

Fueling an **EPIDEMIC**

REPORT THREE



A Flood of 1.6 Billion Doses of Opioids
into Missouri and the Need for
Stronger DEA Enforcement

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EXECUTIVE SUMMARY

The three major pharmaceutical distributors in the United States—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—each recorded 2017 revenue in excess of \$125 billion and ranked within the top 15 companies on the 2017 Fortune 500 list. Although unknown to many Americans, these companies play a critical role in preventing the diversion of opioid products from pharmacies and other customers to the black market.

Under the Controlled Substances Act (CSA), distributors carry a legal obligation to monitor and report suspicious orders of controlled substances to the Drug Enforcement Administration (DEA). The sheer volume of opioid products distributed in the United States makes compliance with CSA obligations a key component of the fight against the opioid epidemic. According to information McKesson, AmerisourceBergen, and Cardinal Health provided to the Committee, for example, these companies shipped around 1.6 billion dosage units of opioid products to Missouri alone between 2012 and 2017. This volume of opioids equated to more than 260 dosage units for every Missourian during the five-year period. During 2015—the peak year for opioid shipments to Missouri during 2012-2017—the three major distributors shipped approximately 52 opioid dosage units per person in the state.

These “big three” distributors have also consistently failed to meet their reporting obligations over the past ten years—in some cases surrendering licenses for distribution facilities and paying escalating fines after DEA and Department of Justice investigations.

Pharmaceutical manufacturers also carry the same reporting responsibilities under the law. DEA has accused at least one high-volume generic manufacturer of opioids—Mallinckrodt Pharmaceuticals—of failing to design an effective system to detect and report suspicious orders and concluded a \$35 million settlement with the company in January 2017.¹ Another manufacturer, Endo Pharmaceuticals Inc., reached a settlement with the Attorney General of New York in March 2016 based, in part, on a finding that certain sales representatives should have recognized and reported potential signs of opioid diversion.² In addition, Teva Pharmaceuticals USA, Inc., and Allergan plc both appear as defendants in many of the complaints counties and other governmental entities have brought against distributors and manufacturers in response to the opioid epidemic.

This report examines the efforts McKesson, AmerisourceBergen, Cardinal Health, Mallinckrodt, and Endo have undertaken to meet their obligations under the CSA, as well as the suspicious order reports these companies have provided to DEA for Missouri orders between 2012 and 2017. The report does not, however, address efforts by Teva, which failed to provide information in response to Ranking Member McCaskill’s specific requests.

By mapping county-level suspicious order reporting data from these companies and comparing the information to other county-level data from the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and other sources, this report also identifies several potential hotspots for opioid diversion and prescribing in Missouri. In general, data suggests significant

opioid prescribing and diversion activity occurs in the Missouri counties to the south and southwest of St. Louis and in counties along the Missouri-Arkansas border—particularly Barry, Howell, and St. Francois counties.

Despite the highly sophisticated methods and significant resources the three major distributors have deployed, their suspicious order reporting between 2012 and 2017 varied widely. McKesson and AmerisourceBergen, for example, both shipped around 650,000,000 dosage units to Missouri in this five-year period, but McKesson reported 16,714 suspicious orders to DEA while AmerisourceBergen reported only 224—around 75 times fewer reports than McKesson. Although Cardinal Health shipped fewer than half of the total opioid dosage units AmerisourceBergen distributed to Missouri between 2012 and 2017, it reported 5,125 suspicious orders to DEA—or almost 23 times more reports than AmerisourceBergen. The total suspicious orders McKesson reported also far exceed both the AmerisourceBergen and Cardinal Health totals, despite the fact that the McKesson total only reflects company reporting to DEA between August 2013 and December 2017. Among pharmaceutical manufacturers, Mallinckrodt reported 905 Missouri orders to DEA compared to no orders reported from Endo between 2012 and 2017.

These divergent reporting results alone do not in any way indicate violations of the CSA by the companies involved. But they do highlight the importance of ongoing outreach from DEA to industry regarding legal obligations for distributor and manufacturer registrants. More importantly, the findings discussed below underscore the need to return DEA administrative enforcement activity to pre-2011 levels and restore earlier standards for the use of immediate suspension orders (ISOs)—the most critical tool in the DEA arsenal for deterring and punishing lax compliance. In fact, according to information the minority staff has reviewed, DEA did not issue an ISO against a distributor or a manufacturer between 2012 and 2017, and ISOs against all DEA registrants fell from 58 in 2011 to eight in 2014, with five orders in 2015, nine in 2016, and six in 2017. Moreover, although DEA has touted voluntary surrenders of registrations as a measure of enforcement activity, only 22 distributors have voluntarily surrendered registrations between 2011 and 2017, and this list does not include McKesson, AmerisourceBergen, or Cardinal Health.

METHODOLOGY

On July 26, 2017, Ranking Member McCaskill issued requests for documents and information to the three major drug distribution companies operating in the United States—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—related to their efforts to prevent opioid diversion.³ The requests sought materials and data concerning internal estimates of diversion risk, company compensation policies, suspicious order reporting, on-site investigations of pharmacies and other customers, and total opioid shipments to Missouri between 2012 and 2017.⁴ The same day, Ranking Member McCaskill also issued requests to Allergan, Endo, Mallinckrodt, and Teva—four of the largest generic pharmaceutical manufacturers—covering many of these same issues and focusing specifically on company efforts to monitor transactions between distributor partners and pharmacies.⁵ These requests followed extensive briefings regarding anti-diversion efforts from each of the recipient companies.

Over the course of several months, each of the distributors provided documents and information in response to the majority of the requests Ranking Member McCaskill issued. In some cases, distributors declined to provide information to preserve confidentiality or to protect business sensitive information.⁶ The July 2017 requests, for example, sought information on opioid shipments and suspicious order reports at the level of individual pharmacies or other customers; this data might have enabled the minority staff to gauge whether shipments were appropriate given local demand and whether suspicious order reports were warranted. Because distributors provided aggregated shipment and reporting data for Missouri, however, the minority staff lacked the data necessary to determine whether these companies complied—or not—with their obligations under the CSA. Distributors also declined to provide written performance reviews for their chief compliance officers since January 2012, as well as certain other information on compliance metrics and compensation adjustments. As a result, the minority staff cannot determine the degree to which historic compliance failures directly affected senior management at the three major distributors.

Mallinckrodt and Endo also provided extensive information regarding their anti-diversion efforts.⁷ Teva, however, refused to provide information in response to the specific July 2017 requests, and Allergan delayed a written response for months. In correspondence with the Committee on August 30, 2017, for example, Teva provided general information on its anti-diversion efforts but failed to answer specific requests or provide information responsive to several questions minority staff had raised after an earlier briefing.⁸ The company emphasized that it considered its August 30 letter “to be a full response to your inquiry.”⁹ In response, on September 28, 2017, Ranking Member McCaskill sent a non-public letter to incoming Teva CEO Kåre Schultz urging him to cooperate fully with the investigation.¹⁰ The letter noted recent significant legal and management issues at Teva and stated that “the company’s decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders.”¹¹ The letter also provided Teva with one week to respond and arrange for document production.¹²

Teva responded in a letter on October 5, 2017, stating that it had already provided information relevant to the July 2017 requests and that disclosing the identity of customers submitting suspicious orders would “chill the willingness of such customers to share information with your Committee and participate in our collective efforts to address opioid abuse.”¹³ The company also asserted that DEA was better suited to provide certain information Ranking Member McCaskill had requested and that releasing information could impact ongoing litigation against the company.¹⁴ On December 21, 2017, Ranking Member McCaskill requested that Chairman Ron Johnson approved the issuance of a subpoena to Mr. Schultz to compel the production of responsive documents and information.¹⁵ On January 12, 2018, Chairman Johnson declined to approve a subpoena.¹⁶ Without additional documents and data from Teva, the minority staff lacks sufficient information to understand fully the efforts the company has undertaken to

meet its CSA obligations. As Ranking Member McCaskill stated on March 6, 2018, however, "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide. I'd hope that everyone involved or associated with the company takes note that they're dealing with an entity that's stonewalling a Senate investigation examining a national public health crisis."¹⁷

Despite initial assurances of compliance,¹⁸ Allergan failed for months to provide any written response to the July 2017 requests. On May 21, 2018, Ranking Member McCaskill wrote to Brenton L. Saunders, Chairman, President, and CEO of Allergan, and urged him to comply with the requests.¹⁹ Counsel for Allergan responded on May 29, 2018, explaining that the company currently markets only three branded opioid products in the United States and was not a DEA registrant for Schedule II or Schedule III drugs.²⁰ Instead, since November 2015 Allergan has contracted with UPS Supply Chain Solutions, a third-party logistics provider that "evaluates all orders for controlled substances it receives from Allergan's customers."²¹ According to Allergan, UPS Supply Chain Solutions has reported no orders for the three branded Allergan opioid products currently on the market.²² The company further explained that prior to November 2015, entities sold to Teva in August 2016 performed all suspicious order monitoring functions for the company; Allergan therefore no longer possesses information relating to these functions.²³ Based on an investigation, however, the company reported that it was not aware of any suspicious order notifications it or its distributor partners had provided to the DEA regarding orders of branded opioid products originating from Missouri.²⁴

OPIOID DIVERSION HAS SIGNIFICANTLY CONTRIBUTED TO THE OPIOID EPIDEMIC IN MISSOURI

Over 3,400 Missouri residents died between 2012 and 2016 due to opioid-involved overdoses,²⁵ and 664 Missourians died from prescription opioid overdoses in 2016 alone.²⁶ From July 2016 through September 2017, Missouri also experienced a 21% increase in the rate of individuals visiting emergency departments as a result of opioid overdoses,²⁷ and the number of quarterly Missouri resident non-heroin opioid deaths almost doubled from the first quarter of 2013 to the first quarter of 2017.²⁸ Based on data from the DEA Automation of Reports and Consolidated Orders System (ARCOS), Missouri ranks 14th among the 50 states in terms of grams of hydrocodone and oxycodone distributed per 100,000 state residents in 2016.²⁹ And according to the St. Louis County drug monitoring program, county physicians prescribe enough painkillers per month to provide every resident with three pills.³⁰

The opioid epidemic—in Missouri and elsewhere—has arisen, in part, from the diversion of prescription opioids through illegal dispensing practices at pharmacies. In Missouri, the Board of Pharmacy initiated at least 20 disciplinary actions against pharmacies or pharmacy employees for opioid diversion between 2012 and 2016.³¹ One pharmacy in Webb City, for example, could not account for more than 35,000 hydrocodone dosage units and almost 20,000 oxycodone dosage units between May 2014 and March 2015.³² A pharmacy in Buffalo, Missouri, was disciplined in 2015 for diverting 21,978 hydrocodone and hydrocodone/APAP dosage units for the personal use of a pharmacist-in-charge.³³ And another pharmacy in St. Louis was cited for the diversion of 3,054 hydrocodone/APAP dosage units in 2014;³⁴ investigators discovered "that quantities of controlled substances had been increased when the orders were placed on the wholesaler website the Pharmacy used to order its drugs."³⁵ After placing an order, any pharmacy employee could "add a medication to the order or change the quantity of drugs on the order because all Pharmacy staff had access to and shared the password to the [distributor] website."³⁶

