opioids to Family Discount Pharmacy in Stollings and failed to conduct any due diligence on the pharmacy for nearly sixteen months.

**FINDING: At various times during a ten-year period, McKesson shipped more than 8.29 million doses of opioids to two commonly owned pharmacies, located just three miles apart in rural West Virginia.**

*i. McKesson's 2014 Termination of Family Discount Pharmacy in Mount Gay-Shamrock*

On March 27, 2014, McKesson conducted a site visit to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, to follow up on the pharmacy's request to increase its monthly threshold for alprazolam.<sup>1128</sup> According to a report authored by McKesson's Director of Regulatory Affairs, at the time of the site visit, Family Discount Pharmacy had purchased more than half a million dosage units of alprazolam over the past year.<sup>1129</sup> The pharmacy's alprazolam purchase history between April 2013 and March 2014 was included in the report, and reproduced in relevant part below:

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Discount Pharmacy's Mount Gay-Shamrock location was included on a list of pharmacies McKesson terminated for compliance reasons and e-mailed to the DEA on February 6, 2009. *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). In 2010, Family Discount Pharmacy's Mount Gay-Shamrock location once again became a McKesson customer. This engagement was short-lived, however, as McKesson told the Committee, "McKesson records indicate that Family Discount Pharmacy (Mount Gay-Shamrock)'s first controlled substances order in 2010 was on March 2, and its last controlled substances order in 2010 was on March 26. Currently available records do not make clear why McKesson discontinued supplying controlled substances to the pharmacy in 2010." E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee). Thereafter, Family Discount Pharmacy's Mount Gay-Shamrock location resumed its relationship with McKesson in September 2012.

<sup>1126</sup> American FactFinder, *Stollings (CDP), West Virginia* (<https://factfinder.census.gov>).

<sup>1127</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>1128</sup> Alprazolam is a type of benzodiazepine, a sedative commonly involved in opioid overdoses. In 2016, the Food and Drug Administration mandated that 'black box' warnings be added to opioid and benzodiazepine packaging, warning of the dangers that could result from taking both types of medication simultaneously. *See* Nat'l Inst. on Drug Abuse, *Benzodiazepines and Opioids* (last updated Mar. 2018) available at <https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids>; *see also* Press Release, U.S. Food and Drug Admin., FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from coming use (Aug. 31, 2016), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518697.htm>.

<sup>1129</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

## PURCHASE HISTORY REVIEW

A purchase history review indicated from April 2013 through March 2014, Family Discount Pharmacy ordered 561,320 dosage units of Alprazolam. See chart below:

APR 2013	65,000	65	62,620
MAY 2013	65,000	48	47,500
JUN 2013	65,000	59	57,600
JUL 2013	65,000	52	51,500
AUG 2013	65,000	58	52,880
SEP 2013	65,000	65	63,600
OCT 2013	19,000	64	60,720
NOV 2013	19,000	19	19,000
DEC 2013	36,930	42	36,920
JAN 2014	36,930	45	36,800
FEB 2014	36,930	42	36,480
MAR 2014	36,930	38	35,700
Total	36,930	597	561,320

The report also indicated that Family Discount was receiving hydrocodone in addition to what was supplied by McKesson, and that the pharmacy purchased nearly five times the amount of hydrocodone than a nearby Rite Aid Pharmacy, which was also a McKesson customer.<sup>1130</sup> With respect to Family Discount Pharmacy's purchases of hydrocodone, the report stated, "[i]n particular, the hydrocodone dispensing data indicates that Family Discount Pharmacy purchases more hydrocodone than McKesson supplied (70,000 doses monthly versus 81,367 doses dispensed for four month period of December 2013 through March 27, 201[4])."<sup>1131</sup> The report continued, "[o]ther information obtained during this investigation revealed that another McKesson customer, Rite Aid Pharmacy, located in the same area as Family Discount Pharmacy, only purchased approximately 15,000 doses of hydrocodone monthly."<sup>1132</sup> During an earlier site visit, McKesson also observed that there were several national retail chain pharmacies within a ten-mile radius of Family Discount Pharmacy.<sup>1133</sup>

During the March 27, 2014, site visit, the pharmacy's owner told the McKesson investigator, "he utilizes McKesson as his primary distributor but uses Miami-Luken in Ohio as a secondary distributor. No other distributor has ever restricted or ceased controlled substances sales from any pharmacy [the owner] has owned or been employed."<sup>1134</sup> As discussed earlier in section VI(A)(2)(b)(ii) of this report, however, McKesson told the Committee that it informed

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<sup>1130</sup> *Id.*

<sup>1131</sup> *Id.*

<sup>1132</sup> *Id.*

<sup>1133</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), Mar. 24, 2014 (On file with Committee).

<sup>1134</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

the DEA in a 2009 e-mail that it terminated Family Discount Pharmacy as a customer “for compliance reasons.”<sup>1135</sup>

A week after the March site visit, the Director of Regulatory Affairs spoke to a local law enforcement officer who said that the county where Family Discount was located had “serious prescription drug abuse issues.”<sup>1136</sup> The officer also alerted McKesson to area doctors that provided cause for concern, including two whose “controlled substances prescriptions are frequently dispensed at Family Discount Pharmacy.”<sup>1137</sup> McKesson noted that the Rite Aid had ceased filling prescriptions written by two area doctors, one of whom had been identified by the law enforcement officer, due to questionable prescribing patterns, but Family Discount had not.<sup>1138</sup>

**FINDING: Family Discount Pharmacy in Mount Gay-Shamrock purchased nearly five times the amount of hydrocodone from McKesson than a nearby Rite Aid Pharmacy. McKesson fulfilled the orders placed by Family Discount Pharmacy during a time when the surrounding area had “serious prescription drug abuse issues” per a local law enforcement officer.**

Following the site visit and discussion with local law enforcement, the company discontinued selling controlled substances to Family Discount Pharmacy on April 8, 2014.<sup>1139</sup> This decision was documented by McKesson in a subsequent Regulatory Investigative Report and is reproduced in relevant part below:

#### **CONCLUSION/RECOMMENDATION**

On April 8, 2014, DRA [REDACTED] via SAP reduced this customer’s controlled substance to zero and entered “ineligible” coding for future sales.

Documents produced to the Committee indicate the pharmacy continued to attempt to order controlled substances from McKesson, even after its ability to do so had been terminated by the company. For example, out of the 138 total orders placed by Family Discount Pharmacy that McKesson reported to the DEA as suspicious, 36 were placed after April 8, 2014, with latest order being October 19, 2015.<sup>1140</sup> The documents produced to the Committee give no indication

<sup>1135</sup> See *supra* Section VI(A)(2)(b)(ii); see also Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>1136</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

<sup>1137</sup> *Id.*

<sup>1138</sup> *Id.*

<sup>1139</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), Apr. 11, 2014 (On file with Committee).

<sup>1140</sup> McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

why the pharmacy continued to place orders for controlled substances after its ability to do so was terminated on April 8, 2014, or whether any orders placed after this date were filled.

*ii. McKesson's Distribution to Family Discount Pharmacy-Stollings*

McKesson also supplied controlled substances to Family Discount Pharmacy's secondary location in Stollings, West Virginia, located just three miles from the Mount Gay-Shamrock store. The common ownership between the two pharmacies emerged multiple times in documents produced by McKesson. For example, a January 2010 questionnaire regarding the Mount Gay-Shamrock location mentions the Stollings location, as does an August 2012 questionnaire.<sup>1141</sup> During the March 27, 2014 site visit to the Mount Gay-Shamrock location, the pharmacy's owner again disclosed that he was also a co-owner of the Stollings location.<sup>1142</sup> Despite McKesson's decision in April 2014 to terminate Family Discount Pharmacy in Mount Gay-Shamrock, the company continued to supply the Stollings location with opioids.

Documents initially produced to the Committee indicated that McKesson did not perform a review of the Stollings pharmacy until August 2015—sixteen months after McKesson terminated the Mount Gay-Shamrock location. The Committee accordingly asked McKesson to confirm whether it performed a site visit or conducted supplemental due diligence on the Stollings pharmacy between the April 2014 termination of the Mount Gay-Shamrock location, and the August 2015 review.<sup>1143</sup> In response, McKesson told the Committee:

Yes, McKesson did conduct a review of the Stollings pharmacy around the time of its decision to terminate access to controls with the Mt. Gay pharmacy. [McKesson's Senior Director of Regulatory Affairs and Regional Director of Regulatory Affairs] reviewed purchase data associated with both pharmacies and concluded from their review that purchasing levels from the Stollings pharmacy were measurably different from the Mt. Gay pharmacy. Attached are handwritten notes from [McKesson's Senior Director of Regulatory Affairs] which McKesson was able to locate documenting the assessment of both Family Discount Pharmacy locations at the time. McKesson also conducted an on-site regulatory review of the Stollings pharmacy in August 2015.<sup>1144</sup>

McKesson further told the Committee, “[t]he review referenced was not an on-site review. The review was conducted at approximately the same time as the decision to terminate the Mount Gay-Shamrock location's access to controlled substances, but the exact date is not

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<sup>1141</sup> See McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Mount Gay-Shamrock), Jan. 26, 2010 (On file with Committee); see also McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Mount Gay-Shamrock), Aug. 24, 2012 (On file with Committee).

<sup>1142</sup> McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

<sup>1143</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

<sup>1144</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

known.”<sup>1145</sup> The notes documenting McKesson’s review of both Family Discount Pharmacy locations, and referenced in the company’s response to the Committee, were a single page which is reproduced in its entirety below.<sup>1146</sup>

198468

[Redacted] Family Discount #2

Q2

1.	35%	Control/EX	77,000	Monthly	25,647
			33,100	EX 20	20 - 43%
Q2 Avg monthly purchase hydro 89,867					
hydro 267,600 dose, 35D					
Threshold 43,000 (92) 47% hydro 10					

Q2. 35%. Control EX  
hydro dose 81,208

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Q3 I 12,000 - 4,600

1.	38%	Control/EX	85,000	EX	
MT. GAY WV			33,700	EX 20	
hydro dose 226,514					
Logans w/v 10,000 off 79,112 hydro					
75,504 month					
114,104 hydro 10					

[Redacted]

<sup>1145</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>1146</sup> McKesson Corp., Due Diligence Notes – Family Discount Pharmacies (Mount Gay-Shamrock and Stollings) (On file with Committee).

Aside from these notes, which McKesson told the Committee “are the only available record of which McKesson is currently aware[,]”<sup>1147</sup> McKesson has not produced any other documents that demonstrate analysis or review of the Stollings location following McKesson’s April 2014 termination of the Mount Gay-Shamrock location and prior to August 2015. McKesson’s response to the Committee indicates the company did not conduct additional due diligence on the Stollings location for sixteen months after it terminated the Mount Gay-Shamrock location in April 2014.

**FINDING: McKesson terminated Family Discount’s Mount Gay-Shamrock pharmacy in April 2014, but did not undertake an on-site regulatory review of the co-owned Stollings location until sixteen months later. McKesson did review purchase data from the Stollings pharmacy around the time it terminated the Mount Gay-Shamrock location, however, documentation produced to the Committee regarding that review consisted of only a single page of handwritten notes.**

McKesson performed a proactive on-site regulatory review of the Stollings location on August 6, 2015.<sup>1148</sup> With respect to this review, McKesson told the Committee, “[t]he review conducted by McKesson’s regulatory affairs team revealed no issues with the Family Discount Pharmacy of Stollings.”<sup>1149</sup>

Given McKesson’s prior termination of the Mount Gay-Shamrock location, which had common ownership with the Stollings pharmacy, certain disclosures made by the pharmacy during the August 2015 review should have been a source of concern for McKesson. For example, in the CSMP questionnaire dated the same day as the site visit, the pharmacy did not answer the question regarding whether any other pharmacy that was owned or is owned by any of the pharmacy’s owners had its ability to purchase controlled substances restricted or terminated in the past ten years.<sup>1150</sup> This portion of the August 6, 2015 CSMP questionnaire is reproduced below:

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<sup>1147</sup> E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

<sup>1148</sup> See McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Stollings), Oct. 8, 2015 (On file with Committee).

<sup>1149</sup> Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

<sup>1150</sup> McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Stollings), Aug. 6, 2015 (On file with Committee).



x. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to a pharmacy that was owned or is owned by current owner/s during the past ten years?