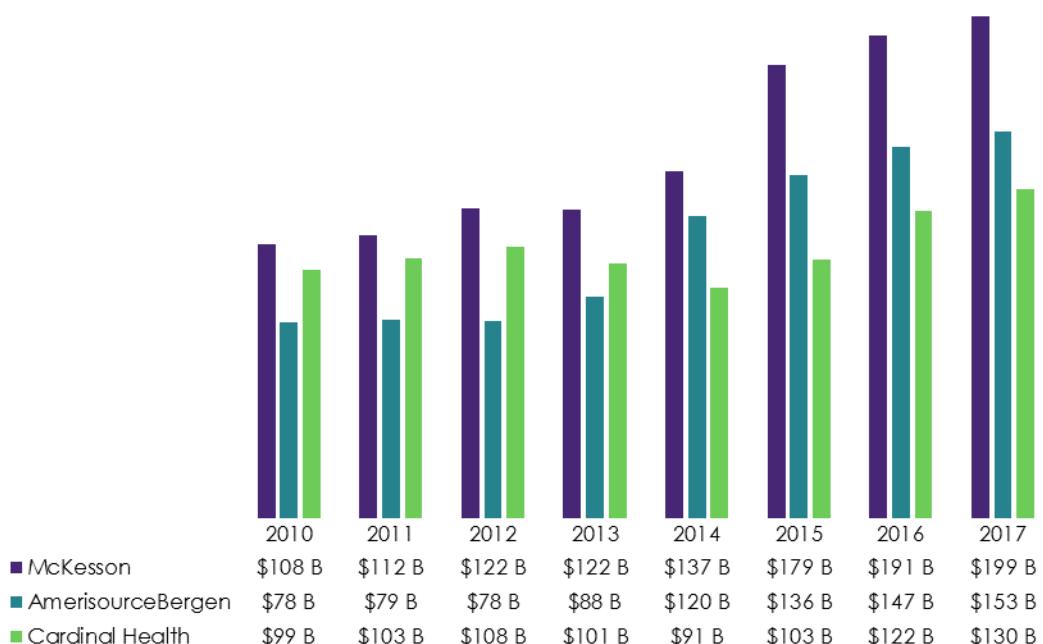
A number of Missouri disciplinary actions have also involved national chain-affiliated pharmacies in Joplin, Independence, Chesterfield, and Kansas City.³⁷ At these pharmacies between 2012 and 2016, illicit activity allegedly resulted in more than 54,000 unaccounted or diverted dosage units of various opioid medications.³⁸

Illicit prescribing practices have also contributed to opioid diversion in Missouri. In 2013, for example, a federal grand jury indicted a St. Louis doctor for dispensing large quantities of opioid products "with little or no medical examination and for no legitimate medical purpose."³⁹ This physician allegedly wrote "approximately 1300 controlled substance prescriptions generating approximately \$195,481 cash revenue."⁴⁰ Similarly, a Bolivar physician pleaded guilty in 2013 to writing multiple "prescriptions for OxyContin, Oxycodone Hydrochloride, and Oxycodone-Aspirin ... [outside] the usual course of professional practices and for a person who had no legitimate medical need for the prescriptions" between 2009 and 2010.⁴¹ The physician also met patients in a parking lot near his clinic to provide prescriptions.⁴² During this time period, a local hospital reported "96 overdose incidents at the hospital, 29 of whom were connected to [the Bolivar physician]," including six patients who fatally overdosed.⁴³

CERTAIN MAJOR DISTRIBUTIONS AND MANUFACTURERS HAVE CONSISTENTLY FAILED TO MEET THEIR ANTI-DIVERSION OBLIGATIONS

Three companies—McKesson, AmerisourceBergen, and Cardinal Health—account for approximately 90% of drug distribution revenue in the United States.⁴⁴ Each of the "big three" distributors appears in the top 15 companies ranked in the 2017 Fortune 500 list,⁴⁵ and each recorded revenues of over \$125 billion for fiscal year 2017—following years of steady growth.⁴⁶

FIGURE 1: Revenue for Major Distributors, FY 2010-2017 (In Billions)



These companies—and other drug distributors—each carry an obligation under the CSA to report to DEA any suspicious orders of controlled substances, which include "orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency."⁴⁷ According to the *Washington Post*, however, at least 13 distributors, including McKesson, AmerisourceBergen, and Cardinal Health, "knew or should have known that hundreds of millions of pills were ending up on the black market."⁴⁸ In some cases, distributors continued to send pills "[e]ven when they were alerted to suspicious pain clinics or pharmacies by the DEA and their own employees."⁴⁹

In response to these failures, DEA has concluded several settlements with major opioid distributors. In January 2017, for example, McKesson agreed to pay a \$150 million penalty to resolve allegations that it “failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances distributed to its independent and small chain pharmacy customers.”⁵⁰ In December 2016, Cardinal Health resolved similar allegations, paying \$44 million after allegedly violating the CSA in Maryland, Florida, and New York.⁵¹

Recent DEA actions against distributors have also paralleled a federal effort to hold opioid manufacturers accountable for failing to monitor and report suspicious orders of their products. In April 2017, the generic manufacturer Mallinckrodt agreed to pay a \$35 million fine following DEA allegations that the company “ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state.”⁵² (DOJ confirmed the settlement on July 11, 2017.⁵³) DEA alleged, for example, that Mallinckrodt continued to supply opioids—as many as 2.1 million tablets of oxycodone—to a Florida distributor despite knowing the company delivered oxycodone to the operator of a notorious Florida clinic.⁵⁴ Mallinckrodt had also allegedly continued to pay “chargebacks,” in which manufacturers provide distributors certain reimbursements following sales to pharmacies, in connection with this clinic.⁵⁵ In total, DEA estimated that Mallinckrodt failed to report at least 43,991 opioid orders.⁵⁶

More recently, Mallinckrodt received a grand jury subpoena in January 2018 from the U.S. Attorney for the Southern District of Florida “for documents related to the Company’s distribution, marketing and sale of its oxymorphone generic products.”⁵⁷ The company also received a subpoena seeking similar information from the Department of Justice for “documents related to the marketing and sale of the Company’s opioid products.”⁵⁸ Similarly, Endo received a subpoena from the U.S. Attorney for the Southern District of Florida “seeking documents and information relating to products containing oxymorphone.”⁵⁹ In addition, a 2016 settlement between the Attorney General of New York and Endo included a finding that, “[a]lthough Endo had issued a written policy requiring [sales representatives] to report signs of abuse, diversion and inappropriate prescribing, certain Endo sales representatives who detailed New York [healthcare providers] testified that they did not know about any policy or duty to report problematic conduct observed in [providers’] offices, and did not report anyone, even when they saw suspicious behavior.”⁶⁰ As part of the 2016 settlement, Endo agreed to “maintain and enhance its program consisting of internal procedures designed to identify potential abuse, diversion, or inappropriate prescribing of opioids.”⁶¹ Plaintiffs in federal litigation have also accused both Endo and Mallinckrodt of failing to meet their legal obligations to report suspicious orders of controlled substances.⁶²

Teva and Allergan both appear as defendants in many of the complaints counties and other governmental entities have brought against distributors and manufacturers in response to the opioid epidemic. According to a complaint from Wayne County and Oakland County, Michigan, in federal court, for example, the Cephalon unit of Teva engaged in false and off-label marketing of the fentanyl product Fentora and promoted materials minimizing the risk of opioid addiction.⁶³ A similar complaint from the City of Chicago alleges that Cephalon sought to “expand the market for its branded opioids...far beyond their FDA-approved use in opioid-tolerant cancer patients,” in part through “misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.”⁶⁴ According to a complaint from the State of Ohio, Actavis—which acquired and retained the name of Allergan in 2015—created and disseminated “advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain,” as well as materials “that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.”⁶⁵

DISTRIBUTOR AND MANUFACTURER SUSPICIOUS ORDER REPORTING FOR MISSOURI VARIED WIDELY BETWEEN 2012 AND 2017

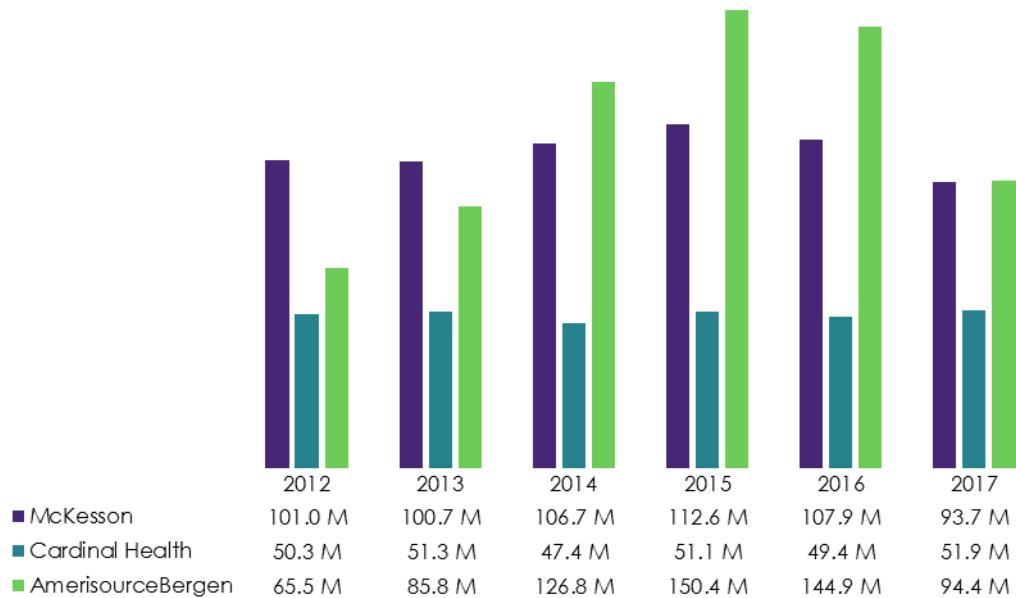
Between 2012 and 2017, according to information provided to the Committee, the three major drug distributors shipped approximately 1.6 billion opioid dosage units to Missouri—or around 260 doses per resident. At the same time, the number of suspicious order reports these companies reported to DEA in 2012-2017 varied significantly—from a high of 16,714 reports from McKesson to a low of only 224 reports from AmerisourceBergen. Suspicious order reporting from the generic manufacturers Endo and Mallinckrodt also varied between 2012 and 2017, with Mallinckrodt reporting 905 orders to DEA and Endo reporting no orders during the same five-year period.

By mapping county-level suspicious order reporting data and comparing the information to other county-level data from CMS, the CDC, and other sources, the minority staff identified several potential hotspots for opioid diversion and prescribing in Missouri. In general, data suggests significant opioid prescribing and diversion activity occurs in the Missouri counties to the south and southwest of St. Louis and in counties along the Missouri-Arkansas border—particularly Barry, Howell, and St. Francois counties.

A. Distributor Opioid Shipments and Suspicious Order Reporting

According to data provided to the Committee, McKesson, Cardinal Health, and AmerisourceBergen shipped roughly 1.6 billion opioid dosage units to Missouri between 2012 and 2017.⁶⁶ Shipments during this period peaked in 2015 before falling in 2016 and 2017. See Figure 2.

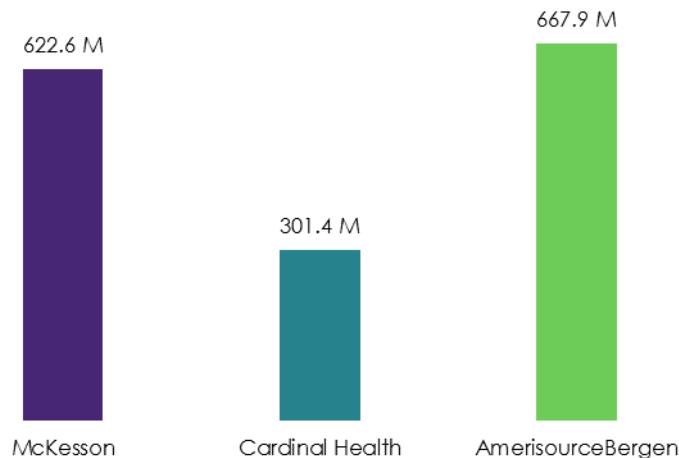
FIGURE 2: Opioid Dosage Units Distributed to Missouri per Year, 2012-2017⁶⁷



The volume of opioids shipped into Missouri between 2012 and 2017 from the big three distributors alone equated to more than 260 dosage units for every Missourian during the five-year period.⁶⁸ During the peak year of 2015, the three major distributors shipped approximately 52 opioid dosage units per person in the state.⁶⁹ McKesson and AmerisourceBergen distributed roughly equivalent total dosage units—

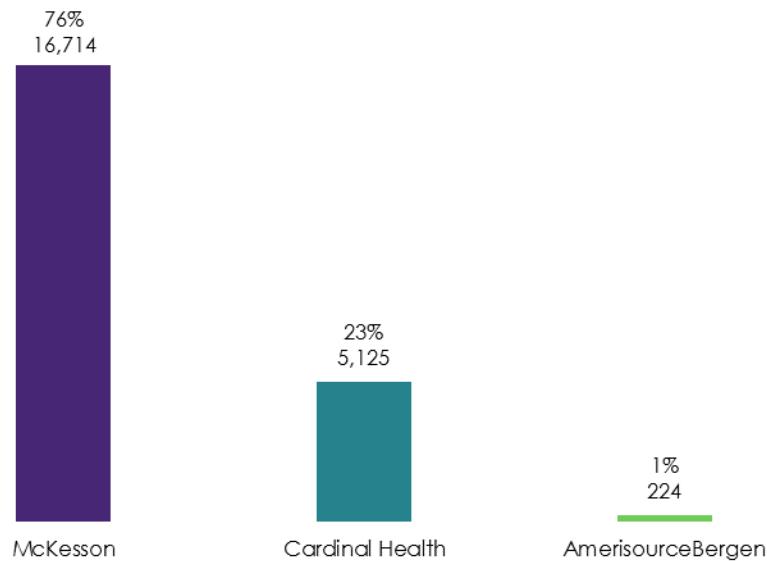
around 622,600,000 and 667,900,000, respectively—to Missouri between 2012 and 2017, and Cardinal Health shipped around 301,400,000 dosage units, or roughly half of these totals. See Figure 3.

FIGURE 3: Total Opioid Dosage Units Distributed to Missouri, 2012-2017⁷⁰



Suspicious order reporting from the three major distributors for orders originating from Missouri varied widely during this period, even in cases in which distributors shipped roughly equivalent opioid dosage unit amounts. McKesson and AmerisourceBergen, for example, both shipped around 650,000,000 dosage units between 2012 and 2017, but McKesson reported 16,714 suspicious orders to DEA while AmerisourceBergen reported only 224—around 75 times fewer reports than McKesson.⁷¹ Although Cardinal Health shipped fewer than half of the total opioid dosage units AmerisourceBergen distributed to Missouri between 2012 and 2017, it reported 5,125 suspicious orders to DEA—or almost 23 times more reports than AmerisourceBergen.⁷² The total suspicious orders McKesson reported also far exceed both the AmerisourceBergen and Cardinal Health totals, despite the fact that the McKesson total only reflects company reporting to DEA between August 2013 and December 2017.⁷³ See Figure 4.

FIGURE 4: Total Suspicious Orders Reported by Major Distributors for Orders Originating From Missouri, 2012-2017⁷⁴

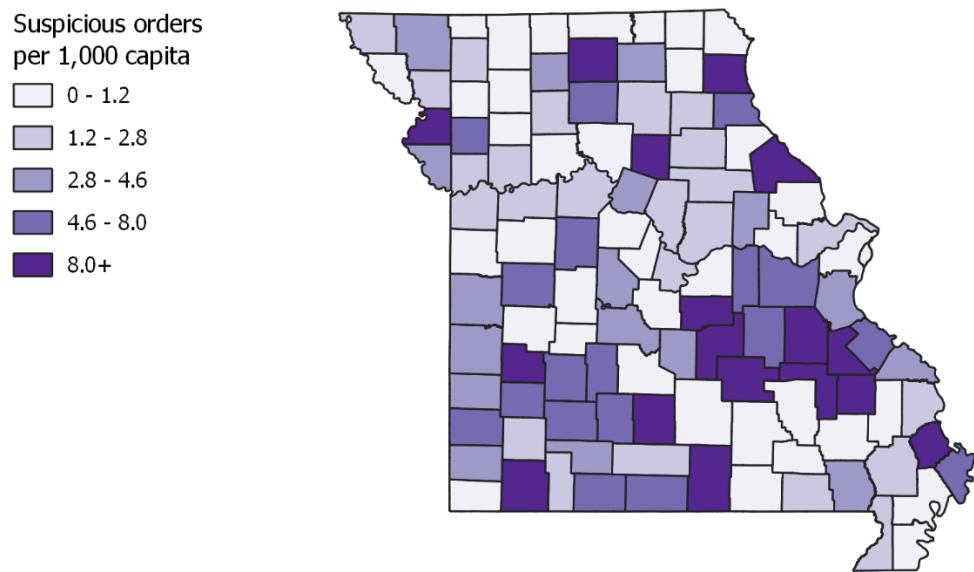


On April 2, 2018, DEA produced to the Committee records of suspicious order reports McKesson, Cardinal Health, and AmerisourceBergen filed with DEA headquarters for orders originating from Missouri between 2012 and 2017.⁷⁵ (According to DEA, it appears these distributors have not filed any suspicious order reports locally with the DEA St. Louis Field Division since January 2012.⁷⁶ This lack of reporting may be due to the fact that distributors subject to memoranda of understanding with DEA file directly with headquarters.⁷⁷) According to information DEA provided, AmerisourceBergen electronically filed 245 suspicious order reports for orders originating from Missouri between 2012 and 2017, Cardinal Health filed 1,266 reports, and McKesson filed 7,025 reports.⁷⁸ Although the AmerisourceBergen total closely matches the data the company provided to the Committee, the Cardinal Health and McKesson totals fall significantly below the levels in the data these companies provided in response to the July 2017 requests.

B. Suspicious Order Reporting and County-Level Information

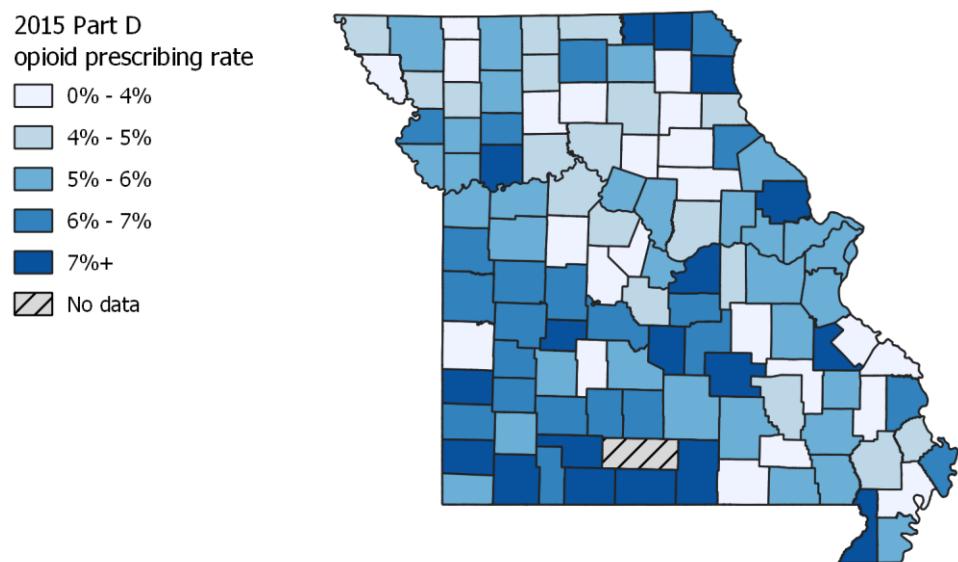
By tallying suspicious order reports per county and comparing these totals to 2017 population statistics,⁷⁹ the minority staff identified several hotspots for suspicious order reporting in Missouri between 2012 and 2017. See Figure 5. For example, Buchanan, Barry, and Howell counties all appear in the highest category of counties by suspicious order reports per 1,000 residents, alongside counties south and southwest of St. Louis—Washington, St. Francois, Madison, Iron, Dent, and Phelps. Sullivan County near the Iowa border and Scott County along the Illinois border have similarly high rates. Cedar County in western Missouri falls in the same high category.

FIGURE 5: Suspicious Orders Per Capita by Missouri County, 2012-2017

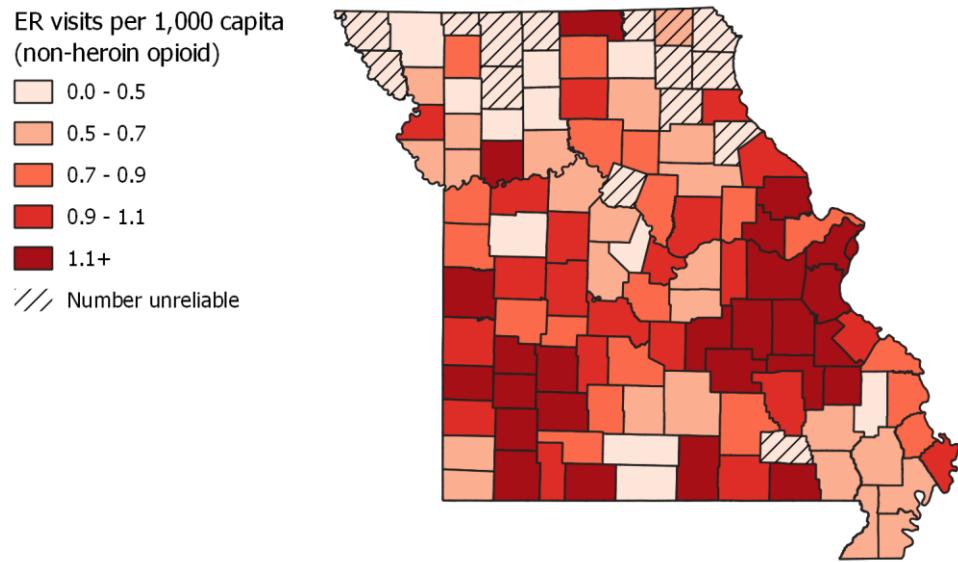


Through examinations of county-level information from CMS, CDC, and the Missouri Department of Health and Senior Services, the minority staff identified other potential trends in Missouri county-level data. For example, St. Francois, Barry, Howell, and Lewis counties all fall in the highest category of Missouri counties based on 2015 Medicare Part D opioid prescribing rates, as well as the highest category of counties by suspicious order reports per capita. See Figure 6.

FIGURE 6: 2015 Medicare Part D Opioid Prescribing Rates by County⁸⁰



Barry and Howell counties place in the highest category of Missouri counties based on emergency room visits per 1,000 residents as a result of non-heroin opioids, as well as the highest category of counties by suspicious order reports per capita. The same applies to the cluster of counties to the south and southwest of St. Louis—Washington, St. Francois, Madison, Iron, Dent, and Phelps—and Cedar County in the west. Greene County also falls in the highest category of counties based on emergency room visits and the second-highest category based on suspicious order reports per capita. See Figure 7.

FIGURE 7: Per 1,000 Capita Emergency Room Visits Due to Non-Heroin Opioid Use by County, 2011-2015⁸¹

Although the Missouri Department of Health and Senior Services has designated certain death rates from non-heroin opioids by county as unreliable due to the total number of incidents,⁸² reliable data shows that both Greene and St. Francois counties fall within the highest category of counties based on death rates per capita between 2012 and 2016. These two counties also fall within the two highest categories of counties based on suspicious order reporting. See Figure 8.