Yes  No

Explanation:

The documents produced to the Committee give no indication that McKesson questioned Family Discount about this omission, and the report summarizing the site visit made no mention of the action the company took against the pharmacy’s Mount Gay-Shamrock location for compliance concerns, or the pharmacy’s continued attempts to order controlled substances from McKesson despite having its ability to do so terminated by the company.<sup>1151</sup> In addition, the report noted that during the August 2015 site visit, the pharmacy provided McKesson with the names of two doctors who had oxycodone prescriptions filled at the Stollings location<sup>1152</sup>—one of whom McKesson referenced in the report detailing the company’s reasoning for terminating the Mount Gay-Shamrock location, after the doctor was identified by local police as being a cause for concern.<sup>1153</sup>

The report also made no reference to suspicious orders related to the Stollings location that McKesson reported to the DEA. From the time it began reporting suspicious orders to the DEA in August 2013, McKesson reported 85 suspicious orders placed by the Stollings location, 49 of which came after McKesson discontinued selling controlled substances to the pharmacy’s Mount Gay-Shamrock location.<sup>1154</sup> By the time of the August 2015 site visit, McKesson had reported 82 suspicious orders to the DEA about the Family Discount Pharmacy in Stollings.<sup>1155</sup>

Despite the significant number of suspicious orders originating from the Stollings pharmacy, warnings about drug abuse issues in the community, and the common ownership with a nearby pharmacy McKesson terminated for concerning dispensing practices, McKesson continued to supply the Stollings location with controlled substances. It was not until the pharmacy elected to discontinue its business relationship with McKesson in early 2016 that McKesson stopped supplying controlled substances to the Stollings location.<sup>1156</sup>

<sup>1151</sup> See McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Stollings), Oct. 8, 2015 (On file with Committee)

<sup>1152</sup> See *Id.*

<sup>1153</sup> See McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

<sup>1154</sup> McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee). In total, McKesson submitted 223 suspicious order reports to the DEA for orders placed by both Family Discount locations.

<sup>1155</sup> *Id.*

<sup>1156</sup> See Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).



Had McKesson undertaken a proactive review of the Stollings location in a timelier manner, and incorporated the findings which prompted the company to terminate the Mount Gay-Shamrock location's ability to purchase controlled substances into any such review, it would have been better positioned to identify and mitigate any potential red flags of diversion associated with the Stollings location.

c. *Case Study on H.D. Smith: Common Diversion Concerns Involving Pharmacies in the Same Geographic Area*

Between 2007 and 2008, H.D. Smith provided Hurley Drug Company in Williamson, West Virginia, with more than 2.88 million doses of hydrocodone and oxycodone.<sup>1157</sup> In the same time period, H.D. Smith provided Tug Valley Pharmacy, also located in Williamson, with more than 2.1 million doses of hydrocodone and oxycodone.<sup>1158</sup> Hurley Drug Company and Tug Valley Pharmacy are located approximately four blocks apart from each other in Williamson, which had a population of 3,191 in 2010.<sup>1159</sup> In total, H.D. Smith provided these two pharmacies with nearly five million doses of hydrocodone and oxycodone in just two years.<sup>1160</sup>

H.D. Smith's analysis of dispensing data produced by these pharmacies provided the company with concern, however, prompting it to alert the DEA in April 2008. Despite this action, the company continued to supply Tug Valley with controlled substances until August 2009, and continued to supply Hurley Drug Company until September 2011. In total, H.D. Smith supplied both pharmacies with more than 6.82 million doses of hydrocodone and oxycodone between 2007 and 2011.<sup>1161</sup>

H.D. Smith told the Committee that it requested dispensing and prescribing data from pharmacy customers in situations when the company deemed that further investigation of a particular customer was necessary.<sup>1162</sup> Specifically, H.D. Smith told the Committee:

Dispensing and prescribing data provides greater insight to H.D. Smith into the total purchases by a pharmacy and the prescriptions being filled at that pharmacy. H.D. Smith can analyze the data to identify prescribing patterns that raise possible red flags regarding the pharmacy. By way of example, in February 2008, H.D. Smith requested, obtained, and evaluated dispensing and prescribing data from Hurley Drug Company ("Hurley Drug"), Tug

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<sup>1157</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>1158</sup> *Id.*

<sup>1159</sup> U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml).

<sup>1160</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>1161</sup> *Id.*

<sup>1162</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

Valley Pharmacy (“Tug Valley”) and Strosnider Pharmacy d/b/a Sav-Rite Pharmacy No. 1 (“Sav-Rite No. 1”).<sup>1163</sup>

According to the company, “[u]pon completing its analysis, H.D. Smith determined that Dr. Katherine Hoover and Dr. Diane Shafer were frequently writing prescriptions for hydrocodone, and that these doctors’ prescribing habits were cause for concern.”<sup>1164</sup>

H.D. Smith told the Committee that the company “reported its concerns and its analysis to the DEA on April 25, 2008. The DEA responded by requesting additional information. On May 12, 2008, H.D. Smith provided to the DEA the dispensing data analysis for Hurley Drug, Tug Valley, and Sav-Rite No. 1.”<sup>1165</sup> Documents produced to the Committee suggest that H.D. Smith’s analysis revealed that in a single month, February 2008, Dr. Hoover was responsible for 262,689 doses of hydrocodone that were filled at three West Virginia pharmacies – this extrapolates to more than 3.15 million doses of hydrocodone being attributed to a single doctor over the course of a year.<sup>1166</sup>

*i. H.D. Smith’s Distribution to Tug Valley Pharmacy*

With respect to its analysis of the dispensing data provided by Tug Valley Pharmacy in February 2008, H.D. Smith told the Committee:

H.D. Smith analyzed dispensing and prescribing data for Tug Valley. As a result of that analysis, H.D. Smith notified the DEA on April 25, 2008 that Tug Valley was ordering a significant amount of hydrocodone and that approximately 87% of the prescriptions for hydrocodone were collectively written by Dr. Katherine Hoover and Dr. Diane Shafer.<sup>1167</sup>

The Committee’s calculation of the dispensing data obtained from H.D. Smith revealed that Dr. Hoover alone prescribed more than 158,000 doses of hydrocodone dispensed by Tug Valley Pharmacy in February 2008.<sup>1168</sup> In the same month, the Committee’s calculation showed that Dr. Shafer prescribed more than 40,000 doses of hydrocodone dispensed by the

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<sup>1163</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee). Sav-Rite Pharmacy No. 1, discussed later in was located in Kermit, West Virginia, a 25-minute drive from Williamson.

<sup>1164</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee). More information regarding Dr. Hoover and Dr. Shafer can be found at *supra* Section VI (B)(2)(c)(i). More information regarding Dr. Shafer can be found at *supra* fn. 751.

<sup>1165</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1166</sup> See, E-Mail from Staff, U.S. Drug Enforcement Admin., to Dir., Corporate Security, H.D. Smith Wholesale Drug Co. (May 8, 2008 9:28 am) (On file with Committee).

<sup>1167</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1168</sup> H.D. Smith Wholesale Drug Co., February 2008 Dispensing Data – Tug Valley Pharmacy, Mar. 19, 2008 (On file with Committee).

pharmacy.<sup>1169</sup> To put these figures into context, according to the DEA, the average retail pharmacy in rural West Virginia received approximately 22,500 doses of hydrocodone a month in 2008.<sup>1170</sup> This means that H.D. Smith possessed data demonstrating that, in February 2008, Dr. Hoover was responsible for writing seven times the volume of hydrocodone prescriptions that an entire pharmacy in West Virginia received on average in a month, and that Dr. Shafer was additionally responsible for writing two times the volume of hydrocodone prescriptions that an entire pharmacy received on average in a month. Combined, H.D. Smith's data showed that these two doctors wrote nearly nine times the volume that an entire pharmacy in West Virginia would receive on average in a month.

**FINDING:** According to an analysis done by H.D. Smith, a single doctor was responsible for prescribing more than 158,000 doses of hydrocodone dispensed by Tug Valley Pharmacy in February 2008. During the same month, a second doctor was responsible for prescribing more than 40,000 doses of hydrocodone dispensed by the pharmacy. Combined, these two doctors prescribed, and Tug Valley Pharmacy dispensed, nine times the then-monthly volume for an average retail pharmacy in rural West Virginia.

Excerpts from Tug Valley's February 2008 dispensing report showing some of the pharmacy's aggregate hydrocodone dispensing figures attributable to prescriptions written by Drs. Hoover and Shafer are included below.<sup>1171</sup>

Date: 3/19/08		Doctor Usage: Top 99999 Doctors by Quantity Volume						Page: 1	
For Prescriptions Filled From 2/01/08 thru 2/29/08		Drug: HYDROCO/APAP* 7.5-750 500							
Doctor Name	Address	DEA	\$ Volume	Avg Prc	Tot Rx	Tot Pat	Tot Qty	Avg Qty	
HOOVER, KATHERINE	MD [REDACTED]	[REDACTED]	1,875.46	23.74	79	64	6,710	84	
SHAHER, D.E.	MD [REDACTED]	[REDACTED]	1,196.59	15.95	75	72	4,560	60	

Date: 3/19/08		Doctor Usage: Top 99999 Doctors by Quantity Volume						Page: 1	
For Prescriptions Filled From 2/01/08 thru 2/29/08		Drug: HYDROCO/APAP* 7.5-650 500							
Doctor Name	Address	DEA	\$ Volume	Avg Prc	Tot Rx	Tot Pat	Tot Qty	Avg Qty	
SHAHER, D.E.	MD [REDACTED]	[REDACTED]	5,450.01	16.22	336	328	20,428	60	
HOOVER, KATHERINE	MD [REDACTED]	[REDACTED]	3,622.68	21.95	165	139	14,165	85	

Date: 3/19/08		Doctor Usage: Top 99999 Doctors by Quantity Volume						Page: 1	
For Prescriptions Filled From 2/01/08 thru 2/29/08		Drug: HYDROCO/APAP* 10-650M 500							
Doctor Name	Address	DEA	\$ Volume	Avg Prc	Tot Rx	Tot Pat	Tot Qty	Avg Qty	
HOOVER, KATHERINE	MD [REDACTED]	[REDACTED]	26,560.49	28.40	935	780	88,742	94	
SHAHER, D.E.	MD [REDACTED]	[REDACTED]	422.88	16.26	26	23	1,530	58	

<sup>1169</sup> *Id.*

<sup>1170</sup> See U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee) (citing market reports).

<sup>1171</sup> H.D. Smith Wholesale Drug Co., February 2008 Dispensing Data – Tug Valley Pharmacy, Mar. 19, 2008 (On file with Committee).

ii. H.D. Smith's Distribution to Hurley Drug Company

In specific reference to its analysis of the data provided by Hurley Drug Company, H.D. Smith told the Committee:

H.D. Smith analyzed dispensing and prescribing data for Hurley Drug in February 2008. H.D. Smith notified the DEA on April 25, 2008 that several pharmacies, including Hurley Drug, were ordering a significant amount of hydrocodone. Approximately, 69% of the prescriptions for hydrocodone being filled at Hurley Drug were written by a single doctor, Dr. Katherine Hoover.<sup>1172</sup>

The Committee's calculation revealed that, in February 2008, Dr. Hoover was responsible for prescribing 93,000 doses of hydrocodone that were filled at Hurley Drug Company, amounting to nearly four times the average amount of hydrocodone an entire pharmacy in West Virginia would receive in a month at that time.<sup>1173</sup> As discussed above, Dr. Hoover also accounted for more than 158,000 doses of hydrocodone dispensed by Tug Valley Pharmacy, located four blocks away.

**FINDING: H.D. Smith reported its concerns regarding Tug Valley Pharmacy and Hurley Drug Company to the DEA in April 2008, including that two doctors wrote 87 percent of the hydrocodone prescriptions filled by Tug Valley Pharmacy, and that a single doctor wrote 69 percent of the hydrocodone prescriptions filled by Hurley Drug Company. But the company did not stop doing business with either pharmacy at that time.**

Hurley Drug Company's February 2008 dispensing report included numerous prescriptions attributable to Dr. Hoover.<sup>1174</sup> An excerpt from the dispensing report, showing some of the hydrocodone prescriptions filled on February 1, 2008, is reproduced below:

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<sup>1172</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1173</sup> H.D. Smith Wholesale Drug Co., February 2008 Dispensing Data – Hurley Drug Company, Mar. 19, 2008 (On file with Committee).