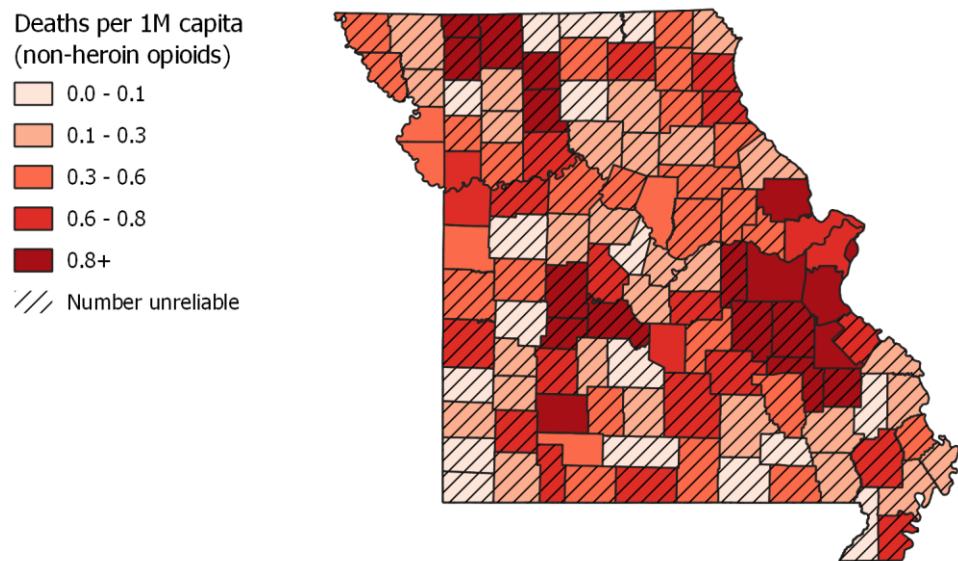
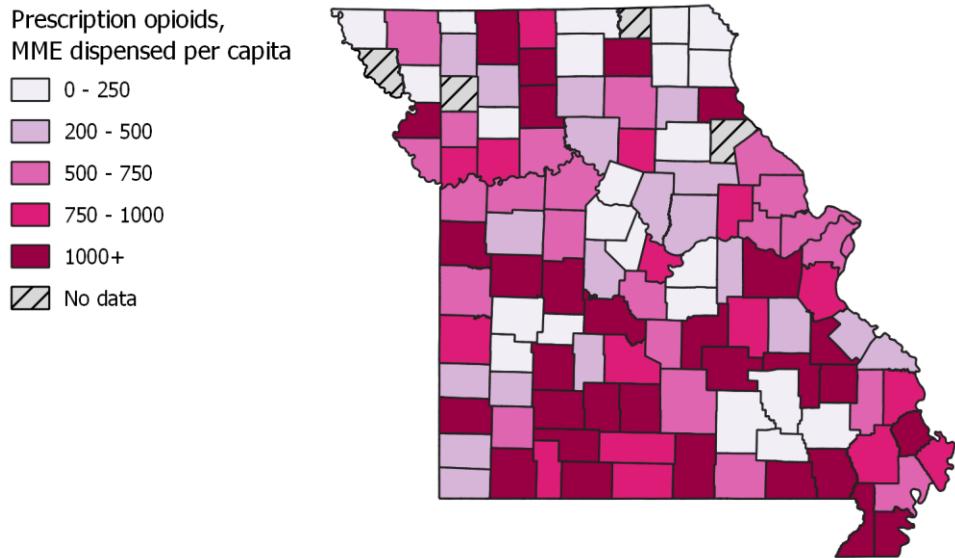
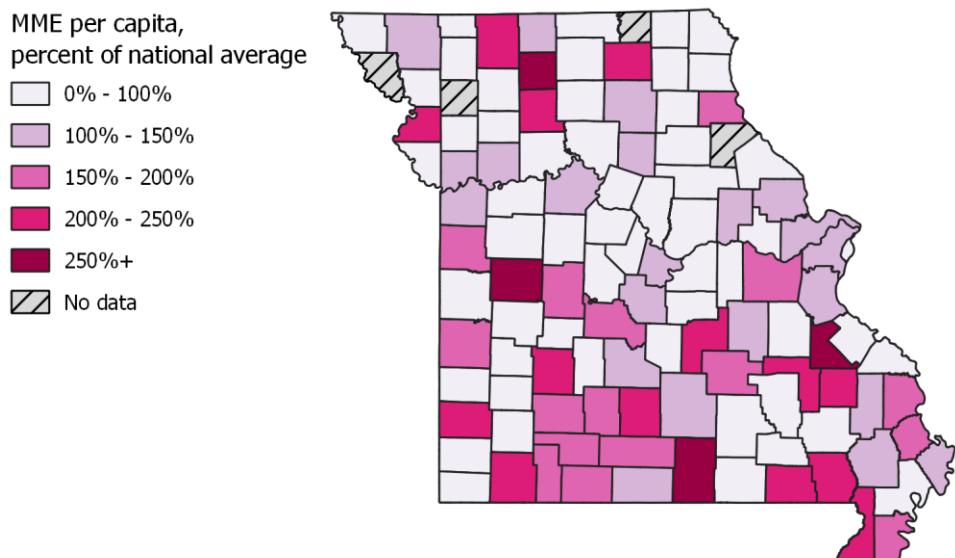
FIGURE 8: Per 1,000,000 Capita Non-Heroin Opioid Death Rates by County, 2012-2016⁸³

FIGURE 9: 2015 Morphine Milligram Equivalent Opioid Dispensing Per Capita by County⁸⁴

CDC prescribing data also show that Buchanan, Barry, Howell, Scott, St. Francois, Wright, Madison, and Phelps counties fall within the top category of Missouri counties based on morphine milligram equivalent (MME) opioid dispensing per capita in 2015, as well as the highest category of Missouri counties based on suspicious order reports per capita. See Figure 9. St. Francois and Howell counties also fall in the highest category of Missouri counties based on MME dispensing per capita over the national average, based on CDC data. See Figure 10.

FIGURE 10: 2015 Morphine Milligram Equivalent Opioid Dispensing Per Capita over National Average by County⁸⁵

C. Manufacturer Suspicious Order Reporting

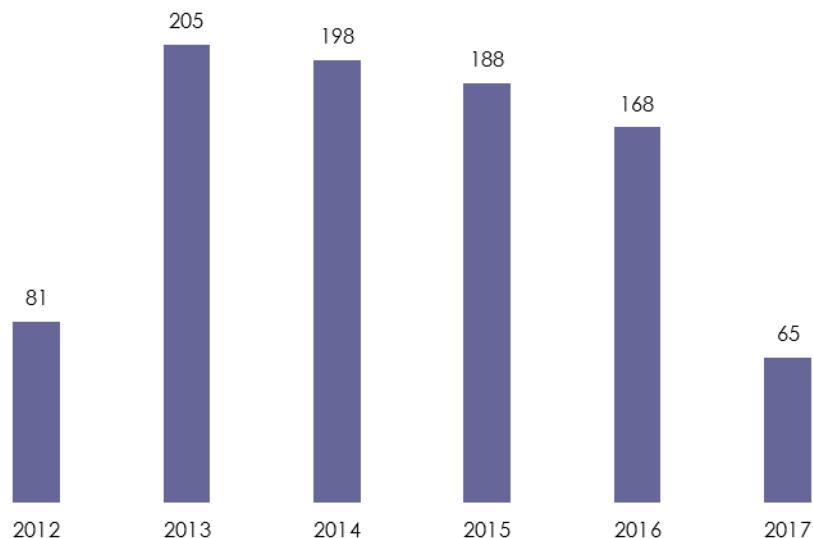
Endo and Mallinckrodt have pursued contrasting approaches to reporting suspicious opioids orders originating from Missouri to DEA. While Endo flagged hundreds of orders as orders of interest and conducted further review, it did not identify any order as suspicious following its review and thus did not report any order to DEA. Mallinckrodt reported every flagged order to DEA, regardless of the outcome of the company's internal review.

Endo provided a list to the Committee of 516 Missouri-based opioid products orders the company held pending internal review.⁸⁶ Of these orders, 238 were listed as “[p]ended [d]ue to [o]rder [h]istory”—meaning that “the requisite amount of historical order data was not available to calculate an algorithm score”; Endo then conducted a manual evaluation of the order “for any unusual activity and against the customer-specific boundaries established for that particular drug family.”⁸⁷ Endo also held 23 orders for further review because the orders originated from a distribution facility other than the two McKesson and Cardinal facilities to which the company ships the vast majority of its products.⁸⁸ Endo also held 30 orders because the amount of controlled substance at issue exceeded the rolling 30-day threshold Endo had calculated for the specific customer.⁸⁹ Many of the remaining orders Endo held involved large spikes in the quantity each customer ordered.⁹⁰

In each of the cases described above, however, Endo cleared the order after finding it fell within established boundaries for the customer at issue. As the company noted in correspondence with the Committee, Endo “did not identify any schedule CII or CIII opioid product orders, originating in Missouri, that required DEA suspicious order notification” between 2012 and 2017.⁹¹

In contrast to the approach Endo adopted with regard to suspicious orders, Mallinckrodt has stated in correspondence with the Committee that it has reported to DEA every instance in which the company has flagged an order—regardless of whether the company released the order following investigation.⁹² Between January 2012 and July 2017, Mallinckrodt reported 905 suspicious orders originating from Missouri to DEA.⁹³ See Figure 11.

FIGURE 11: Mallinckrodt Suspicious Order Reports for Missouri Orders, January 2012-July 2017



DISTRIBUTOR AND MANUFACTURERS EMPLOY SIMILAR ANTI-DIVERSION STRATEGIES

Despite the divergent results in suspicious order reporting described above, McKesson, AmerisourceBergen, and Cardinal Health have all used similar anti-diversion strategies to comply with their reporting and investigative obligations under the CSA. With a few important exceptions, Mallinckrodt and Endo likewise undertake similar anti-diversion efforts.

These commonalities should—theoretically—allow major distributors and manufacturers to arrive at similar compliance outcomes. The fact that these companies reported widely divergent totals for reports of suspicious orders originating from Missouri between 2012 and 2017 suggests, at the very least, that other factors played a role in preventing more uniform outcomes.

A. Distributor Efforts to Monitor and Report Suspicious Orders

McKesson, AmerisourceBergen, and Cardinal Health all employ similar techniques to monitor and report opioid diversion. Each of these distributors, for example, uses data analytics to compare customer orders against objective metrics, including “established monthly thresholds,”⁹⁴ “high percentage of controlled versus noncontrolled substances purchases,” and “increased volume of high risk controlled substances ordered.”⁹⁵ After detecting indicators of diversion, distributors also pursue similar actions within a range of responses. Cardinal Health, for example, has noted in correspondence with the Committee that these actions include “blocking and reporting individual orders, raising or lowering controlled substance distribution thresholds on a pharmacy-by-pharmacy basis, and cutting off pharmacies from our business when the data from our models and from our direct observations tells [Cardinal Health] those steps are warranted.”⁹⁶

B. Distributor Investigations of Pharmacy Customers

McKesson and AmerisourceBergen also provided information to the Committee on the vetting they perform for potential pharmacy customers before supplying them with controlled substances. McKesson, for example, “requires all prospective customers to complete a detailed questionnaire, provide three months of dispensing data for analysis, undergo a site visit, and provide copies of all licenses.”⁹⁷ AmerisourceBergen also requires potential customers to complete a questionnaire concerning “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...and whether another supplier is known to have suspended or ceased controlled substance sales to the customer.”⁹⁸

Each of the three major distributors also engages in ongoing investigation of pharmacies and other customers, including on-site audits and other reviews. According to McKesson, “pharmacies can be subjected to a complete due diligence examination that may include an analysis of its purchase data for red flags, licensing verification, and open-source searches for adverse information about a pharmacy.”⁹⁹ These reviews can occur when a customer requests an increase in monthly controlled substances ordering thresholds or when the company receives a subpoena or other relevant information concerning the customer.¹⁰⁰ AmerisourceBergen also described to the Committee its efforts to conduct on-site customer investigations upon notice of concerning behavior through ongoing monitoring activities and communications with law enforcement, among other sources.¹⁰¹ Similarly, Cardinal Health investigates signs of diversion through physical checks of pharmacy customers; according to the company, it performs around 20,000 unannounced “surveillance” visits and 1,000 announced site visits per year.¹⁰²

According to McKesson, the company has “either denied onboarding as a customer or ‘cut-off’ the ability to order controlled substances” for only 11 DEA registrants in Missouri between 2012 and 2017.¹⁰³ Three of these registrants were located in Berry County, two were located in St. Louis City, two were located in Butler County, and the remaining four registrants were located in Washington, Phelps, Dunklin, and Jackson counties.¹⁰⁴ AmerisourceBergen declined to provide requested details regarding its investigative efforts for customers in Missouri—citing confidentiality and privilege concerns¹⁰⁵—but Cardinal Health noted in a briefing to minority staff that it had blocked approximately 1,000 customers nationwide from receiving drug shipments during the past five years.¹⁰⁶

C. Distributor Hiring of Former DEA Officials

In correspondence with the Committee, distributors have also highlighted their hiring of former DEA officials to direct anti-diversion efforts and other compliance activities. AmerisourceBergen, for example, stated that its “Diversion Control Team...is led by...a retired career DEA agent who was the Assistant Special Agent in Charge of the Atlanta Field Office at the time of his retirement.”¹⁰⁷ The company has also partnered with “a consulting group comprised of former DEA employees” to conduct on-site visits to certain customers; “investigators prepare comprehensive reports for use by [Corporate Security and Regulatory Affairs] in determining what, if any, action to take as a result of the visit.”¹⁰⁸ Similarly, the Controlled Substances Monitoring Program at McKesson “now includes individuals with more than 240 years of cumulative DEA enforcement experience.”¹⁰⁹ At Cardinal Health, D. Linden Barber—who previously served as associate chief counsel at DEA—now serves as Chief Regulatory Counsel and Senior Vice President.¹¹⁰

D. Distributor Compensation Policies

Each of the three major distributors has denied in correspondence with the Committee that compensation policies have impacted the volume of opioids they have distributed or the efficacy of their compliance efforts. According to McKesson, for example, “[t]here has never been a direct correlation between the sale of controlled substances and incentive compensation for McKesson sales personnel.”¹¹¹ In 2012, moreover, “McKesson began purposely excluding sales of certain medications that are commonly diverted and abused from compensation metrics involving total sales results to eliminate any incentive for sales professionals to increase sales of those products.”¹¹² Similarly, Cardinal Health has stated that “[t]he performance-based component of executive pay includes consideration of the overall performance of the entire company,” and the company does “not measure or compensate employee performance by any particular product, including opioids.”¹¹³ (At the same time, however, “Cardinal Health has not made any specific downward adjustments in executive compensation related to the opioid epidemic.”¹¹⁴) According to AmerisourceBergen, company “employees do not receive incentive compensation directly tied to sales of controlled substances.”¹¹⁵ The company has also stated that it conducted an internal risk assessment “to identify any compensation plans and practices that may encourage employees to take unnecessary risks that could threaten the Company. No such plans or practices were identified.”¹¹⁶

Between 2012 and 2016, the CEOs of McKesson, AmerisourceBergen, and Cardinal Health received compensation packages worth more than \$450 million,¹¹⁷ and according to recent litigation, McKesson CEO John Hammergren received \$692 million in realized compensation between fiscal year 2008 and October 2017.¹¹⁸ Total 2017 compensation—including salary, cash awards, exercised options, vested stock, and the cash value of other perks—for the CEOs of McKesson, AmerisourceBergen, and Cardinal Health appears in Figure 12 below.