<sup>1174</sup> *Id.*



iii. H.D. Smith's Continued Shipments to Tug Valley Pharmacy and Hurley Drug Company

Despite these overwhelming numbers, as well as its e-mail to the DEA on April 25, 2008 to report concerns regarding these pharmacies and provide analysis regarding the dispensing data, H.D. Smith continued to supply both pharmacies with opioids. As discussed previously, in 2007, the DEA Deputy Administrator chided another distributor for failing to “immediately stop distributing hydrocodone” to a number of pharmacies the distributor had received information from which should have led the distributor to question the legitimacy of the pharmacies’ dispensing practices.<sup>1175</sup>

However, on November 19, 2008, an H.D. Smith representative conducted a site visit to Hurley Drug Company “based upon a continued pattern of suspended controlled substance orders, customer complaints regarding suspended orders and a request from the KY Division to visit this pharmacy[.]”<sup>1176</sup> The report noted that the pharmacy “has been with H.D. Smith since 1974 but experienced difficulty during the [Controlled Substance Order Monitoring Program] (CSOMP) rollout and has since been troubled with receiving orders.”<sup>1177</sup>

During the site visit, the H.D. Smith representative interviewed the pharmacy’s owner and made general observations about the pharmacy’s physical condition as well as its operations. In the summary of the interview, the report noted, “[b]oth [Hurley’s owner and his daughter] appear to have a working knowledge of their customers and doctors alike.”<sup>1178</sup> In addition it was highlighted, “they fill about 600 scripts a day, for about 300 people servicing about 30-35 doctors.”<sup>1179</sup>

The report did not mention the concerns H.D. Smith communicated to the DEA just months earlier in April 2008, nor does it mention the 87 orders placed by Hurley Drug Company that H.D. Smith reported to the DEA as suspicious between May 1, 2008 and November 19, 2008, the date of the site visit.<sup>1180</sup>

Ultimately, based on the site visit, the H.D. Smith representative recommended increasing Hurley Drug Company’s thresholds to levels that would prevent its orders from being

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<sup>1175</sup> See 72 Fed. Reg. 36,500, July 3, 2007.

<sup>1176</sup> H.D. Smith Wholesale Drug Co., Site Survey of Hurley Drug Company, Nov. 19, 2008 (On file with Committee).

<sup>1177</sup> *Id.* H.D. Smith told the Committee that it began developing its CSOMP in 2007, with the program being implemented in all of the company’s divisions through 2008. For the initial phase of the CSOMP implementation, the company developed an algorithm to establish thresholds for controlled substances sales that was based upon a pharmacy’s sales volume and the specific characteristics of various drug families. If a pharmacy’s order reached the established threshold for a given month, the order would be blocked absent an approval from H.D. Smith or an adjustment being made to the pharmacy’s threshold. See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

<sup>1178</sup> H.D. Smith Wholesale Drug Co., Site Survey of Hurley Drug Company, Nov. 19, 2008 (On file with Committee).

<sup>1179</sup> *Id.*

<sup>1180</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

blocked, noting, the pharmacy’s “due diligence and experience is obvious. Based upon the long-time relationship with H.D. Smith, the daily due diligence, and family values there doesn’t appear to be a high degree of risk to mitigate.”<sup>1181</sup>

The H.D. Smith representative’s conclusion and recommendation seem to be at odds with the company’s concerns regarding Hurley Drug Company’s dispensing practices, which the company reported to the DEA approximately six months prior. In a later final order issued by the DEA’s then-Acting Administrator, revoking the registration for another wholesale distributor, it was noted, among other things, “a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious order monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer’s dispensing practices.”<sup>1182</sup>

**FINDING: Approximately six months after the company reported concerns about Hurley Drug Company’s opioid dispensing to the DEA, an H.D. Smith representative recommended increasing the pharmacy’s thresholds for controlled substances purchases, noting that the pharmacy did not “appear to [have] a high degree of risk to mitigate.”**

In total, H.D. Smith supplied Tug Valley Pharmacy and Hurley Drug Company with more than 6.82 million doses of hydrocodone and oxycodone between 2007 and 2011.<sup>1183</sup> H.D. Smith terminated Tug Valley as a customer in August 2009. According to H.D. Smith, the company “conducted a site visit on July 15, 2009 and determined that Tug Valley was still filling prescriptions for Dr. Hoover and Dr. Shafer. Based on this site visit, H.D. Smith terminated Tug Valley’s account in August 2009.”<sup>1184</sup> In March 2011, H.D. Smith blocked Hurley Drug Company from purchasing hydrocodone and oxycodone.<sup>1185</sup> The Committee asked H.D. Smith what prompted the company to take this action.<sup>1186</sup> In response, H.D. Smith told the Committee that its decision to block Hurley Drug Company from purchasing hydrocodone and oxycodone was a “result of its ongoing due diligence and review of customer order activity[,]” adding that the company subsequently blocked Hurley from ordering any controlled substances in September

<sup>1181</sup> H.D. Smith Wholesale Drug Co., Site Survey of Hurley Drug Company, Nov. 19, 2008 (On file with Committee). The Committee could not determine from the documents provided by H.D. Smith whether the thresholds were, in fact, increased after the November 19, 2008, site visit.

<sup>1182</sup> 80 Fed. Reg. 55,478, Sept. 15, 2015.

<sup>1183</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee). H.D. Smith supplied Tug Valley Pharmacy with more than 2.23 million doses of hydrocodone and 78,000 doses of oxycodone between 2007 and 2009. H.D. Smith supplied Hurley Drug Company with more than 4.25 million doses of hydrocodone and more than 260,000 doses of oxycodone between 2007 and 2011.

<sup>1184</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee); *See also* H.D. Smith Wholesale Drug Co., Pharmacy Site Report – Tug Valley Pharmacy, July 15, 2009 (On file with Committee).

<sup>1185</sup> *See* Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

<sup>1186</sup> *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to H.D. Smith Wholesale Drug Co. (July 23, 2018 3:13 pm) (On file with Committee).

2011.<sup>1187</sup> H.D. Smith, however, did not provide the Committee with documentation underscoring the company's actions with respect to Hurley.

In their own right, the volume of opioids ordered by Hurley Drug Company and Tug Valley Pharmacy should have been a significant red flag for H.D. Smith, given the pharmacies were located four blocks apart from each other in a town with a population of 3,191, and in a region with significant controlled substance abuse issues. When adding the guidance provided by the DEA, and the additional due diligence conducted by H.D. Smith, including its own analysis on the percentage of prescriptions written by two doctors in particular, the company had ample information which would have allowed it to make the determination to discontinue its relationship with these pharmacies in a much timelier manner.

*d. Case Study on H.D. Smith: Responding to Red Flags Presented During a Pharmacy Site Visit*

Between December 2007 and April 2009, H.D. Smith provided Sav-Rite Pharmacy No. 1 in Kermit, West Virginia, population 406, with more than 1.48 million doses of hydrocodone and oxycodone.<sup>1188</sup> At various points during its engagement with Sav-Rite No. 1, H.D. Smith was presented with information that should have prompted the company to reexamine its relationship with the pharmacy months earlier than its decision to terminate the pharmacy as a customer in April 2009.

**FINDING: Between December 2007 and April 2009, H.D. Smith provided Sav-Rite No. 1 in Kermit, West Virginia, population 406, with more than 1.48 million doses of hydrocodone and oxycodone.**

As noted in the case study examining H.D. Smith's continued shipments to Hurley Drug Company and Tug Valley Pharmacy, the company obtained dispensing data from these pharmacies, as well as from Sav-Rite Pharmacy No. 1 in February 2008, that provided the company with concerns that it communicated to the DEA. A customer profile for Sav-Rite Pharmacy No. 1, and included in the due diligence materials H.D. Smith produced to the Committee, also included a handwritten notation "2000 census pop: 209" and "332,500 hydrocodone shipped Feb 2008."<sup>1189</sup> This notation is reproduced below:

<sup>1187</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>1188</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>1189</sup> H.D. Smith Wholesale Drug Co., Customer Profile – Strosnider Drug dba: Sav-Rite Pharmacy, Jan. 17, 2008 (On file with Committee).



2600 CEAKUS  
POP: 209

332,500  
HYDROCODONE  
SHIPPED  
FEB 2008

H. D. Smith has the statutory obligation to exercise due diligence and maintain effective controls against diversion into other than legitimate medical channels. Therefore, our customers must also maintain effective controls to prevent the dispensing of prescription drugs based on prescriptions that are written for other than legitimate medical purposes.

DEA Guidelines are as follows:

- Prescriptions can only be issued by a doctor acting in the usual course of professional practice.
- Prescriptions not issued in the usual course of professional practice are not valid.
- Drugs dispensed pursuant to invalid prescriptions are deemed not for legitimate medical purpose, therefore, ILLEGAL.
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances.

Company Name: Strosnider Drug  
DBA: Sav-Rite Pharmacy Website:

With respect to Sav-Rite No. 1, H.D. Smith told the Committee, “H.D. Smith reported Sav-Rite No. 1 to the DEA on April 25, 2008 because it was ordering a significant amount of hydrocodone and approximately 25% of the hydrocodone prescriptions were written by Dr. Katherine Hoover.”<sup>1190</sup> H.D. Smith continued to supply controlled substances to Sav-Rite No. 1 after this report to the DEA.

**FINDING: H.D. Smith reported Sav-Rite No. 1 to the DEA in April 2008 “because it was ordering a significant amount of hydrocodone and approximately 25% of the hydrocodone prescriptions were written by Dr. Katherine Hoover.” The company did not stop doing business with Sav-Rite No. 1 at that time.**

On November 19, 2008, approximately six months after reporting the pharmacy to the DEA, representatives from H.D. Smith conducted a site visit at Sav-Rite Pharmacy No. 1 in response to the pharmacy’s complaints that its orders were being blocked by H.D. Smith’s recently-implemented CSOMP.<sup>1191</sup> This site visit occurred on the same day as H.D. Smith’s site visit to Hurley Drug Company discussed above.

According to the report, during the visit, the H.D. Smith representatives conducted an interview with the pharmacy’s technician, who was responsible for all of the pharmacy’s ordering, as well as the pharmacy’s owner. During the interview, the H.D. Smith representatives inquired about the number of prescriptions handled by the pharmacy, with the report noting, “[w]hen queried about the number of scripts, [the pharmacy’s technician] claimed to have 600-1000 scripts a day then stated that 90 – 95% were for controlled substances.”<sup>1192</sup> The report indicates the H.D. Smith representatives followed up on the estimate provided by the pharmacy’s

<sup>1190</sup> Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

<sup>1191</sup> See H.D. Smith Wholesale Drug Co., Site Survey of Strosnider (Sav-Rite) Pharmacy, Nov. 19, 2008 (On file with Committee).

<sup>1192</sup> H.D. Smith Wholesale Drug Co., Site Survey of Strosnider (Sav-Rite) Pharmacy, Nov. 19, 2008 (internal quotation marks omitted) (On file with Committee).

technician, stating, “[w]hen [H.D. Smith representative] questioned her about the dosage units for the number of scripts she was claiming, about 54,000 a day, she without hesitation said, that’s right.”<sup>1193</sup>

The DEA advised H.D. Smith on multiple occasions, including during an in-person meeting at DEA headquarters in 2006, that factors such as a pharmacy having a high percentage of controlled substances purchases and ordering excessive amounts of particular controlled substances were indicators of possible diversion.<sup>1194</sup> In a 2007 final order revoking the registration of another distributor, the DEA Deputy Administrator also quoted guidance that had been provided by DEA in which it was stated, “in a typical retail pharmacy, controlled substances might amount to between five and twenty percent of the pharmacy’s purchases with the other eighty to ninety percent of its purchases being non-controlled drugs.”<sup>1195</sup>

In addition to the significant overall volume and controlled substance dispensing estimates provided by the pharmacy’s technician, the report of the interview also documented disclosures made by the pharmacy’s owner during the site visit which should have been a cause for concern for the company.<sup>1196</sup> Specifically, the report noted:

[The pharmacy’s owner] wasn’t sure how many scripts were serviced a day, nor did he know what percentage of those scripts were controlled substances. Yet, he admitted that he did not know all the customers (contrary to what [the pharmacy’s technician] had stated) and inferred that some of the doctors he serviced had disciplinary issues and diversion was likely (again contrary to [the pharmacy’s technician]). He also mentioned that he was named in a wrongful death lawsuit.<sup>1197</sup>

**FINDING: H.D. Smith conducted a site visit at Sav-Rite No. 1 in November 2008 that presented numerous red flags, including the pharmacy’s owner telling H.D. Smith he inferred diversion from the pharmacy was likely. H.D. Smith did not terminate Sav-Rite No. 1 as a customer or restrict its ability to purchase controlled substances at that time.**

The documents produced to the Committee give no indication that H.D. Smith conducted any additional due diligence related to the pharmacy owner’s inference that diversion was likely

<sup>1193</sup> H.D. Smith Wholesale Drug Co., Site Survey of Strosnider (Sav-Rite) Pharmacy, Nov. 19, 2008 (On file with Committee).

<sup>1194</sup> See Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin., to Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee). See also, 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 Committee); 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 Committee).

<sup>1195</sup> 72 Fed. Reg. 36,492, July 3, 2007 (internal quotation marks omitted).

<sup>1196</sup> H.D. Smith Wholesale Drug Co., Site Survey of Strosnider (Sav-Rite) Pharmacy, Nov. 19, 2008 (On file with Committee).

<sup>1197</sup> *Id.*

or the wrongful death lawsuit that named the owner. The November 2008 site visit report also made no mention of the concerns H.D. Smith communicated to the DEA about Sav-Rite No. 1 approximately six months earlier, in April 2008, nor of the 106 orders placed by Sav-Rite No. 1 that H.D. Smith reported to the DEA as suspicious between May 1, 2008 and November 19, 2008, the date of the site visit.<sup>1198</sup> In this time period, H.D. Smith reported, on average, one suspicious order to the DEA every two days for Sav-Rite No. 1.

Despite the red flags disclosed during the site visit, which were in addition to the company's prior concerns regarding the volume of Sav-Rite No. 1's hydrocodone ordering, including the number of prescriptions it was filling for Dr. Hoover, H.D. Smith did not terminate Sav-Rite No. 1 as a customer, or restrict its ability to purchase controlled substances after the site visit, electing to keep the pharmacy at its established thresholds.<sup>1199</sup>

H.D. Smith justified this decision based on the fact that the pharmacy's orders were potentially necessary to meet the legitimate need of the area, telling the Committee:

H.D. Smith conducted a site visit to Sav-Rite No. 1 on November 19, 2008. H.D. Smith noted that there were two pharmacies in the area servicing four hospice centers, two medical clinics as well as four hospitals in the neighboring area, suggesting that there may be a legitimate need for increased controlled substances. Nonetheless, H.D. Smith determined that no adjustments would be made to Sav-Rite No. 1's URL without a supplemental review of Sav-Rite No. 1's dispensing data.<sup>1200</sup>

As discussed above, however, H.D. Smith alone was supplying far more opioids to this region of West Virginia than what would appear to be reasonably necessary to meet the "legitimate need" of the area. In November 2008, when it conducted its site review of Sav-Rite No. 1, H.D. Smith was also supplying large amounts of hydrocodone and oxycodone to Hurley Drug Company and Tug Valley Pharmacy, both located a 25-minute drive from Sav-Rite No. 1. In total, H.D. Smith supplied these three pharmacies with more than 3.85 million doses of hydrocodone and oxycodone in 2008 alone.<sup>1201</sup> Additionally, the documents produced to the Committee give no indication that H.D. Smith made any attempt to ascertain what the area's legitimate need for controlled substances was at the time it conducted its site visit to Sav-Rite No. 1, or took the presence of other area pharmacies into account, whether H.D. Smith customers or not.

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<sup>1198</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

<sup>1199</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

<sup>1200</sup> *Id.*

<sup>1201</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee). In 2008, and discussed below, H.D. Smith also supplied Family Discount Pharmacy in nearby Mount Gay-Shamrock with more than 1.13 million doses of hydrocodone and oxycodone.

H.D. Smith ultimately terminated Sav-Rite No. 1 as a customer on April 1, 2009, a decision that was precipitated by a federal investigation into, and forced closure of, Sav-Rite No. 2, another H.D. Smith customer, in March 2009.<sup>1202</sup>

e. *Case Study on H.D. Smith: Assessing Disclosures Made by a Pharmacy and Previous Due Diligence*

H.D. Smith began supplying controlled substances to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779, on December 18, 2007.<sup>1203</sup> In the customer profile questionnaire that Family Discount pharmacy submitted on the same day that H.D. Smith opened its account, the pharmacy estimated that 50 percent of its controlled substance purchases would be from H.D. Smith.<sup>1204</sup>

In 2008, the first full year of its relationship with Family Discount Pharmacy, H.D. Smith supplied the pharmacy with more than 1.13 million doses of hydrocodone and oxycodone.<sup>1205</sup> The equated to roughly half of the 2.01 million doses of hydrocodone and oxycodone the pharmacy received in total that year.<sup>1206</sup> A pharmacy in town of 1,779 people receiving more than 1.13 million opioids should have been a red flag for H.D. Smith on its own, but when taking into account the pharmacy's December 2007 estimate that only 50 percent of its controlled substance purchases would be from H.D. Smith, the volume of opioids the company supplied in 2008 should have been especially concerning.

**FINDING: In 2008, the first full year of its relationship with Family Discount Pharmacy in Mount-Gay Shamrock, H.D. Smith supplied the pharmacy with more than 1.13 million doses of hydrocodone and oxycodone. The pharmacy estimated it would purchase 50 percent of its controlled substances purchases from H.D. Smith, meaning the company would have had reason to believe the pharmacy was receiving far more opioids than those H.D. Smith supplied.**

The volume of opioids H.D. Smith provided to Family Discount Pharmacy in 2008 is in addition to the more than 3.85 million doses of hydrocodone and oxycodone the company provided that year to Hurley Drug Company, Tug Valley Pharmacy, and Sav-Rite No. 1, all located within 34 miles of Family Discount Pharmacy. As discussed earlier in this section, H.D. Smith told the Committee that it reported concerns to the DEA on April 25, 2008 regarding the volume of these pharmacies' hydrocodone orders and the fact that a significant percentage of the

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<sup>1202</sup> E-Mail from Vice President Division Manager, H.D. Smith, to Vice President, Operations, H.D. Smith (Apr. 1, 2009 1:56 pm) (On file with Committee). *See also* Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

<sup>1203</sup> *See* Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee).

<sup>1204</sup> H.D. Smith Wholesale Drug Co., Customer Profile – Family Discount Pharmacy, Dec. 18, 2007 (On file with Committee).

<sup>1205</sup> U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

<sup>1206</sup> *Id.*

hydrocodone prescriptions being filled by the pharmacies were attributable to two doctors, Dr. Katherine Hoover and Dr. Diane Shafer.<sup>1207</sup>

In November of the following year, 2009, the company noted in Family Discount's account file that the pharmacy was continuing to have its hydrocodone orders suspended because it was reaching its ordering threshold, and that Dr. Hoover was responsible for writing 51 percent of the hydrocodone prescriptions that were filled.<sup>1208</sup>

Between May 1, 2008, and May 3, 2009, H.D. Smith reported 110 suspicious orders placed by Family Discount Pharmacy to the DEA.<sup>1209</sup> Yet H.D. Smith provided no documentation to the Committee that indicates whether any subsequent suspicious orders placed by Family Discount Pharmacy were reported to the DEA, including any orders placed after H.D. Smith determined that Dr. Hoover was writing 51 percent of the hydrocodone prescriptions filled by the pharmacy. H.D. Smith told the Committee:

As reflected in the records produced by the Company, H.D. Smith's practice after 2009 was to inform the DEA via email whenever it identified suspicious activity or blocked a customer's ability to purchase controlled substances. These changes were made pursuant to its discussions with the DEA. In late 2009, [DEA Staff Investigator] had a discussion with [H.D. Smith's Director of Corporate Security] and explained that an order is not "suspicious" and does not need to be reported to the DEA simply because it triggers H.D. Smith's Controlled Substance Order Monitoring Program ("CSOMP") system.<sup>1210</sup> Thus, from that point forward while H.D. Smith

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<sup>1207</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee). More information regarding Dr. Hoover can be found at *supra* Section VI (B)(2)(c)(i). More information regarding Dr. Shafer can be found at *supra* fn. 751.

<sup>1208</sup> H.D. Smith Wholesale Drug Co., Due Diligence Notes – Family Discount Pharmacy (Mount Gay-Shamrock) (On file with Committee).

<sup>1209</sup> H.D. Smith Wholesale Drug Co., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee)

<sup>1210</sup> Following the D.C. Circuit's June 2017 decision to uphold the Acting Administrator's order revoking the registration of Masters Pharmaceutical, a former Associate Chief Counsel at DEA wrote, "DEA field division offices across the country have historically differed on how they interpret their own regulations. Some offices demand that registrants provide notice of all orders that are flagged by the registrant's suspicious order monitoring program, while others only want orders reported that are deemed to be suspicious after the registrant has conducted an investigation of the order. The Court's decision clearly supports the former reporting system." Larry P. Cote, *DEA Prevails over Masters Pharmaceutical, Inc.*, DEA Chronicles, July 2, 2017, <https://deachronicles.quarles.com/2017/07/dea-prevails-over-masters-pharmaceutical-inc/>. In the D.C. Circuit case, the court reviewed Masters' suspicious order monitoring system and the company's compliance policy manual which stated the suspicious order monitoring system, "[h]olds all orders for controlled drugs that meet or exceed the [suspicious order] criteria set out in 21 C.F.R. § 1301.74(b)[.]" *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335, 11 (D.C. Cir. 2017) (quoting Masters' compliance policy manual). The Court stated, "[i]n other words, the Computer Program was designed to hold orders that are suspicious within the meaning of the regulation, even as it gave Masters' employees the opportunity – through the due-diligence investigation contemplated by the Compliance Protocol – to dispel the suspicion surrounding the held orders." *Id.* at 12. The court later stated with respect to the reporting requirement of 21 C.F.R. § 1301.74(b), "[i]t was therefore entirely reasonable for the Administrator to hold that orders held by the Computer Program met the regulatory definition of "suspicious orders" unless Masters' staff dispelled that suspicion." *Id.*

did stop automatically submitting as suspicious every order that triggered H.D. Smith's CSOMP, it continued to report activity it identified as suspicious to the DEA in accord with the information it received from DEA.<sup>1211</sup>

Despite H.D. Smith's statement that it changed its approach to suspicious order reporting to focus on suspicious activity instead of automatically reporting orders that were blocked by its CSOMP system, the company did not report its November 2009 finding that Dr. Hoover was writing 51 percent of the hydrocodone prescriptions that were being filled at Family Discount Pharmacy. This failure to report is more notable considering that H.D. Smith previously expressed concerns about Dr. Hoover to the DEA in April 2008. In addition, at the time, H.D. Smith, along with every other DEA-registered distributor, had received three letters from the DEA, reiterating distributors' obligations under the CSA. In one such letter, sent in December 2007, the DEA emphasized to distributors required to report suspicious orders when they were discovered.<sup>1212</sup> In addition, the DEA warned distributors that they may be failing meet their statutory obligation to maintain effective controls against diversion if they fill suspicious orders without first determining that the orders are not being diverted into other than legitimate channels.<sup>1213</sup>

**FINDING: In November 2009, H.D. Smith documented that Family Discount Pharmacy was continuing to reach its hydrocodone threshold and that 51 percent of the hydrocodone prescriptions filled at the pharmacy were written Dr. Katherine Hoover.**

As discussed earlier, H.D. Smith told the Committee that it terminated Tug Valley Pharmacy as a customer in August 2009 because the pharmacy continued to fill prescriptions written by Dr. Hoover as well as Dr. Shafer.<sup>1214</sup> Just a few months later, in November 2009, H.D. Smith did not terminate Family Discount Pharmacy after identifying that Dr. Hoover was responsible for more than half of the hydrocodone prescriptions filled by the pharmacy. The documents produced to the Committee give no indication that H.D. Smith examined, or considered its earlier findings and actions related to Dr. Hoover and other nearby pharmacies when it discovered that she was writing more than half the hydrocodone prescriptions filled by Family Discount Pharmacy.

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<sup>1211</sup> E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee).

<sup>1212</sup> See 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 Committee).

<sup>1213</sup> *Id.*

<sup>1214</sup> More information regarding Dr. Hoover can be found at *supra* Section VI (B)(2)(c)(i). More information regarding Dr. Shafer can be found at *supra* fn. 751.



**FINDING: Upon discovering that Dr. Hoover was responsible for 51 percent of the hydrocodone prescriptions filled at Family Discount Pharmacy, documents produced to the Committee give no indication that H.D. Smith examined, or considered its earlier findings and actions related to Dr. Hoover and other nearby pharmacies.**

In February 2011, H.D. Smith blocked Family Discount Pharmacy from ordering hydrocodone after it identified that nearly 80 percent of the pharmacy's orders were for controlled substances.<sup>1215</sup> After the company took this action, H.D. Smith told the Committee that Family Discount terminated its relationship with H.D. Smith.<sup>1216</sup>

*f. Case Study on Miami-Luken: Continuing to Supply a Pharmacy After Documented Deceit*

Between 2009 and 2015, Miami-Luken shipped more than 4.38 million doses of hydrocodone and oxycodone to Westside Pharmacy.<sup>1217</sup> Westside Pharmacy is located in Oceana, West Virginia, which had a population of 1,394 in 2010.<sup>1218</sup> The company terminated its relationship with the pharmacy in December 2015, after receiving an Order to Show Cause from the DEA in which the company's distribution of controlled substances to Westside Pharmacy was cited among the reasons why its DEA registration should be revoked.<sup>1219</sup> Prior to this action, however, Miami-Luken was presented with information on several different occasions, and no later than 2011, which should have prompted the company to reexamine its relationship with the pharmacy, independent of any enforcement action taken by the DEA.