FIGURE 12: FY 2017 Compensation for Major Distributor CEOs¹¹⁹

Name	Company	Compensation
John H. Hammergren	McKesson	\$97,624,527
George S. Barrett	Cardinal Health	\$44,852,053
Steven H. Collis	AmerisourceBergen	\$16,172,171

E. Manufacturer Efforts to Monitor and Report Suspicious Orders

Like major distributors, high-volume generic manufacturers also employ certain sophisticated screening techniques before shipping opioid products to customers. According to Mallinckrodt, for example, the company begins by confirming the validity of DEA registrations for customers and conducting background checks and analyses of public information.¹²⁰ Similarly, Par Pharmaceutical, an Endo subsidiary that manufactures generic opioid products, requires “customers to complete initial and annual questionnaires regarding their [suspicious order monitoring] programs, and provide certain accompanying documentation.”¹²¹

Mallinckrodt also screens each incoming order for controlled substances through a “proprietary algorithm that evaluates the order in light of the customer's order history” and “orders being placed by similar customers. Any order flagged under the algorithm is held back from shipment, reported to DEA, and investigated.”¹²² Likewise, both Par Pharmaceutical and Endo Pharmaceuticals, which manufactures branded opioid products for Endo, employ algorithms to identify orders of interest and will halt flagged shipments.¹²³ Endo Pharmaceuticals also communicates cleared orders to a third-party logistics provider, which uses a separate algorithm to identify “orders of interest” for further review; the provider halts any order identified as “suspicious” after this additional scrutiny, and both DEA and Endo receive notifications.¹²⁴

Endo also produced to the Committee emails and correspondence between the company and its distributor customers concerning their obligations to monitor and report suspicious orders.¹²⁵ In this correspondence, employees of the Endo subsidiary Qualitest contacted distributor customers regarding orders of controlled substances that exceeded established parameters. In some cases, correspondence from Qualitest alerted distributors to secondary customers the company had identified as suspicious as a result of a review of chargeback data and due diligence information. A December 2014 letter to Morris & Dickson, for example, stated that “[a]fter reviewing the due diligence information provided, we are unable to justify the quantities of Hydrocodone sold” to “a list of customers identified while reviewing chargeback data.”¹²⁶ As a result, Qualitest requested that Morris & Dickson “immediately cease distribution and selling of Qualitest Hydrocodone to the customers listed because sales represent an undue risk as defined by the [Code of Federal Regulations].”¹²⁷ In the bulk of the exchanges detailed in the correspondence Endo produced to the Committee, however, a Qualitest representative attempted to determine the reason for an unusual order—and if the distributor customer provided a legitimate explanation, the representative released the shipment.¹²⁸

F. Manufacturer Monitoring of Chargeback Data

Both Mallinckrodt and Endo also undertake efforts to use data on “chargebacks”—an industry practice in which manufacturers reimburse distributors after their sales to pharmacies and other customers—to identify potentially suspicious opioid orders. As Mallinckrodt has explained in correspondence with the Committee, a “chargeback is a contractual payment from a manufacturer to a distributor made after a distributor sells a...product to the distributor's customer for less than the price the distributor paid...for the product.”¹²⁹ When requesting payments from manufacturers to cover this difference, distributors

provide sales information that, according to Mallinckrodt, "may provide...limited insight into the pharmacies that ultimately purchase...products from distributors."¹³⁰

Although Mallinckrodt has asserted that certain limitations exist regarding the usefulness of chargeback information,¹³¹ the company "regularly evaluates the overall purchasing patterns of downstream pharmacies and identifies any pharmacies that appear to be purchasing a potentially concerning quantity of opioid products."¹³² Mallinckrodt employees will then contact distributor customers selling to these pharmacies to determine "whether the pharmacies' purchasing volumes or patterns are readily explainable by legitimate factors."¹³³ If not, Mallinckrodt "can restrict chargebacks to distributors in connection with any Mallinckrodt product sold by the distributors to the downstream pharmacies in question."¹³⁴ The company also reports any decision to restrict chargebacks in connection with a particular pharmacy to DEA and other distributor customers.¹³⁵ According to Mallinckrodt, since 2012 the company has restricted chargebacks on distributor sales to approximately 175 pharmacies nationwide and reinstated approximately 59 pharmacies.¹³⁶

Through an operating company, Endo also reviews available chargeback data twice per year to identify "a customer facility of interest."¹³⁷ Following this identification, Endo may ask its distributor partner for due diligence information regarding the customer, may deny chargebacks, or may request that the distributor cease distributing Endo products to the customer and report the customer to DEA.¹³⁸

Relatedly, Mallinckrodt provided the Committee with hundreds of pages of correspondence between the company and its distributor partners regarding reviews of suspicious order information from certain pharmacies.¹³⁹ These letters include attachments listing pharmacies for which Mallinckrodt will no longer process chargeback requests from distributors. In a letter dated October 23, 2012, for example, Mallinckrodt explained to distributors that as a result of its suspicious order review process, the company would "no longer process chargebacks from distributor sales of Mallinckrodt's dosage pharmaceuticals products to the pharmacies identified on Attachment 1 hereto."¹⁴⁰ Attachment 1 for this letter listed two pharmacies in Poplar Bluff, Butler County, Missouri.¹⁴¹

As mentioned above, the Department of Justice alleged in 2017 that Mallinckrodt had "failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances."¹⁴² In announcing a \$35 million settlement agreement with Mallinckrodt, the Department reiterated its "position that controlled substance manufacturers need to go beyond 'know your customer' to use otherwise available company data to 'know your customer's customer' to protect these potentially dangerous pharmaceuticals from getting into the wrong hands."¹⁴³ In providing information on its chargeback program to the Committee, however, Mallinckrodt expressly noted that "there is no regulatory or legal requirement that Mallinckrodt undertake chargeback analysis."¹⁴⁴

G. Manufacturer On-Site Investigation of Distributor and Pharmacy Partners

Both Mallinckrodt and Endo conduct on-site investigations of their distributor partners. Mallinckrodt, for example, "conducts audits of its distributor customers to confirm that they maintain robust suspicious order monitoring programs of their own."¹⁴⁵ Similarly, Par Pharmaceutical, an Endo subsidiary, has "conducted site visit audits at customers' DEA-registered facilities."¹⁴⁶

Mallinckrodt also described to the Committee its limited on-site investigative efforts into diversion at the pharmacy level.¹⁴⁷ Information Mallinckrodt produced to the Committee indicates the company did not identify any substantiated examples of diversion at the pharmacy level in Missouri from 2012 to 2017 after investigation. According to Mallinckrodt, for example, company representatives performed only seven on-site visits for Missouri pharmacies during this period—with five of these visits occurring in September 2012—and in no case identified "issues warranting Mallinckrodt's restriction of chargeback payments to distributors that sold product to the audited pharmacy."¹⁴⁸ Instead, the company

"[a]dvised and reminded [the] pharmacy of common anti-diversion practices and referred [the] pharmacy to [the] DEA website for more information."¹⁴⁹ (In a briefing with Committee staff, Endo noted that the branded manufacturing arm of the company does not ship to or see ordering patterns from pharmacies; Par Pharmaceutical, which manufactures generic Endo products, also does not distribute to pharmacies and lacks the ability to investigate or audit these entities.¹⁵⁰)

Mallinckrodt did, however, note in correspondence with the Committee that "[a]udits identified a pain clinic (Advanced Pain Center) that was a significant prescriber at certain of these pharmacies and notified DEA accordingly."¹⁵¹ In 2010, according to the *St. Louis Business Journal*, the owners of six pain management clinics operating in Missouri under the Advanced Pain Center name paid an \$820,000 settlement to resolve "allegations of submitting false claims to Medicare, Medicaid and Tricare."¹⁵² In 2013, DEA agents raided several Advanced Pain Center locations in Missouri,¹⁵³ and in 2015, the owner of the company entered a settlement agreement with the Missouri Board of Registration for the Healing Arts in which he agreed to place his license on probation until August 2019.¹⁵⁴ (The owner had previously entered a similar probation term with the Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, in 2014.¹⁵⁵)

H. Manufacturer Questionnaires to Distributor Partners

Both Mallinckrodt and Endo also distribute questionnaires to their distributor partners seeking information on suspicious order monitoring activities, although the depth of the information requested varies by manufacturer. Mallinckrodt, for example, issues relatively straightforward surveys requesting yes/no answers to questions concerning whether a distributor maintains a suspicious order monitoring program in compliance with federal requirements at 21 C.F.R. 1301.47(b); whether the distributor complies with state laws; and whether the distributor monitors pharmacy customers for suspicious activities associated with the diversion of controlled substances.¹⁵⁶ Mallinckrodt questionnaires also include a prompt for more detailed explanation in the event a distributor answers "no" to any question.¹⁵⁷

In contrast, the questionnaires Endo submits to its distributor partners consist of five sections with over 30 questions, including prompts for written answers and instructions to provide summaries describing suspicious order monitoring procedures.¹⁵⁸ Endo questionnaires also request that distributor respondents attach documentation regarding any suspension or revocation of their DEA registration, any crimes certain employees have committed relating to the distribution of controlled substances, or any disciplinary action against the distributor at the state level.¹⁵⁹

CERTAIN DISTRIBUTORS AND MANUFACTURERS HAVE CRITICIZED DEA APPROACHES TO ENFORCEMENT

While undertaking comparable efforts to prevent opioid diversion, major distributors and manufacturers have also expressed similar criticisms regarding DEA enforcement activities and a lack of information sharing that could potentially aid CSA compliance. Most prominently, these companies have claimed DEA has provided unclear or inconsistent explanations regarding the definition of "suspicious" orders and the extent of registrant obligations to investigate potential opioid diversion.

Although DEA outreach and administrative decisions appear to have provided extensive direction to distributors, the recent investigation of Mallinckrodt suggests DEA may have provided conflicting guidance to manufacturers. At a minimum, confusion among distributors and manufacturers—and the divergent compliance results shown above—highlights the importance of continued DEA outreach efforts to industry.

A. Distributor Concerns

In a letter to Ranking Member McCaskill in November 2017, distributors argued that “[f]or many years... a lack of communication and information sharing from DEA to its registrants—pharmacies, healthcare providers, manufacturers and distributors—exacerbated the challenges and weakened any system-wide efforts to counter the opioid crisis.”¹⁶⁰ According to the Healthcare Distribution Alliance (HDA)—the major trade association for drug distributors—“communication between the DEA, which serves as the primary regulator for controlled substances, and DEA registrants certified to handle controlled substances...was virtually non-existent [prior to 2016]. Despite many requests for clarity, the DEA too often did not help pharmacies, doctors and distributors understand exactly how the DEA wanted them to operate and what information the DEA wanted them to report.”¹⁶¹

Current and former DEA officials have disagreed with these criticisms from distributors. Acting DEA Administrator Robert W. Patterson explained in March 2018 testimony that the “Diversion Control Division has...worked to improve communication and cooperation with the registrant community. As an example of this outreach, DEA offers year-round training free of charge to pharmacists, distributors, importers, and manufacturers.”¹⁶² In remarks during a HSGAC minority roundtable in November 2017, Joseph Rannazzisi, former head of the DEA Office of Diversion Control, also described face-to-face efforts by DEA to educate distributors on their obligations.¹⁶³ These efforts included meetings in 2006 “where [DEA] explained what their obligations were under the law”:

We showed them what a suspicious order is. We showed them why it was suspicious. We showed ordering patterns that showed that they were doing something that they probably should not be doing. And then with that information—we gave them binders of information, we gave them their own ARCOS reports—and with that information we sent them back out and said “now you should have the tools.” Then we also went to distributor conferences. We had our own distributor conferences. And every time we met we told them what their obligations were under the law.¹⁶⁴

Mr. Rannazzisi also described two prominent administrative decisions that supplemented the letters DEA sent to distributors and the briefings it held with company representatives.¹⁶⁵ According to Mr. Rannazzisi and other former DEA officials, these decisions regarding Southwood Pharmaceuticals, Inc., and Masters Pharmaceuticals, Inc., represented important milestones in the effort to establish parameters for distributor behavior.¹⁶⁶ In particular, the Masters decision and order from Acting DEA Administrator Chuck Rosenberg—later upheld by the U.S. Court of Appeals for the D.C. Circuit¹⁶⁷—provided detailed information on the definition of “suspicious” orders and the investigative responsibilities of distributors.¹⁶⁸

Finally, distributors have also “repeatedly asked DEA to share data showing the amount of controlled substances that individual pharmacies receive from all of their suppliers.”¹⁶⁹ Although DEA collects opioid shipment reporting from all distributors in the ARCOS database, HDA has noted that “[d]istributors are only aware of the amount that their company has shipped. Only DEA, through its ARCOS database, has the complete picture of the totality of distributors serving an individual customer. To date, distributors still do not have access to this critical data.”¹⁷⁰ HDA President and CEO John Gray has further argued that aggregated, blinded ARCOS data could “allow wholesale distributors to consider a customer’s orders in the context of that entity’s overall ordering. This would provide additional data points in determining whether an order is suspicious.”¹⁷¹ (In February 2018, DEA added a feature to ARCOS to allow manufacturers and distributors “to view the number of competitors who have sold a particular controlled substance to a prospective customer in the last six months.”¹⁷²)

B. Manufacturer Concerns

Like major distributors, Mallinckrodt has also criticized DEA for imposing unreasonable standards for monitoring and reporting suspicious orders and providing conflicting advice on compliance efforts. Mallinckrodt has “said that it should not be held responsible for what happens to its drugs once the distributors send them to their customers, such as doctors and pharmacies” and has “contended that the DEA has never required manufacturers to know their customers’ customers and that the agency provided the company with conflicting advice about its responsibilities under the law.”¹⁷³ Descriptions of an internal case summary by DOJ prosecutors from August 2014 appear to support this view, at least in part; prosecutors reportedly “noted that the DEA had provided conflicting guidance to Mallinckrodt about its responsibilities to report suspicious orders from retailers.”¹⁷⁴ For example, although the DEA supervisor in St. Louis, Missouri, reportedly notified Mallinckrodt of its responsibility to monitor pharmacies and physicians—as well as distributors—in 2010, a DEA investigator in New York expressed ignorance of obligations to “know your customer’s customer and [stated] that the regulations do not reflect such a requirement” during the same year.¹⁷⁵

Mallinckrodt echoed language above in correspondence with the Committee, asserting that “[b]ecause DEA has declined to provide clear guidance regarding whether manufacturers should report orders flagged for further investigation—or only those ultimately not filled after investigation—Mallinckrodt has adopted a more conservative approach and reports all flagged orders.”¹⁷⁶ As mentioned previously, this result appears in contrast to the approach Endo adopted between 2012 and 2017, whereby the company reviewed potential suspicious orders but ultimately filed no related reports with DEA during the five-year period.

DECLINING DEA ANTI-DIVERSION EFFORTS MAY EXPLAIN DISPARATE INDUSTRY COMPLIANCE RESULTS

The discrepancies in suspicious order reporting and other anti-diversion practices described above occurred against the backdrop of declining DEA administrative enforcement from 2011 to the present. According to former DEA officials, the revolving door between the agency and the distribution industry created an institutional resistance to issuing immediate suspension orders (ISOs)—the most potent enforcement action available to diversion control officials—against major distributors. In fact, DEA did not issue an ISO against a distributor or a manufacturer between 2012 and 2017, according to information the minority staff has reviewed.¹⁷⁷ In 2016, the Ensuring Patient Access and Effective Drug Enforcement Act formally heightened standards for ISOs—eliminating, as Chief Administrative Law Judge John J. Mulrooney II has explained, even the credible threat of the most impactful DEA enforcement tool.

As Frank Younker, former diversion group supervisor of the DEA Cincinnati field office, explained during a HSGAC roundtable in November 2017, ISOs were “in essence, the only way to get a distributor or manufacturer or large pharmacy chain to listen and comply with its obligations under the CSA. During my time at DEA, it seemed to me that these larger corporations in the industry were not interested in doing the right thing, at least not until their profits were hurt and their names were being tied to the opioid epidemic in the headlines.”¹⁷⁸ Jonathan Novak, a former DEA enforcement attorney, agreed, noting that “it seems like the only time that any of the distributors and manufacturers want to listen is when it is hurting their bottom line. If we cannot stop them, we cannot affect their bottom line; they have no reason to listen, not just for goodwill.”¹⁷⁹

The two overlapping trends described in this report—disparities in industry compliance behavior and declining DEA enforcement—suggest, at the very least, a connection between weak DEA oversight

and varying anti-diversion efforts. Without the serious threat of an ISO to spur industry compliance, distributors may lack the incentive to fully adhere to their responsibilities under the CSA. As Ranking Member McCaskill explained during the November 2017 roundtable, “[t]he ISO statute was a deterrent to some of the largest companies in America, that there were serious and significant consequences if they did not do it by the book. When you remove that deterrent, then things get even sloppier, and when things get sloppy in the area of opioids, people die.”¹⁸⁰

A. DEA Enforcement Efforts Declined After 2011

Information the minority staff has reviewed suggests that changing agency standards for enforcement action—later codified in the 2016 law—have impacted enforcement efforts on multiple fronts. In a 2014 report, for example, Chief Administrative Law Judge John J. Mulrooney II noted “an alarmingly low rate of Agency Diversion enforcement activity on a national level relative to historical data.”¹⁸¹ In a report later the same year, Judge Mulrooney described “an unprecedented year in the Agency for lack of administrative enforcement actions [n]otwithstanding the most current Center for Disease Control data which reflects that controlled-drug overdose deaths are at record levels and still on the increase.”¹⁸²

In fact, according to a quarterly report Judge Mulrooney filed in October 2017, the total number of charging documents DEA has issued has fallen since 2010, while the percentage of charging documents requiring essentially no action on the part of DEA has risen.¹⁸³ (Judge Mulrooney has explained that in “no state authority” or NSA cases—“summary disposition cases where the various states have acted on their own to abrogate controlled substance authority”—“DEA’s role is essentially a paper drill.”¹⁸⁴) Judge Mulrooney also noted in his October 2017 report that “8 DEA states/areas of responsibility have filed no administrative charging document in over 7 years...and 19 states/areas of responsibility have filed 2 or less cases.”¹⁸⁵ See Figure 13.

FIGURE 13: DEA Charging Documents and Claims, 2010-2017¹⁸⁶

Fiscal Year	Total Charging Documents	NSA (% of total charging documents)	Charging Documents Without NSA Claims
2010	113		
2011	125		
2012	99		
2013	64		
2014	41	14 (34%)	23 (56%)
2015	69	23 (33%)	27 (39%)
2016	64	34 (53%)	21 (33%)
2017*	87	46 (53%)	32 (37%)

*As of 9/30/17

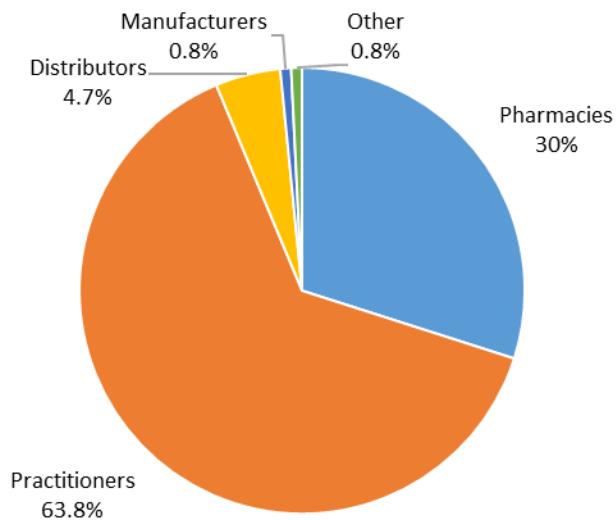
According to information the Committee has received from DEA, moreover, ISOs against all DEA registrants fell from 58 in 2011 to eight in 2014, with five orders in 2015, nine in 2016, and six in 2017.¹⁸⁷ Less severe enforcement actions, including orders to show cause and letters of admonition, remained at relatively consistent levels during the same time period.¹⁸⁸ These statistics suggest the willingness of DEA to issue ISOs had already changed dramatically years before the passage of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016. See Figure 14.

FIGURE 14: Orders to Show Cause and Immediate Suspension Orders, 2011-2018¹⁸⁹

Fiscal Year	Orders to Show Cause Filed	Immediate Suspension Orders Filed
2011	66	58
2012	54	46
2013	43	16
2014	32	8
2015	62	5
2016	57	9
2017	79	6
2018*	40	10

*As of 5/01/2018

A further breakdown of ISO statistics shows that DEA did not issue an ISO to a pharmaceutical distributor or manufacturer between fiscal years 2012 and 2017. Instead, each ISO during that period applied to pharmacies and practitioners. According to a former assistant special agent in charge of the DEA Denver field division, DEA attorneys would frequently ask: "Why would you go after a Fortune 50 company that's going to cause all these problems with Ivy League attorneys, when we can go after other [DEA registrants] that are much lower, that are going to put up no fight?"¹⁹⁰ In total, around 30% of ISOs between 2007 and 2017 applied to pharmacies, 63.8% applied to practitioners, and only 4.7% and 0.8% applied to distributors and manufacturers, respectively. See Figure 15. In total, DEA issued only 12 ISOs to distributors between fiscal years 2007 and 2017.¹⁹¹

FIGURE 15: Percentage of ISOs by Party, 2007-2017¹⁹²

This relatively small total might suggest that internal policy changes inside DEA had a minimal effect on overall enforcement efforts against distributors; however, according to former DEA officials—including Frank Younker, former diversion group supervisor of the Cincinnati field office—even the credible threat of an ISO represented a powerful tool for changing distributor behavior.¹⁹³ And as Mr. Rannazzisi noted during the HSGAC roundtable on DEA enforcement Ranking Member McCaskill held in November 2017, “[h]istorically, the ISO was judiciously deployed in the most egregious circumstances as an action of last resort.”¹⁹⁴

According to DEA, the decline in ISOs “does not completely reflect other efforts of DEA and its partners in continuing programs to address this important issue,” including increased diversion personnel, stronger state laws to curb diversion, and a greater emphasis on the use of prescription drug monitoring programs.¹⁹⁵ DEA has also pointed to the greater role of tactical diversion squads, which it claims have boosted voluntary surrenders of DEA registrations for cause through their criminal investigations.¹⁹⁶ See Figure 16.

FIGURE 16: Tactical Diversion Squad Arrests, Case Initiations, and Voluntary Surrenders

Year	Number of Arrests	Case Initiations (Opened)	Voluntary Surrenders
2011	1,577	1,185	839
2012	1,710	1,345	979
2013	1,715	1,454	1,047
2014	2,525	1,747	922
2015	2,568	1,647	972
2016	2,109	1,591	786
2017*	1,950	1,565	776

*As of 9/21/2017

Mr. Rannazzisi, however, has explained that pursuing voluntary surrenders of DEA registrations is simply not a viable tactic against most drug distributors, which have a strong incentive—and the financial means—to contest DEA actions.¹⁹⁷ In fact, information from DEA shows that only 22 distributors have voluntarily surrendered their DEA registrations between 2011 and 2017, and this list does not include McKesson, AmerisourceBergen, or Cardinal Health. As Mr. Rannazzisi explained in November 2017, when DEA officials point to voluntary surrenders as effective enforcement tools, “they just show their ignorance of the law. A voluntary surrender is not an immediate suspension order. [...] [With a] voluntary surrender, the agency is at the behest of the company. And I have asked for voluntary surrenders, and big companies do not want to give it.”¹⁹⁸ See Figure 17.