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<sup>1215</sup> See E-Mail from Dir., Corporate Compliance and Security, H.D. Smith, to Vice President, H.D. Smith (Feb. 1, 2011 12:48 pm) (On file with Committee).

<sup>1216</sup> See Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al. Feb. 26, 2018 (On file with Committee). H.D. Smith resumed its business relationship with Family Discount Mount-Gay Shamrock in 2015. That year, the company also agreed to begin supplying Family Discount Pharmacy's Stollings location with controlled substances as well. H.D. Smith blocked both Family Discount Pharmacy locations from ordering controlled substances on February 16, 2018, noting "Reference Negative News Article" in the due diligence file. See H.D. Smith Wholesale Drug Co., Due Diligence Notes – Family Discount Pharmacy, Aug. 2015 – Feb. 2018 (On file with Committee). See also E-Mail from Counsel to H.D. Smith Wholesale Drug Co., to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018 7:35 pm) (On file with Committee). H.D. Smith's 2015 prospective customer due diligence efforts for Family Discount Pharmacy's Mount Gay-Shamrock location are discussed in greater detail in Section VI. (A)(2)(e)(ii) of this report.

<sup>1217</sup> Miami-Luken, Inc., Sales Data – Westside Pharmacy (On file with Committee).

<sup>1218</sup> American FactFinder, *Oceana (town), West Virginia* (<https://factfinder.census.gov>).

<sup>1219</sup> See U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee). As discussed in greater detail in Section V.(B)(2), it has been alleged that the DEA's issuance of the November 23, 2015 Order to Show Cause had been delayed by the DEA attorneys for approximately two years; see also Lenny Bernstein, David Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job.'* WASH. POST, Oct. 22, 2016, available at [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\\_story.html?utm\\_term=.abe834ac4993](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.abe834ac4993).

**FINDING: Between 2009 and 2015, Miami-Luken shipped more than 4.38 million doses of hydrocodone and oxycodone to Westside Pharmacy, located in Oceana West Virginia, population 1,394.**

On May 27, 2011, Miami-Luken obtained a dispensing report from Westside Pharmacy, providing the company with the physician-level oxycodone prescriptions filled by the pharmacy over the preceding three months.<sup>1220</sup> Miami-Luken requested the dispensing report from the pharmacy after the company's CEO sent a memo to a Miami-Luken senior account manager in which the CEO noted, "I have been monitoring this accounts [sic] purchases of Oxycodone HCL 15mg and 30 mg as well as some other controlled products. I understand their business has increased significantly since the other drug store in town [sic] pharmacist quit and when [sic] to work for Westside."<sup>1221</sup>

The dispensing information obtained by the company showed that Drs. David Morgan, Michael Kostenko, Victor Georgescu, and Alen Salerian were among the pharmacy's prescribing oxycodone physicians.<sup>1222</sup> As discussed previously, Dr. Morgan was located in Pembroke, Virginia while Dr. Salerian was located in Washington, D.C. –an approximate four-hour, and eleven-and-a-half-hour round-trip drives from the pharmacy, respectively.<sup>1223</sup> Meanwhile Dr. Georgescu was located in Wheelersburg, Ohio, an approximate six-hour round-trip drive from the pharmacy,<sup>1224</sup> and Dr. Kostenko was located in Daniels, West Virginia, an approximate two-hour round-trip drive from the pharmacy.<sup>1225</sup> The dispensing report also showed a significant number of cash payments for opioids prescribed by these doctors. The DEA has identified cash payments for prescriptions and prescriptions written by physicians located significant distances from the pharmacy as being red flags of diversion.<sup>1226</sup>

An excerpt from the dispensing report Miami-Luken received from Westside Pharmacy on May 27, 2011 is reproduced below:<sup>1227</sup>

<sup>1220</sup> Facsimile from Westside Pharmacy to Miami-Luken, Inc., May 27, 2011 (On file with Committee)

<sup>1221</sup> Memorandum from Chief Exec. Officer, Miami-Luken, Inc., to Senior Account Manager, Miami-Luken, Inc. (May 12, 2011) (On file with Committee).

<sup>1222</sup> Miami-Luken, Inc., Westside Pharmacy Dispensing Data – Mar. 1, 2011 to May 27, 2011– Westside Pharmacy (On file with Committee).

<sup>1223</sup> More information regarding Dr. Salerian can be found *supra* at fn. 570.

<sup>1224</sup> Dr. Georgescu was the principal doctor at the Greater Medical Advance clinic in Wheelersburg, Ohio. In 2011, Dr. Georgescu, along with the clinic's owner, were arrested after being indicted by a Scioto County grand jury on four felony counts, including funding drug trafficking, permitting drug abuse, and conspiracy to engage in a pattern of corrupt activity. *See* Alan Johnson, *Scioto County's last 'pill mill' shut down*, COLUMBUS DISPATCH, Dec. 20, 2011, <http://www.dispatch.com/article/20111220/NEWS/312209701>. In 2012, the owner of Greater Medical Advance was sentenced to 10 years in prison in Ohio after pleading guilty to the charges stemming from his operation of the clinic. Dr. Georgescu committed suicide before standing trial. *See* Press Release, Ohio Att'y Gen., Pill Mill Owner Sentenced to 10 Years in Prison (Oct. 12, 2012) <https://www.ohioattorneygeneral.gov/Media/News-Releases/October-2012/Pill-Mill-Owner-Sentenced-to-10-Years-in-Prison>.

<sup>1225</sup> More information regarding Dr. Kotensko can be found *supra* Section VI (A)(2)(d)(ii)(B).

<sup>1226</sup> *See* 77 Fed. Reg. 62,316, Oct. 12, 2012.

<sup>1227</sup> Miami-Luken, Inc., Westside Pharmacy Dispensing Data – Mar. 1, 2011 to May 27, 2011– Westside Pharmacy (On file with Committee).



FROM: 03/01/2011 THROUGH: 05/27/2011

RX#	DATE	PATIENT	ITEM	QTYD	PRESCRIBER	DISP COST	TOT ADJ AMT	PAT PAY	PRIM CVG	PRIM SEC AMT CVG	SEC AMT	Cl AMT RPH	TECH
N 352786	03/10/2011		OXYCODONE 30MG TAB	48.00	MORGAN, DAVID MD				CASH				
N 352790	03/10/2011		OXYCODONE 30MG TAB	44.00	MORGAN, DAVID MD				CASH				
N 352791	03/10/2011		OXYCODONE 30MG TAB	180.00	MORGAN, DAVID MD				CASH				
N 352821	03/10/2011		OXYCODONE 30 MG TABLETS	224.00	MORGAN, DAVID MD				CASH				
N 352822	03/10/2011		OXYCODONE 30 MG TABLETS	224.00	MORGAN, DAVID MD				CASH				
N 352860	03/10/2011		OXYCODONE 30MG TAB	120.00	MORGAN, DAVID MD				WVW				
R 352898	03/10/2011		OXYCODONE 30MG TAB	48.00	MORGAN, DAVID MD				CASH				
N 352874	03/10/2011		OXYCODONE 30 MG TABLETS	112.00	MORGAN, DAVID MD				ADV				
N 352963	03/11/2011		OXYCODONE 30 MG TABLETS	120.00	DERAKHSHAN, I MD				WVW				
R 352963	03/11/2011		OXYCODONE 30 MG TABLETS	80.00	DERAKHSHAN, I MD				CASH				
N 353395	03/12/2011		OXYCODONE 30MG TAB	168.00	MORGAN, DAVID MD				HUMI				
N 353955	03/14/2011		OXYCODONE 30MG TAB	300.00	SALERIAN, ALEN MD				AMH				
N 353953	03/14/2011		OXYCODONE 30MG TAB	120.00	KOSTENKO, MICHAEL				HUMI				
N 353610	03/14/2011		OXYCODONE 30 MG TABLETS	60.00	GEORGESCU, VICTOR				CASH				
N 353630	03/14/2011		OXYCODONE 30 MG TABLETS	120.00	GEORGESCU, VICTOR				CASH				
N 353639	03/14/2011		OXYCODONE 30 MG TABLETS	120.00	GEORGESCU, VICTOR				CASH				
N 350191	03/15/2011		OXYCODONE 30MG TAB	120.00					WVW				
R 350191	03/15/2011		OXYCODONE 30MG TAB	60.00					CASH				
N 353906	03/15/2011		OXYCODONE 30 MG TABLETS	21.00	KOSTENKO, MICHAEL				CASH				
N 354032	03/15/2011		OXYCODONE 30 MG TABLETS	84.00	KOSTENKO, MICHAEL				CASH				
N 354067	03/15/2011		OXYCODONE 30 MG TABLETS	400.00	SALERIAN, ALEN MD				MEDCO				
N 354167	03/15/2011		OXYCODONE 30 MG TABLETS	224.00	MORGAN, DAVID MD				MEDCO				
N 354123	03/15/2011		OXYCODONE 30 MG TABLETS	120.00	MORGAN, DAVID MD				MEDCO				
R 354123	03/15/2011		OXYCODONE 30 MG TABLETS	120.00	MORGAN, DAVID MD				CASH				
N 354134	03/15/2011		OXYCODONE 30MG TAB	120.00	MORGAN, DAVID MD				CASH				
N 354137	03/15/2011		OXYCODONE 30 MG TABLETS	120.00	MORGAN, DAVID MD				WVW				
N 354138	03/15/2011		OXYCODONE 30 MG TABLETS	120.00	MORGAN, DAVID MD				CASH				
N 354205	03/15/2011		OXYCODONE 30 MG TABLETS	224.00	MORGAN, DAVID MD				SIL				
N 354383	03/16/2011		OXYCODONE 30 MG TABLETS	20.00	MORGAN, DAVID MD				CASH				
R 354383	03/16/2011		OXYCODONE 30 MG TABLETS	120.00	MORGAN, DAVID MD				WVW				
N 354385	03/16/2011		OXYCODONE 30 MG TABLETS	224.00	MORGAN, DAVID MD				PCS				
N 354394	03/16/2011		OXYCODONE 30 MG TABLETS	112.00	MORGAN, DAVID MD				PUS				
N 354420	03/16/2011		OXYCODONE 30 MG TABLETS	180.00	GEORGESCU, VICTOR				CASH				
N 354430	03/16/2011		OXYCODONE 30 MG TABLETS	80.00	GEORGESCU, VICTOR				CASH				
R 354430	03/16/2011		OXYCODONE 30 MG TABLETS	120.00	GEORGESCU, VICTOR				WVW				
N 354794	03/17/2011		OXYCODONE 30MG TAB	80.00	MORGAN, DAVID MD				CASH				

Despite receiving notice of these red flags, Miami-Luken continued supplying Westside Pharmacy with controlled substances while simultaneously failing to report any of the pharmacy's orders to the DEA as being suspicious. The Committee asked Miami-Luken for documents that would show the company's analysis of the May 27, 2011 dispensing information, and whether the company expressed any concerns to the pharmacy regarding its prescribing practices or physicians.<sup>1228</sup> In response, the company told the Committee, "[w]ith regard to Westside's dispensing report for March 1, 2011 to May 27, 2011, [Miami-Luken's Chairman of the Board] Dr. Mastandrea is unable to provide any information in addition to what has already been provided to the Committee."<sup>1229</sup> The documents produced to the Committee give no indication that Miami-Luken analyzed the dispensing information it received on May 27, 2011, or expressed any concerns to the pharmacy regarding its prescribing practices or physicians.

Miami-Luken continued to supply Westside Pharmacy for the next four years. In this time, the pharmacy received more than 3.36 million opioids from the company.<sup>1230</sup>

<sup>1228</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Miami-Luken, Inc. (Aug. 2, 2018 4:48 pm) (On file with Committee).

<sup>1229</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>1230</sup> Miami-Luken, Inc., Sales Data – Westside Pharmacy (On file with Committee).

**FINDING:** As early as 2011, Miami-Luken was aware that Westside Pharmacy was filling prescriptions for doctors located hours away, and that a large number of prescriptions for hydrocodone and oxycodone were paid for with cash. Despite this knowledge, the company continued to supply the pharmacy with more than 3.36 million opioids over the next four years..