FIGURE 17: Voluntary Surrenders of DEA Registrations by Distributors, 2011-2017

Name	City	State
Krs Global Biotechnology, Inc.	West Palm Beach	FL
Marnel Pharmaceuticals	New Orleans	LA
Keysource Medical	Cincinnati	OH
Aidapak Services, LLC	Seattle	WA
Ct International	Los Angeles	CA
Onsite Meds, Inc.	Birmingham	AL
Nulife Pharmaceuticals, Inc.	Los Angeles	CA
Trump Wholesale Pharmaceutical, Inc.	Miami	FL
Martin Surgical Supply Co.	Houston	TX
Vertical Source Pharma Inc.	Miami	FL
Ameridose, LLC	Boston	MA
Sircle Laboratories, LLC	Jackson	MS
Westside Medical Supply	Houston	TX
Value Drug Co.	Pittsburgh	PA
Goodwin Drug Co.	Charleston	WV
Anda Puerto Rico, Inc.	San Juan	PR
Axiscare Health Logistics, Inc.	San Juan	PR
Fox Health Care Co., Inc.	Salt Lake City	UT

Name	City	State
Patterson Veterinary Supply, Inc.	Columbus	OH
Safe Prep International LLC	Greensboro	NC
Cina Pharmaceutical Inc.	Houston	TX
Frank W Kerr Inc.	Detroit	MI

Despite alleged changes to ISO standards, however, DOJ has recently levied significant civil penalties against distributors, as mentioned above. After penalties declined from around \$80 million in 2013 to a little over \$100,000 in 2016, DOJ assessed civil penalties of nearly \$200 million in 2017. See Figure 18. According to DEA, the total fine amount since FY 2011 “includes fines levied against CVS Pharmacy, Inc., (\$50 million in FY 2011); Walgreens (\$80 million in FY 2013); McKesson (\$150 million in FY 2017) and Cardinal and Kinray (\$44 million in FY 2017).”¹⁹⁹ According to March 2018 testimony from Acting DEA Administrator Robert W. Patterson, DOJ “has levied fines totaling nearly \$390 million against opioid distributors nationwide” over the past decade.²⁰⁰

FIGURE 18: Civil Penalties Paid by Controlled Substances Distributors, 2010-2017

Fiscal Year	Civil Penalties
2010	\$3,073,496
2011	\$58,315,000
2012	\$493,276
2013	\$80,015,000
2014	\$4,000,000
2015	\$865,000
2016	\$115,000
2017	\$194,200,000

Yet these most recent settlements, coming years after compliance failures by distributors, raise the implication that DEA actions have been “too little, too late.”²⁰¹ McKesson, for example, paid \$13.25 million to settle allegations regarding three of its warehouses—and “millions of dosage units of controlled substances...diverted from legitimate channels”—nine years before its January 2017 settlement.²⁰² In 2008, Cardinal Health paid a \$34 million fine after its warehouses filled “thousands of suspicious orders from Internet pharmacies without reporting them,” but DEA investigators later found evidence of widespread drug diversion at a Cardinal Health client in 2010, and the company settled a related administrative case without paying a fine in 2012.²⁰³ Similarly, an AmerisourceBergen warehouse previously escaped paying a fine to DEA in 2007 “amid allegations that it was not controlling shipments of hydrocodone.”²⁰⁴

These fine amounts also pale in comparison to the revenue each distributor reported for the years in which DEA levied fines. The \$150,000,000 fine McKesson paid in 2017, for example, amounts to only .08% of FY 2017 revenue for the company.²⁰⁵ Similarly, the \$44,000,000 fine Cardinal paid in late 2016 amounts to only .03% of annual revenue.²⁰⁶ (The generic manufacturer Mallinckrodt paid a comparable fine—\$35,000,000—in January 2017, which only comprised a little over 1% of the net sales the company recorded for the year ending December 29, 2017.²⁰⁷)

FIGURE 19: McKesson and Cardinal Health Fines and Revenue²⁰⁸

Company	FY 2017 Fines	FY 2017 Revenue	Fines as Percent of Revenue
McKesson	\$150,000,000	\$198,533,000,000	0.08%
Cardinal Health	\$44,000,000	\$129,976,000,000	0.03%

B. The Revolving Door Between DEA and Industry Has Significantly Impacted Enforcement Efforts

Statements from a roundtable Ranking Member McCaskill held on November 28, 2017, news accounts of internal agency deliberations, and interviews with former senior officials suggest the revolving door between DEA and industry significantly impacted enforcement efforts from 2011 to the present.

This alleged revolving door phenomenon at DEA has led ethics experts to raise “serious questions about whether the ability of the diversion division to carry out its mission has been compromised by the pharmaceutical industry.”²⁰⁹ In fact, “beginning in 2013, some officials at DEA headquarters began to block and delay enforcement actions against wholesale drug distributors and others, frustrating investigators in the field.”²¹⁰ Specifically, DEA leadership allegedly required a higher burden of proof—“beyond a reasonable doubt” instead of “a preponderance of evidence”—before allowing enforcement actions against distributors to proceed.²¹¹

According to Mr. Younker, DEA attorney Clifford Lee Reeves II warned of vague agency standards and stated “that we were going to lose all of our cases and we didn’t have enough information to go forward.”²¹² As Mr. Novak has explained, “discussions turned to an almost palpable fear that if DEA utilized the ISO, and one of these larger companies challenged the ISO, DEA could receive a bad ruling against it in federal court, which could ultimately take away DEA’s ability to use the ISO at all.”²¹³ When the number of ISOs and DEA civil cases filed against distributors and other registrants dropped starting in 2011, Mr. Younker noticed a significant effect on his work in the field. As he explained to Ranking Member McCaskill in November 2017, Mr. Younker felt DEA had “a prosecutor that lost the...respect of the people in the field.”²¹⁴ In a call, Mr. Younker complained to Mr. Reeves that “these cases are lingering here, they’re down in your shop for six to 12 months.”²¹⁵

DEA has denied in correspondence with the Committee that its attorneys have required a higher standard of proof before proceeding with civil cases, asserting that “the ultimate legal question to be decided is, and remains, whether, by a preponderance of the evidence, the DEA registrant’s continued registration is ‘in the public interest.’”²¹⁶ Accordingly, DEA has denied (and DEA officials have disputed in testimony) reporting from the *Washington Post* that the burden of proof for administrative cases changed from a “preponderance of the evidence” to “beyond a reasonable doubt.”²¹⁷ Former DEA employees, however, have claimed in conversations with minority staff that while officials did not formally change the standard, they unofficially raised the bar for proceeding with enforcement actions.²¹⁸

In response to these allegations, Ranking Member McCaskill requested that the Department of Justice Office of the Inspector General (DOJ OIG) investigate whether DEA has the capacity to hold distributors accountable for their lack of diversion oversight.²¹⁹ On June 1, 2017, DOJ OIG announced it would undertake this review.²²⁰

C. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 Has Further Undermined DEA Enforcement Efforts

The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 passed the Senate by unanimous consent on March 17, 2016, and became law on April 19, 2016.²²¹ Sponsored by Sen. Hatch and Sen. Whitehouse and Representatives Marino and Blackburn in the House, the bill purported to “improve enforcement efforts related to prescription drug diversion and abuse” by altering DEA procedures for revoking or suspending registrations under the CSA.²²² The bill amended the revocation and suspension process in two critical ways:

- Before revoking or suspending a registration under normal circumstances, the DEA must now “notify...the registrant of the opportunity to submit a corrective action plan on or before the date of appearance.” DEA must then determine whether “denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.”
- DEA can also suspend a registration immediately when it finds an “imminent danger to the public health or safety.” The 2016 bill, however, defines this term as “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.”²²³

The Washington Post has explained that the 2016 bill “was the crowning achievement of a multifaceted campaign by the drug industry to weaken aggressive DEA enforcement efforts against drug distribution companies.”²²⁴ In fact, according to an October 2017 report, the legislation “effectively stripped the Drug Enforcement Administration of its most potent weapon against large drug companies suspected of spilling prescription narcotics onto the nation’s streets.”²²⁵ Mr. Rannazzisi—a major critic of the law—has claimed that the new standard for immediate suspension makes it so “[t]here’s no way that we could meet that burden...because immediate, by definition, means right now.”²²⁶ The requirement that DEA consider a corrective action plan before issuing a show cause order also provided “the industry something it had desperately sought: protection from having its drugs locked up with little notice.”²²⁷

The 2016 bill also received support from a number of patient advocacy groups and professional societies—many of which were funded in part by opioid manufacturers.²²⁸ In a letter dated March 4, 2015, for example, the American Academy of Pain Management, the American Society for Pain Management Nursing, and the U.S. Pain Foundation—among other groups—argued that the legislation would “improve the balance between effective enforcement against prescription drug diversion and abuse, while ensuring patients who are appropriately prescribed medications continue to have access to their treatments.”²²⁹ Similarly, the Academy of Integrative Pain Management, the American Society for Pain Management Nursing, and the U.S. Pain Foundation, among other groups, sent a letter in November 2017 praising the 2016 law and warning that “unchecked DEA authority can result in profound consequences for chronic pain sufferers.”²³⁰ John Gray, President and CEO of the Healthcare Distribution Alliance, later mentioned the advocacy from these groups in his testimony to the U.S. Senate Committee on the Judiciary.²³¹

As Ranking Member McCaskill showed in the February 2018 report titled, “Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups,” the Academy of Integrative Pain Management, the American Society for Pain Management Nursing, and the U.S. Pain Foundation received \$1,265,566.81, \$323,212.85, and \$2,922,800, respectively, from a number of major opioid manufacturers between 2012 and 2017.²³²

On October 16, 2017, Ranking Member McCaskill introduced legislation repealing amendments the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 made to the CSA.²³³ On November 14, 2017, attorneys general for 42 states, the District of Columbia, and the U.S. Virgin Islands wrote in support of the repeal.²³⁴ In their letter, the bipartisan group stated that the law “neither safeguards patient access to medication nor allows for effective drug enforcement efforts.”²³⁵ Accordingly, the group urged Congress “to repeal the act so that the public is protected and drug manufacturers and distributors may be held accountable for their actions.”²³⁶

In recent months, current DEA officials have recognized the impact of the 2016 law on DEA enforcement efforts, as well as the need to amend or repeal the law to ensure proper oversight of the distribution industry. In her written testimony before the U.S. Senate Committee on the Judiciary on December 12, 2017, for example, Acting DEA Assistant Administrator Demetra Ashley stated that “DEA

supports changing the Ensuring Patient Access and Effective Drug Enforcement Act, to allow DEA to more effectively stop bad actors from engaging in opioid diversion.²³⁷ Ms. Ashley also noted during the hearing that “the new standard does make it more difficult to issue an [immediate suspension order] to non-compliant manufacturers and distributors.”²³⁸

Similarly, in a February 2018 letter to Chairman Greg Walden of the House Committee on Energy and Commerce, Assistant Attorney General Stephen E. Boyd recommended replacing the “substantial likelihood” standard in the 2016 law with a “probable cause” standard.²³⁹ The Department of Justice and DEA also recommended that Congress remove the language regarding corrective action plans in the law; Mr. Boyd noted that allowing distributors to “submit [these plans] to DEA is duplicative, as a registrant has always had the opportunity to present mitigating factors and evidence of corrective action as part of any administrative proceeding.”²⁴⁰

CONCLUSION

While the divergent suspicious order reporting outcomes discussed above in no way indicate violations of the Controlled Substances Act, they do highlight the difficulties involved in ensuring similar compliance levels among major distributors and manufacturers. These difficulties exist despite the highly sophisticated—and substantially similar—efforts these companies have undertaken to monitor and report suspicious opioid orders. Varying compliance results may also reflect declining DEA enforcement efforts since 2011—a period in which, according to former DEA officials, the agency disfavored the use of immediate suspension orders against major distributors. As Ranking Member McCaskill has stated, without at least the credible threat of an ISO at its disposal, DEA will struggle to achieve sufficient compliance among companies with well-documented histories of lax anti-diversion approaches. Repealing the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 will serve as a critical first step to avoid this outcome and stem the excessive flow of prescription opioids into American communities.

¹ Department of Justice: *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017) (www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

² Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 (Mar. 2016) (ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

³ See, e.g., Letter from Sen. Claire McCaskill to John H. Hammergren, Chairman, President, and CEO, McKesson Corporation (July 26, 2017).