On May 27, 2015, Miami-Luken analyzed Westside Pharmacy’s dispensing information once again. The dispensing data showed that Drs. Morgan, Kostenko, and Mehta accounted for 74 percent of the oxycodone prescriptions filled by the pharmacy between February 2015 and April 2015.<sup>1231</sup> Dr. Morgan alone accounted for 42 percent of the oxycodone prescriptions filled during that time period.<sup>1232</sup> Miami-Luken’s analysis of Westside Pharmacy’s February 2015 through April 2015 dispensing data is reproduced in relevant part below:

Top 5 Oxycodone Prescribers	Specialty & Title	# of Pills	Rx Count	% of Total Oxy Vol	% of Total CII
Morgan, David		48076	353	42%	21%
Kostenko, Michael		13229	256	11%	6%
Mehta, Sanjay		24057	215	21%	10%
		11584	104	10%	5%
Derakhshan, Iraj		5100	47	4%	2%

As discussed previously, prior to Miami-Luken’s analysis of Westside Pharmacy’s dispensing data, public reports stated that federal and state law enforcement officials raided Dr. Mehta’s office in March 2015,<sup>1233</sup> and that the West Virginia Department of Health and Human Resources subsequently ordered him to close his practice.<sup>1234</sup> Miami-Luken’s due diligence file for Westside Pharmacy did not include any press reports related to the raid and ordered closure of Dr. Mehta’s practice. The company’s due diligence file for the pharmacy, however, did include a copy of the consent order the Virginia Board of Medicine issued against Dr. Morgan in 2014 after finding, among other things, multiple instances in which Dr. Morgan prescribed medications, including oxycodone, without having seen the patient.<sup>1235</sup>

<sup>1231</sup> Miami-Luken, Inc., Dispensing Analysis Trend Assessment “DATA” Tool – Westside Pharmacy, May 27, 2015 (On file with Committee). By May 2015, Drs. Georgescu and Salerian, previously included among the pharmacy’s top prescribing physicians, had already been indicted on charges related to fraudulent controlled substance prescribing. See *supra* fn. 1224; see also fn. 570.

<sup>1232</sup> Miami-Luken, Inc., Dispensing Analysis Trend Assessment “DATA” Tool – Westside Pharmacy, May 27, 2015 (On file with Committee).

<sup>1233</sup> See Daniel Tyson, *Update: Hope Clinic raided by various agencies*, REGISTER-HERALD, Mar. 19, 2015, [http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article\\_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.htm](http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.htm).

<sup>1234</sup> See Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, [http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article\\_bf69155e-bec2-5ce6-9a19-53a26ce88670.html](http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html). More information on Dr. Mehta can be found at *supra* Section VI(A)(2)(d)(ii)(A).

<sup>1235</sup> See *In re: David Lee Morgan, D.O.*, Order, 6 -7 (Va. Bd. of Med., Mar. 24, 2014) available at <http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order03242014.pdf>. Dr. Morgan’s disciplinary history, including the 2014 consent order, is discussed in greater detail in Section VI(A)(2)(d)(ii)(C).

Another doctor listed among the physicians who had oxycodone prescriptions filled at Westside was Dr. Iraj Derakhshan, who, according to a 2013 *Charleston Gazette* article, was West Virginia's top hydrocodone prescriber at one time.<sup>1236</sup> This article was included among the due diligence documents for Westside Pharmacy that Miami-Luken produced to the Committee. In its May 27, 2015, analysis of Westside Pharmacy's dispensing information, Dr. Derakhshan was listed among the pharmacy's top 10 controlled substances prescribers, and the company noted his location "[i]n Charleston 1.50 hrs away."<sup>1237</sup> Miami-Luken's due diligence file for Westside Pharmacy also included two other articles which reported that three states and the District of Columbia took disciplinary actions against Dr. Derakhshan related to conduct alleging that he counseled patients to cut time-released oxycodone in half, which nullifies the drug's time-release formulation and makes it easier to abuse.<sup>1238</sup> In addition, Miami-Luken was also in possession of a 2014 consent order from the West Virginia Board of Medicine in which Dr. Derakhshan was reprimanded and fined for obtaining a former patient's medical records without receiving prior authorization and then altering a release in order to remove limitations on the use of the records.<sup>1239</sup>

With respect to Drs. Morgan and Mehta, Miami-Luken told the Committee that it expressed its concerns about these doctors to Westside Pharmacy, saying:

The Company determined in May 2015 that Dr. Morgan and Dr. Mehta were two of the top five prescribers of Oxycodone at the pharmacy, and it later learned that these physicians [sic] prescribing practices had been called into question by the State Medical Board and/or news media. [Miami-Luken's Director of Compliance and Security] spoke with the pharmacy's owner about these issues in June 2015. At that time, the owner assured him that she would no longer fill prescriptions for Dr. Morgan and Dr. Mehta effective June 30, 2015.<sup>1240</sup>

Documents produced to the Committee indicate that Miami-Luken expressed its concerns about Drs. Morgan and Mehta to Westside Pharmacy, and that the pharmacy agreed to stop

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<sup>1236</sup> See Lori Kersey, *Charleston doctor is W.Va.'s top prescriber of hydrocodone*, CHARLESTON GAZETTE, May 20, 2013, [https://www.wvgazette.com/news/charleston-doctor-is-w-va-s-top-prescriber-of-hydrocodone/article\\_07dd75da-750e-5489-895d-d17acc78b6d9.html](https://www.wvgazette.com/news/charleston-doctor-is-w-va-s-top-prescriber-of-hydrocodone/article_07dd75da-750e-5489-895d-d17acc78b6d9.html).

<sup>1237</sup> Miami-Luken, Inc., Dispensing Analysis Trend Assessment "DATA" Tool – Westside Pharmacy, May 27, 2015 (On file with Committee).

<sup>1238</sup> See Zack Harold, *Charleston neurologist has history of pill scrutiny*, CHARLESTON DAILY MAIL, May 21, 2013 (On file with Committee); see also William Heisel, *Contraindications: Dr. Iraj Derakhshan*, Ctr. for Health Journalism – Univ. of S. Cal., May 28, 2009, <https://www.centerforhealthjournalism.org/blogs/contraindications-dr-iraj-derakhshan>.

<sup>1239</sup> See *In re: Iraj Derakhshan, M.D.* Consent Order (W.Va. Board of Medicine, Sept. 16, 2014). In April 2016, Dr. Derakhshan pleaded guilty to federal charges he illegally dispensed fentanyl to a patient without a prescription and without having the authorization to dispense controlled substances. Dr. Derakhshan also admitted to knowingly and intentionally failing to report and record dispensing controlled substances. See Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., *Charleston doctor pleads guilty to Federal crime involving dispensing fentanyl* (Apr. 21, 2016), <https://www.justice.gov/usao-sd-wv/pr/charleston-doctor-pleads-guilty-federal-crime-involving-dispensing-fentanyl>.

<sup>1240</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

filling prescriptions for these two doctors as well as Dr. Derakhshan. Westside Pharmacy e-mailed Miami-Luken a photograph of a sign posted inside the store that informed customers the pharmacy would no longer fill prescriptions written by Drs. Morgan, Mehta, and Derakhshan as of June 30th.<sup>1241</sup>

**FINDING: Miami-Luken’s May 2015 analysis of Westside Pharmacy’s dispensing data showed that three doctors wrote 74 percent of the oxycodone prescriptions filled by the pharmacy between February 2015 and April 2015. Following the company’s analysis, the pharmacy pledged it would no longer fill prescriptions written by several doctors identified by Miami-Luken, including Drs. David Morgan and Sanjay Mehta.**

The Committee asked Miami-Luken whether the company had any concerns over Westside Pharmacy’s filling opioid prescriptions that were written by Dr. Derakhshan given that he was not mentioned by the company in its March 28, 2018 letter to the Committee or during the December 13, 2017 transcribed interview with the company’s chairman, Dr. Mastandrea.<sup>1242</sup> In response, Miami-Luken told the Committee:

Regarding Dr. Iraj Derakhshan, the Company’s former Compliance Officer in 2015 found that Dr. Derakhshan had previously been sanctioned, but was not as large a prescriber of controlled substances as the other two physicians cited in the Company’s March 28, 2018 letter to the Committee. At the time, the Company was looking at all potential outliers and provided this information to Westside. The Company’s concern with Dr. Derakhshan was focused more on his prior sanctions than on the volume of prescriptions at Westside.<sup>1243</sup>

The documents produced to the Committee do not document any communication or concerns Miami-Luken may have conveyed to Westside Pharmacy regarding its relationship to Dr. Derakhshan. Miami-Luken has told that Committee that “[t]he Company has provided the Committee with all documentation in its possession regarding Westside.”<sup>1244</sup>

According to documents produced to the Committee, Miami-Luken did not follow up on Westside’s June 2015 assertion that it would not fill prescriptions for Drs. Morgan, Mehta, and Derakhshan for nearly five months. Miami-Luken told the Committee:

It appeared at the time that the owner was complying with the Company’s request and was taking measures to ensure public safety. To verify that the

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<sup>1241</sup> See *Id.*; see also Miami-Luken, Inc., Due Diligence File – Westside Pharmacy (On file with Committee). The sign produced in Miami-Luken’s due diligence file does not reference a year. The Committee infers the sign to reference June 30, 2015.

<sup>1242</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Miami-Luken, Inc. (Aug. 2, 2018 4:48 pm) (On file with Committee).

<sup>1243</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>1244</sup> *Id.*

owner was honoring her commitment to not fill for these prescribers, however, the Company requested 30 days of dispensing data sometime in late September 2015. The pharmacy owner provided that information to Miami-Luken on October 22, 2015, at which time the Company conducted a further analysis of Dr. Morgan in conjunction with the 30 days of dispensing data provided.<sup>1245</sup>

The due diligence materials provided to the Committee do not include documentation of Miami-Luken's late September 2015 request for dispensing data. Rather, documents indicate that in response to a request made by Westside Pharmacy on October 19, 2015 to increase its Oxycodone threshold, Miami-Luken requested the pharmacy provide 30 days of dispensing data.<sup>1246</sup>

Three days later, on October 22, 2015, Miami-Luken obtained Westside Pharmacy's dispensing data for the previous month, which revealed that the pharmacy continued to fill controlled substance prescriptions written by Drs. Morgan and Mehta, in spite of the pharmacy's purported commitment to stop filling prescriptions written by these doctors in June, as indicated by the sign reproduced above.<sup>1247</sup> In an accompanying report, Miami-Luken's Director of Compliance and Security wrote:

Upon further investigation, it appears that Dr. David Morgan, who is a pain management doctor located in Virginia, is responsible for **33%** of the Oxycodone Prescriptions [sic] filled by Westside Pharmacy and is the pharmacy's top prescriber of CII-Oxycodone. In addition, a pill count analysis revealed that Dr. Morgan's Oxycodone prescriptions account for **39%** of the total Oxycodone pills dispensed by Westside Pharmacy. It is important to note that this doctor's office is located in another state, with a **drive time of 2 hours and 4 minutes from the doctor's office (Ace Medical) to Westside Pharmacy.** This is a distance of 102 miles. According to the information provided, I can reasonably conclude that approximately 72 patients a month travel in excess of 4 hours round trip to get a CII prescription from Dr. Morgan in Virginia and have that prescription subsequently filled by Westside Pharmacy in West Virginia. In the process these patients pass several qualified doctors and pharmacies along the way. Distance aside, Dr. Morgan has a reputation as an over prescriber and has been reprimanded by the Board of Medicine.

On March 24, 2014, Dr. Morgan was sanctioned by the Virginia Board of Medicine for, "... failing to appropriately monitor and manage patient usage

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<sup>1245</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>1246</sup> See E-Mail from Dir. Compliance and Security, Miami-Luken, Inc., to Owner, Westside Pharmacy (Oct. 19, 2015 4:29 pm) (On file with Committee); see also E-Mail from Owner, Westside Pharmacy to Dir. Compliance and Security, Miami-Luken, Inc. (Oct. 19, 2015 4:36 pm) (On file with Committee)

<sup>1247</sup> Miami-Luken, Inc., Dispensing Data Sept. 1, 2015 to Sept. 30, 2015– Westside Pharmacy (On file with Committee).

of narcotics and benzodiazepine medications...” (Virginia Board of Medicine, 03/24/2014). Dr. Morgan was prohibited from prescribing, dispensing, or administering CII and CIII medication pending the completion of CME subjects. That sanction was lifted on May 9, 2014.<sup>1248</sup>

Despite its inclusion in the October 2015 report, however, Miami-Luken should have been aware of this information when it communicated its concerns about Dr. Morgan to the pharmacy in June 2015. For example, on May 26, 2015, Westside Pharmacy’s owner e-mailed the names and addresses of the clinics that were serviced by the pharmacy – included on this list was Dr. Morgan’s clinic, Ace Medical, with the clinic’s Pembroke, Virginia address listed.<sup>1249</sup> In its May 27, 2015 analysis of Westside Pharmacy’s dispensing information, and as indicated below, Miami-Luken identified that Dr. Morgan was among the pharmacy’s top 10 prescribers for controlled substances, and listing his Pembroke, Virginia address in addition to noting that he had two prior sanctions.<sup>1250</sup>

TOP 10 CS PRESCRIBERS			
Prescriber	Specialty	Actions	Address
Morgan, David (D.O.)	Pain Management	2 Sanctions	[REDACTED] Pembroke, VA 24136

Further, the October 2015 report fails to make any mention of the pharmacy’s apparent deceit of the company by continuing to fill prescriptions written by Drs. Morgan and Mehta after June 30, 2015, making no mention of Dr. Mehta at all. The Committee asked Miami-Luken why the October 2015 report failed to make any mention of the commitment the pharmacy made to the company to stop filling prescriptions written by Drs. Morgan and Mehta after June 30, 2015, and why the report failed to mention Dr. Mehta altogether.<sup>1251</sup> In response, Miami-Luken told the Committee:

It is the Company’s understanding that [Drug Usage Report Analyses (DURs)] are not designed to address issues such as commitments made by pharmacies to distributors. Consequently, no mention of Westside’s commitment to the Company was contained in the DUR. Dr. Mastandrea is unaware why data related to Dr. Mehta was not included in the October 22, 2015 DUR.<sup>1252</sup>

Miami-Luken told the Committee that after reviewing the dispensing data in October 2015 the company “determined that the owner of the pharmacy had lied to the Company

<sup>1248</sup> Dir., Corporate Compliance and Security, Miami-Luken, Inc., *Oxycodone Drug Usage Report Analysis 09-01-2015 thru 09-30-2015* (Oct. 22, 2015) (Emphasis in original) (On file with Committee).

<sup>1249</sup> See E-Mail from Owner, Westside Pharmacy, to Dir. Compliance and Security, Miami-Luken, Inc. (May 26, 2015 4:14 pm) (On file with Committee).

<sup>1250</sup> Miami-Luken, Inc., Dispensing Analysis Trend Assessment “DATA” Tool – Westside Pharmacy, May 27, 2015 (On file with Committee).

<sup>1251</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Miami-Luken, Inc. (Aug. 2, 2018 4:48 pm) (On file with Committee).

<sup>1252</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

regarding her commitment not to fill for Dr. Morgan and Dr. Mehta.”<sup>1253</sup> The Committee asked Miami Luken to produce any due diligence documents where the company recorded its determination that the pharmacy continued to fill prescriptions written by Dr. Morgan and Dr. Mehta.<sup>1254</sup> In response, Miami-Luken did not provide the Committee with a single document that would demonstrate Miami-Luken’s identification of the pharmacy’s apparent deceit, telling the Committee “[t]he Company has provided the Committee with all documentation in its possession regarding Westside.”<sup>1255</sup>

In fact, following Miami-Luken’s October 2015 review of the pharmacy’s dispensing information and determination that it had been lied to, Miami-Luken did not terminate or restrict Westside Pharmacy’s ability to purchase controlled substances. Instead, Miami-Luken elected to conduct a site visit to the pharmacy, which occurred on November 4, 2015.<sup>1256</sup> Miami-Luken’s Director of Compliance and Security’s report of the site visit provided an overall positive evaluation of the pharmacy. When asked by the Committee why the company gave the pharmacy a positive evaluation, less than two weeks after it documented red flags regarding one of the pharmacy’s top opioid prescribers, Miami-Luken stated:

It is important to note that site evaluations differ from other methods of review in that they look at the day-to-day operations and security measures on site, as well as document any suspicious activity that an investigator may observe while on site. The site evaluation is therefore necessarily confined to the investigator’s observations of the pharmacy at the time of the evaluation. Because the Company’s investigator observed no suspicious activity or security problems during the site evaluation, the evaluation was deemed acceptable. This, however, had no bearing whatsoever on the earlier findings of red flags relating to Dr. Morgan and his prescribing practices.<sup>1257</sup>

There is no indication in the report that Miami-Luken questioned the pharmacy on its continuing to fill prescriptions from Drs. Morgan and Mehta or the red flags identified in the company’s October 22, 2015 report.<sup>1258</sup> Given that the site visit was prompted by Miami-Luken’s realization that Westside Pharmacy continued to fill prescriptions written by Drs. Morgan and Mehta, the DEA would expect the investigator to ask about the company’s conclusion that the pharmacist lied.<sup>1259</sup> The Committee asked Miami-Luken if it ever confronted

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<sup>1253</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>1254</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Miami-Luken, Inc. (Aug. 2, 2018 4:48 pm) (On file with Committee).

<sup>1255</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>1256</sup> See Miami-Luken, Inc., Pharmaceutical Site Evaluation -Westside Pharmacy, Nov. 4, 2015 (On file with Committee).

<sup>1257</sup> Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee).

<sup>1258</sup> Miami-Luken, Inc., Pharmaceutical Site Evaluation – Westside Pharmacy, Nov. 4, 2015. (On file with Committee).

<sup>1259</sup> See 80 Fed. Reg. 55,457, Sept. 15, 2015.



or sought additional explanation from the pharmacy with respect to the pharmacy's continued fulfillment of prescriptions written by Drs. Morgan and Mehta, and, if it did, to provide the Committee with any documentation of this action or explanation that was provided.<sup>1260</sup> In its response to the Committee, however, Miami-Luken failed to address the Committee's question or provide any documents, thus leaving the Committee with the concern that the company did not seek any explanation from the pharmacy regarding Drs. Morgan and Mehta.<sup>1261</sup>

**FINDING: In October 2015, after determining that Westside Pharmacy continued to fill prescriptions written by Drs. Morgan and Mehta, Miami-Luken did not immediately terminate the pharmacy or restrict its ability to order controlled substances.**

On November 23, 2015, despite being aware of multiple red flags regarding the pharmacy's dispensing practices, and in addition to having reportedly been lied to, Miami-Luken approved a 2,000 dosage unit increase for the pharmacy's November oxycodone threshold.<sup>1262</sup> The same day, Miami-Luken received an Order to Show Cause from the DEA, citing, among other things, the company's distribution of controlled substances to Westside Pharmacy as being among the reasons why its DEA registration should be revoked.<sup>1263</sup> Based on the documents provided to the Committee, however, it is not clear whether Miami-Luken's decision to increase the oxycodone threshold occurred before or after it received the OTSC from the DEA.

**FINDING: In November 2015, Miami-Luken approved an increase to Westside Pharmacy's oxycodone threshold despite being aware of the pharmacy's prior deceit and red flags related to its dispensing practices and prescribing physicians.**

During the Subcommittee's May 8, 2018 hearing, Miami-Luken's Board Chairman, Dr. Joseph Mastandrea, was asked whether he questioned the company's due diligences efforts related to Westside Pharmacy, given the pharmacy's inclusion in the November 23, 2015 Order to Show Cause:

- Q. Given that the DEA cited Miami-Luken's relationship with Westside Pharmacy in its order to show cause, doesn't that raise a question in your mind about your company's due diligent [sic] efforts with respect to this pharmacy?

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<sup>1260</sup> See E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Miami-Luken, Inc. (Aug. 2, 2018 4:48 pm) (On file with Committee).

<sup>1261</sup> See Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

<sup>1262</sup> E-Mail from Dir., Corporate Compliance and Security, Miami-Luken, Inc., to Compliance Agent, Miami-Luken, Inc. (Nov. 23, 2015 3:14 pm) (On file with Committee).

<sup>1263</sup> See U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).



- A. Congressman, we were in the process of vetting that particular customer at the time we received the order to show cause. We had already terminated - - I believe there were 13 different customers that were on the order to show cause and we terminated, prior to receiving the order to show cause, all of them with the exception of Westside Pharmacy, which we were in the process of vetting at the time. When we found that they were on the order to show cause, enough was enough, and we terminated the relationship.<sup>1264</sup>

According to an e-mail sent by Miami-Luken's Director of Compliance and Security, the company terminated its relationship with Westside Pharmacy on December 9, 2015.<sup>1265</sup> Between 2009 and 2015, Miami-Luken shipped more than 4.38 million doses of hydrocodone and oxycodone to Westside Pharmacy.<sup>1266</sup> Had the DEA not issued an Order to Show Cause against Miami-Luken, citing, among other things, the company's engagement with Westside Pharmacy, it unclear whether Miami-Luken would have terminated its relationship with the pharmacy or restricted its ability to purchase controlled substances despite the pharmacy's dispensing practices and earlier deceit by continuing to fill prescriptions written by Drs. Morgan and Mehta. As discussed, in May 2011, more than four years before the DEA issued its Order to Show Cause, Miami-Luken obtained a dispensing report from Westside Pharmacy that should have prompted the company to seriously question its relationship with the pharmacy at that point.

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The case studies examined above demonstrate why the CSA has been interpreted as requiring distributors to conduct meaningful and ongoing due diligence of their customers. Conducting, documenting, and analyzing due diligence is essential to a distributor's core responsibility to maintain effective controls against diversion, and enhances a distributor's ability to recognize red flags of diversion. Such efforts enable a distributor to not only satisfy the regulatory requirement to report suspicious orders to the DEA more easily, but also puts a distributor in a better position to evaluate its business relationship with a pharmacy. For example, in May 2011, after Miami-Luken received Westside Pharmacy's dispensing report which showed the pharmacy was filling opioid prescriptions for doctors located hours away and that the prescriptions were being paid for in cash, both of which have been identified by the DEA as being red flags of diversion, the company should have sought further explanation from the

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<sup>1264</sup> *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong. 128 -129 (2018) available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf>.* Separately, the company has represented to the Committee that its decision to terminate Westside Pharmacy as a customer was "based on multiple factors" including "the pharmacy's failure to identify top opioid prescribers who were subject to, or a part to, disciplinary action; deceitful practices on the part of the owner regarding statements of willingness to cooperate with the Company regarding prescriber concerns; an increasing number of suspicious orders; and an excessive inventory of opioid medications on-site that create a greater risk of drug diversion." Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, Mar. 28, 2018 (On file with Committee).

<sup>1265</sup> See E-Mail from Dir. Compliance and Security, Miami-Luken, Inc., to Diversion Investigator, U.S. Drug Enforcement Admin. and Diversion Investigator, U.S. Drug Enforcement Admin. (Dec. 11, 2015 3:36 pm) (On file with Committee).

<sup>1266</sup> Miami-Luken, Inc., Sales Data – Westside Pharmacy (On file with Committee).

pharmacy and documented its analysis. Had the company done so, it may have elected to dissolve its business relationship with the pharmacy at that point, thereby not putting itself in a position to be deceived by the pharmacy four years later or having its relationship with the pharmacy cited in an Order to Show Cause issued by the DEA.

The case studies also illustrate that through due diligence, a distributor is better able to identify non-statistical red flags that automated algorithms are unable to capture. For example, if a pharmaceutical manufacturer had not placed an inquiry to McKesson regarding Tug Valley Pharmacy, it is unclear when, or if, McKesson would have conducted an on-site review which led to the discovery that the pharmacy had lied and continued to employ a pharmacist with a controlled substance-related felony conviction. Conducting timely, and thorough follow-up places a distributor in a better position to verify that any prior concerns have been properly addressed.

In the case studies examined above, as well as the Committee's investigation generally, it is important to be mindful that the activities examined took place in West Virginia, which had, and continues to have, the highest drug overdose rate in the country. In the final order revoking the registration of Masters Pharmaceutical, the DEA said that existing knowledge of a geographic area's problem with controlled substance abuse is another factor distributors need to take into account, meaning that distributors should have been particularly attuned to any red flags encountered when conducting due diligence on the pharmacies the Committee examined during its investigation. For example, when H.D. Smith had data to show that in a single year it shipped a West Virginia pharmacy, located in a town with a population of 1,779, more than 1.13 million opioids, that should have been a red flag on its own.<sup>1267</sup> But when taking into account the pharmacy estimated that it would only be purchasing 50 percent of its controlled substances from H.D. Smith, that figure should have been especially concerning in light of the opioid epidemic in West Virginia. The DEA has cited excessive orders placed by a pharmacy as well as a pharmacy placing orders for the same controlled substance with multiple distributors as being red flags of diversion.<sup>1268</sup>

The Committee's examination of the pharmacy case studies serves not only to emphasize the importance of conducting due diligence and identifying red flags of diversion, but also to shed light on how some pharmacies in small West Virginia communities received such high volumes of opioids for extended periods of time.

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<sup>1267</sup> See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 222 (D.D.C. 2012). In this case, the United States District Court for the District Columbia found, among other things, that it was not arbitrary and capricious under the Administrative Procedure Act for the DEA Administrator to determine, using her knowledge and experience, the volume of oxycodone sent to two pharmacies in Sanford, Florida, grossly exceeded the needs of the town's population.

<sup>1268</sup> See 72 Fed. Reg. 36,498, July 3, 2007; see also 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 Committee); 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 Committee).

## VII. Conclusion

Both the DEA and wholesale drug distributors play an important role in preventing the diversion and misuse of controlled substances. However, this investigation showed that the DEA and the distributors both faced challenges in meeting their obligations to prevent diversion. Enforcement actions over the last decade indicated distributors had difficulties complying with legal requirements. The case study of West Virginia detailed in this report showcased how acute the problems were, and potentially still may be. In West Virginia, which has the highest overdose death rate in the country, distributors dispersed nearly 800 million opioids between 2007 and 2012, sending a massive number of pills to pharmacies in small, rural towns. As criminal prosecutions and other enforcement actions in West Virginia have subsequently shown, opioids were often illegitimately prescribed, and their misuse contributed to the opioid crisis on a national scale.

With the number of fatal opioid overdoses surging, the Committee opened this investigation in 2017 to determine whether wholesale distributors played a role in the epidemic and to understand how well the DEA responded to the crisis. The inordinate numbers of opioids shipped to small-town pharmacies in the southwestern portion of West Virginia provided case studies through which the investigation identified failures and breakdowns within distributors' anti-diversion policies and practices. The Committee's investigation also uncovered gaps in the DEA's enforcement posture, both related to its capabilities nationwide and its oversight in West Virginia.

On the national scale, the DEA was not proactively using ARCOS data to investigate diversion trends until at least 2010. In recent years, the agency has taken steps to better utilize ARCOS data to identify possible sources of controlled substance diversion. Additionally, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) in October 2018, which requires DEA to provide distributors with greater access to ARCOS data.

In addition to ARCOS data, distributors are also required to submit suspicious order reports to DEA. Unlike ARCOS data, however, the DEA still does not have a centralized way to analyze suspicious order reports submitted by drug distributors. Instead, unless dictated by a memorandum of agreement, distributors report suspicious orders to local DEA offices that hold varying regulatory interpretations, resulting in inconsistent handling of the reports.

Several factors also constrained the DEA's use of ISOs, an enforcement action the agency relies on to immediately revoke the registrations of entities like doctors, pharmacies, and distributors suspected of drug diversion. The DEA told the Committee that it regularly, and recently, deferred ISOs against registrants—potentially jeopardizing the ability to bring enforcement action—to allow prosecutors to develop criminal cases. This was a significant enough occurrence that DEA began exploring with DOJ a way to eliminate the indefinite delay and only provide a time-limited opportunity for federal prosecutors. DEA has not set any limit in the length of time it is willing to delay an ISO, and in one case identified by the Committee,

the agency delayed enforcement action against a West Virginia pharmacy for two years as prosecutors apparently continued to gather evidence.

As DEA battled the worsening opioid epidemic, the agency also developed a more cautious approach to its enforcement strategy. In reaction to its interpretation of certain administrative or court rulings, in certain situations, DEA lawyers began requiring additional levels of evidence on the front end of investigations before they would approve administrative action. This, at times, manifested in requests for medical expert testimony to support ISOs and OTSCs. As highlighted by DEA's Chief Administrative Law Judge, the precipitous decline in the number of ISOs was incongruent with the increasing overdose deaths and other concerns related to the ongoing opioid epidemic. While the number of ISOs issued by the agency increased in FY 2018, concerns remain as the DEA and the DOJ have not resolved the problem of postponing enforcement action to protect the public safety in favor of criminal investigations.

DEA officials have indicated that more could have been done in West Virginia to investigate and prevent controlled substance diversion. The DEA had data regarding the breadth of the prescription drug diversion problem in the state and had been warned by the DOJ OIG in 2002 that it was devoting insufficient resources to combat diversion. Despite that, the agency only had two diversion investigators assigned to West Virginia in 2006 and didn't begin devoting significant resources to the state until 2015. Meanwhile, when distributors did send suspicious order reports regarding West Virginia pharmacies, it was, and remains, unclear regarding what actions the agency took in response, if any. Taken altogether, the DEA became more cautious and deferential in the use of ISOs while failing to adequately respond to the growing danger that prescription opioid diversion presented in West Virginia.

The DEA oversees more than 1.73 million registrants and needs compliance from distributors to successfully identify and investigate evidence of diversion. But as demonstrated by the Committee's investigation, the DEA did not always receive the level of compliance required under the CSA. The five distributors whose actions in West Virginia were examined by the Committee each had unique failures. The companies had various policies and procedures in place to prevent diversion, but in some cases did not adequately follow or carry out those policies. As evidenced in the case studies discussed in each section, distributors had failings on multiple fronts.

For instance, it is not sufficient due diligence for a distributor to only require prospective or existing customers to complete pharmacy questionnaires or supply supplemental data. The information disclosed on such questionnaires or the data submitted must also be critically analyzed to identify any red flags of controlled substance diversion. Once distributors bring pharmacies on board, they need to monitor the volume of controlled substances sold to customers. Many distributors, but not all, use thresholds to track customers' purchases of controlled substances and flag orders as suspicious when purchases exceed those limits. But without analyzing drug usage or the percentage of prescriptions written by a small number of doctors, distributors may not set appropriate limits. Subsequently, when distributors set thresholds for customers, they should be enforced. In cases when thresholds are adjusted, distributors should be able to document the justifications for these changes.

In addition to filing distribution figures through ARCOS, distributors are also required to submit suspicious order reports to DEA. Yet despite efforts by DEA to educate distributors about their responsibility to report suspicious orders—including individual meetings with four of the five distributors involved in the Committee’s investigation—these companies failed in critical ways. One distributor had no suspicious order monitoring program to speak of until recently and instead relied on subjective criteria to identify suspicious orders. Others reported various information to the DEA over the years, including excessive orders encompassing drug shipments that had already been delivered, and suspicious customers such as pharmacies with which distributors had terminated business relationships. Neither of these types of reports inform DEA about orders in real time. When distributors do not have suspicious order monitoring systems in place, they are unable to identify suspicious orders that should be blocked and investigated. Likewise, if distributors block shipments but do not report that information to DEA, they make it more difficult for the agency to identify signs of diversion.

Finally, a key role that distributors play in preventing diversion is through continued oversight of their customers. DEA has said distributors should consider any existing knowledge of a pattern of controlled substance abuse within a geographic area when evaluating red flags and that various characteristics associated with a pharmacy may give rise to suspicion. Given what was publicly known, distributors should have been acutely aware of West Virginia’s struggles with prescription drug abuse and closely monitored for red flags. Despite available information, distributors, at times, apparently did not seriously consider evidence that should have been cause for serious concern. Due diligence efforts cannot stop once a customer is onboarded. Continued due diligence can identify non-statistical red flags that automated algorithms may not flag and is essential to maintaining effective controls against diversion.

Only one chairman or Chief Executive Officer of the five distributors investigated by the Committee believed the actions of his company contributed to the opioid crisis. But other top executives have said their companies should have done better jobs reviewing pharmacy accounts and recognizing problematic customers. While distributors’ policies have evolved over time, and were strengthened in reaction to DEA enforcement actions, the Committee’s investigation identified a variety of breakdowns dating back to 2006 through the present day. Some pharmacies whose actions were the subject of case studies have shuttered. Others remain open but are receiving far fewer hydrocodone and oxycodone pills than in years’ past. It remains essential that distributors continue to evaluate not only whether their policies are relevant, but also whether they are being adequately enforced.

Congress has already begun to act on these issues. In October 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act).<sup>1269</sup> The enactment of this legislation, following the launch of this investigation and the holding of hearings, addressed some of the concerns raised by this investigation by codifying key regulatory requirements, among other actions. The pertinent legislative provisions responsive to the investigative concerns included the following:

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<sup>1269</sup> SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

- Defining a “suspicious order;”<sup>1270</sup>
- Requiring a suspicious order monitoring system;<sup>1271</sup>
- Requiring a report of suspicious order or series of orders to the DEA upon discovery;<sup>1272</sup>
- For the first time, requiring notification of suspicious orders to both DEA headquarters and the local DEA field office;<sup>1273</sup>
- Requiring the Attorney General to report to Congress annually on data concerning suspicious orders and the actions taken in response to suspicious order reports;<sup>1274</sup>
- Making the DEA provide data at least quarterly from ARCOS or any other DEA automated system available to manufacturer and distributor registrants. Such data would include the total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant and the total quantity and type of opioids distributed;<sup>1275</sup>
- Mandating manufacturer and distributor registrant responsibility for reviewing the DEA information made available by the Attorney General;<sup>1276</sup>
- Requiring the Attorney General to report to Congress no later than one year after enactment about how DEA data are being used to identify and stop suspicious orders, including whether aggregate orders from individual pharmacies to multiple distributors in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributor;<sup>1277</sup> and
- Mandating, not later than one year from enactment, that the Secretary of Health and Human Services in consultation with the DEA Administrator, FDA Commissioner, the CDC Director, and the Assistant Secretary for Mental Health and Substance Use, develop and disseminate materials for pharmacists, health care providers, and patients on circumstances when a pharmacist may decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or of doubtful, questionable and suspicious origin, among the requirements.<sup>1278</sup>

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<sup>1270</sup> See Section 3292(a) of the Act.

<sup>1271</sup> See Section 3292(b).

<sup>1272</sup> See Section 3292(b).

<sup>1273</sup> See Section 3292 (b)

<sup>1274</sup> See Section 3292(c).

<sup>1275</sup> See Section 3273(a).

<sup>1276</sup> See Section 3273(a).

<sup>1277</sup> See Section 3274.

<sup>1278</sup> See Section 3212.

Blame for the opioid epidemic is widespread and goes far beyond the bounds of this investigation. Pharmaceutical manufacturers, pharmacists, physicians, drug traffickers, and others have contributed to this problem as well. This investigation has revealed that neither the DEA nor the distributors rose to the occasion to help mitigate the opioid epidemic. The Committee will continue its bipartisan work to examine the causes and effects of the opioid epidemic.

## VIII. Recommendations

- Congress should consider enacting additional suspicious order requirements to clarify registrant responsibilities and to supplement the suspicious order requirements recently codified in the SUPPORT Act.
- Congress should clarify that reporting a suspicious order to the DEA does not relieve the registrant of the responsibility to maintain effective controls against diversion.
- DEA should work to establish a data platform with third-party experts to provide more real-time data to registrants.
- DEA policies should mandate and clarify that all transfers of registrations should be fully evaluated and require DEA's approval, including any transfers effectuated through stock purchase agreements or through corporate ownership.
- DEA should establish guidance on delaying Immediate Suspension Orders or other administrative actions for the furtherance of parallel criminal investigations, including a limit on the amount of time the agency will delay action.
- DEA should evaluate the allotment of diversion resources to determine whether the regions worst afflicted by the opioid epidemic have adequate staffing and resources.
- Distributors should perform, document, and maintain robust due diligence files for both prospective and existing customers.
- Distributors should perform due diligence on any customers that distributors may assume through acquisition of another wholesale distributor.
- Distributors should review and analyze any existing due diligence materials for a prospective customer pharmacy prior to rendering an onboarding decision regarding any such pharmacy's prospective customer application.
- As part of their prospective customer due diligence, and at regular intervals thereafter, distributors should require the production of dispensing data from a pharmacy, preferably in a manner that would enable a distributor to identify the pharmacy's prescribing physicians.
- Distributors should utilize a threshold system as part of their controlled substance monitoring programs, which would assist in identifying potentially suspicious orders and pharmacies.
- Distributors should document and verify all pharmacy threshold events, and increases or decreases to a pharmacy's threshold limits, including the reason for the increase or decrease and the reason for approval or denial of any threshold increase requests.



- Distributors should have policies limiting and delineating the instances in which blocked orders are not reported to DEA as suspicious, for example, when an order is made in error. All other blocked orders should be reported to DEA as suspicious when discovered.
- Distributors' suspicious order reporting policies should provide guidance on warning signs or red flags, or other methods to identify suspicious orders beyond numeric algorithms.
- When red flags are raised and documented regarding a pharmacy, that pharmacy should be subject to heightened monitoring. Distributors' policies should specify the frequency and type of any such heightened monitoring.
- Distributors' policies should clearly require a proactive review of pharmacies that share common ownership with a pharmacy terminated for compliance reasons within a reasonable, and determined, amount of time.