⁴ *Id.*

⁵ See, e.g., Letter from Sen. Claire McCaskill to Paul V. Campanelli, President and CEO, Endo International plc (July 26, 2017).

⁶ See, e.g., Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017); Letter from Counsel for Cardinal Health, Inc., to Sen. Claire McCaskill (Sept. 29, 2017).

⁷ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017); Email from Mark Tyndall to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017); Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).

⁸ Letter from Counsel for Teva to Sen. Claire McCaskill (Aug. 30, 2017).

⁹ *Id.*

¹⁰ Letter from Sen. Claire McCaskill to CEO Kåre Schultz (Sept. 28, 2017).

¹¹ *Id.*

¹² *Id.*

¹³ Letter from Counsel for Teva to Sen. Claire McCaskill (Oct. 5, 2017).

¹⁴ *Id.*

¹⁵ Letter from Sen. Claire McCaskill to Chairman Ron Johnson (Dec. 21, 2017).

¹⁶ Letter from Chairman Ron Johnson to Sen. Claire McCaskill (Jan. 12, 2018).

¹⁷ Sen. Claire McCaskill: *Teva is Stonewalling a Senate Investigation* (Mar. 6, 2018).

- ¹⁸ See Senator Expands Probe into Opioid Addiction Crisis, Wall Street Journal (July 27, 2017) (www.wsj.com/articles/senator-expands-probe-into-opioid-addiction-crisis-1501158600).
- ¹⁹ Letter from Sen. Claire McCaskill to Chairman, President, and CEO Brenton L. Saunders (May 21, 2018).
- ²⁰ Letter from Counsel for Allergan to Sen. Claire McCaskill (May 29, 2018).
- ²¹ *Id.*
- ²² *Id.*
- ²³ *Id.*
- ²⁴ *Id.*
- ²⁵ Missouri Department of Health and Senior Services, Bureau of Vital Statistics, Deaths Due to Opioid Overdoses by County of Residence 2012-2016 (County Data Table) (2017) (health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-4.pdf).
- ²⁶ Kaiser Family Foundation, Prescription Opioid Overdose Deaths and Death Rate per 100,000 Population (Age-Adjusted) (2017) (www.kff.org/other/state-indicator/prescription-opioid-overdose-deaths-and-death-rate-per-100000-population-age-adjusted/).
- ²⁷ Department of Health and Human Services, Centers for Disease Control and Prevention, Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017 (Mar. 9, 2018) (www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm).
- ²⁸ Missouri Department of Health and Senior Services, Bureau of Vital Statistics, Quarterly Missouri Resident Heroin and Non-Heroin Opioid Deaths 2013-2017 (Chart) (2017) (health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-11.pdf).
- ²⁹ See Department of Justice, Drug Enforcement Administration, 2016 ARCOS Retail Drug Summary Report (www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf) (accessed May 14, 2018).
- ³⁰ Over-Prescribing of Opioid Painkillers Abounds in St. Louis County's First Year of Monitoring, St. Louis Post-Dispatch (May 3, 2018) (www.stltoday.com/news/local/metro/over-prescribing-of-opioid-painkillers-abounds-in-st-louis-county/article_a4cf1028-85d3-5de5-ac15-8709951b3183.html).
- ³¹ Missouri Division of Professional Registration, Missouri Board of Pharmacy, Board Disciplinary Actions (Apr. 3, 2018) (pr.mo.gov/boards/pharmacy/805458.pdf).
- ³² Settlement Agreement between Missouri Board of Pharmacy and Bruner's Pharmacy, Complaint No. 2015-00863 (Nov. 29, 2017) (pr.mo.gov/boards/pharmacy/ORDERS/PHY-004952.pdf).
- ³³ Stipulation for Cause to Discipline Nyberg Pharmacy, Case No. 15-00074 PH (July 20, 2015) (pr.mo.gov/boards/pharmacy/orders/PHY-004441.pdf).
- ³⁴ Settlement Agreement between State Board of Pharmacy and People's Health Centers, Inc. dba People's Health Center Pharmacy, Complaint No. 2014-005633 (Jan. 28, 2016) (pr.mo.gov/boards/pharmacy/orders/PHY-005971.pdf).
- ³⁵ *Id.*
- ³⁶ *Id.*
- ³⁷ See Settlement Agreement between State Board of Pharmacy and Missouri CVS Pharmacy LLC d/b/a CVS Pharmacy #5724, Complaint No. 2013-002238 (Oct. 9, 2014) (pr.mo.gov/boards/pharmacy/orders/PHY-2009008131.pdf) (involving 4,760 hydrocodone/APAP dosage units); Settlement Agreement between Missouri Board of Pharmacy and Walgreens #03598 (June 26, 2017) (pr.mo.gov/boards/pharmacy/orders/PHY-005928.pdf) (involving 1,457 hydrocodone/acetaminophen dosage units, 695 oxycodone dosage units, and 1,988 tramadol dosage units); Settlement Agreement between Missouri Board of Pharmacy and Walgreens #04236 (June 26, 2017) (pr.mo.gov/boards/pharmacy/orders/PHY-006484.pdf) (involving 4,246 hydrocodone/APAP dosage units and 3,254 oxycodone/acetaminophen dosage units); Settlement Agreement between State Board of Pharmacy and Walgreens #7185 (Nov. 20, 2015) (pr.mo.gov/boards/pharmacy/orders/PHY-003418.pdf) (involving 254 Norco dosage units, 2,918 Percocet dosage units, and 16 Tussi-Caps dosage units); Settlement Agreement (Mar. 2, 2016) (pr.mo.gov/boards/pharmacy/orders/PHY-2000157695.pdf) (involving 24,495 hydrocodone/APAP dosage units); Settlement Agreement between Missouri Board of Pharmacy and Walgreens #04212 (Aug. 7, 2017) (pr.mo.gov/boards/pharmacy/ORDERS/PHY-006322.pdf) (involving 2,462 hydrocodone/acetaminophen dosage units and 8,067 oxycodone/APAP and oxycodone IR dosage units).
- ³⁸ *Id.*
- ³⁹ Department of Justice: Local Doctor Indicted on Federal Drug Charges (Oct. 17, 2013) (www.justice.gov/usao-edmo/pr/local-doctor-indicted-federal-drug-charges).
- ⁴⁰ *Id.*
- ⁴¹ Department of Justice: Former Bolivar Clinic Physician Pleads Guilty to Illegally Dispensing Narcotics (Apr. 9, 2013) (www.justice.gov/usao-wdmo/pr/former-bolivar-clinic-physician-pleads-guilty-illegally-dispensing-narcotics).
- ⁴² *Id.*
- ⁴³ *Id.*
- ⁴⁴ Modern Distribution Management, 2017 Top Distributors MDM Market Leaders | Top Pharmaceutical Distributors (2018) (www.mdm.com/2017-top-pharmaceuticals-distributors).
- ⁴⁵ Fortune, Fortune 500 (fortune.com/fortune500/list/) (accessed Apr. 12, 2018).
- ⁴⁶ Securities and Exchange Commission, Form 10-K Submitted by McKesson Corporation (Commission File Number: 1-13252) (May 22, 2017) (www.sec.gov/Archives/edgar/data/927653/000092765317000007/mck_10kx3312017.htm); Securities and Exchange Commission, Form 10-K Submitted by AmerisourceBergen Corporation (Commission File Number: 1-16671) (Nov. 11, 2017) (www.sec.gov/Archives/edgar/data/1140859/000114085917000047/abc10-kxseptember302017.htm); Securities and Exchange Commission, Form 10-K Submitted by Cardinal Health, Inc.

(Commission File Number: 1-11373) (Aug. 10, 2017) (www.sec.gov/Archives/edgar/data/721371/000072137117000083/a17q4_10kx63017xform10-k.htm).

⁴⁷ See 21 C.F.R. 1301.74(b).

⁴⁸ How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Washington Post (Oct. 22, 2016) (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).

⁴⁹ *Id.*

⁵⁰ Department of Justice: McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017) (www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders).

⁵¹ Department of Justice: Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016) (www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act). This settlement also resolved "a civil investigation in the Western District of Washington concerning alleged violations of CSA record keeping requirements."

⁵² The Government's Struggle to Hold Opioid Manufacturers Accountable, Washington Post (Apr. 2, 2017) (www.washingtonpost.com/graphics/investigations/dea-mallinckrodt).

⁵³ Mallinckrodt Settles U.S. Opioid Drug Probe for \$35 Million, Reuters (July 11, 2017) (www.reuters.com/article/us-mallinckrodt-settlement-idUSKBN19W2EL).

⁵⁴ The Government's Struggle to Hold Opioid Manufacturers Accountable, Washington Post (Apr. 2, 2017).

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Securities and Exchange Commission, Form 10-K Submitted by Mallinckrodt Public Limited Company (Commission File Number: 001-35803) (Feb. 27, 2018) (www.sec.gov/Archives/edgar/data/1567892/000156789218000010/mnk10-k122917.htm).

⁵⁸ Securities and Exchange Commission, Form 10-Q Submitted by Mallinckrodt Public Limited Company (Commission File Number: 001-35803) (Aug. 8, 2017) (www.sec.gov/Archives/edgar/data/1567892/000156789217000027/mnk10-q063017.htm).

⁵⁹ Securities and Exchange Commission, Form 8-K Submitted by Endo International PLC (Commission File Number: 001-36326) (Jan. 11, 2018) (investor.endo.com/static-files/28d4f332-f141-424d-bb12-a7869219344f).

⁶⁰ Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-228 (Mar. 2016) (ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

⁶¹ *Id.*

⁶² See, e.g., Plaintiff's Complaint for Violation of Michigan Consumer Protection Act, Public Nuisance, Negligence, Unjust Enrichment, and Violation of Racketeer Influenced and Corrupt Organization Act (Jan. 22, 2018) County of Monroe v. Purdue Pharma L.P., et al., E.D. Mich. (No. 2:18 CV 10251).

⁶³ Complaint (Oct. 12, 2017), County of Wayne and County of Oakland v. Purdue Pharma L.P., et al., E.D. Mich. (No. 2:17 CV 13334).

⁶⁴ Third Amended Complaint (Oct. 25, 2016), City of Chicago v. Purdue Pharma L.P., et al., N.D. Ill. (No. 14 CV 04361).

⁶⁵ Complaint (May 31, 2017), State of Ohio v. Purdue Pharma L.P., et al., Common Pleas Ct. of Ross Cty. (No. CV 17 CI 000261).

⁶⁶ Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018); Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017); Letter from Counsel for Cardinal Health to Sen. Claire McCaskill (Mar. 7, 2018).

⁶⁷ McKesson reported opioid orders from January 1, 2012, through December 18, 2017; Cardinal Health reported orders from January 1, 2012, through July 31, 2017; and AmerisourceBergen reported orders from January 1, 2012, through August 15, 2017. See Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018); Letter from Counsel for Cardinal Health to Sen. Claire McCaskill (Mar. 7, 2018); Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017); Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).

⁶⁸ The U.S. Census Bureau reported a 2010 population for Missouri of 5,988,927 residents; using this baseline for the 2012-2017 period results in a per capita opioid dosage unit rate of roughly 265 dosage units per person. Applying the July 2017 Missouri population estimate of 6,113,532 residents to the 2012-2017 period yields a per capita rate of roughly 260 dosage units per person over the five-year period. See Department of Commerce, U.S. Census Bureau, QuickFacts: Missouri (www.census.gov/quickfacts/MO) (accessed Apr. 12, 2018).

⁶⁹ In 2015, the three distributors shipped around 314,000,000 opioid dosage units into Missouri; using the 2010 population count for Missouri yields a rate of approximately 52 opioid dosage units per capita during this year. Applying the July 2017 Missouri population estimate yields a per capita rate of roughly 51 opioid dosage units during 2015.

⁷⁰ McKesson reported opioid orders from January 1, 2012, through December 18, 2017; Cardinal Health reported orders from January 1, 2012, through July 31, 2017; and AmerisourceBergen reported orders from January 1, 2012, through August 15, 2017. See Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018); Letter from Counsel for Cardinal Health to Sen. Claire McCaskill (Mar. 7, 2018); Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017); Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).

- ⁷¹ Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018); Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017).
- ⁷² Letter from Counsel for Cardinal Health to Sen. Claire McCaskill (Mar. 7, 2018).
- ⁷³ Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018).
- ⁷⁴ McKesson provided suspicious order reports between August 2013 and December 18, 2017; Cardinal Health provided reports between January 2012 and July 2017; and AmerisourceBergen provided reports between January 2012 and August 15, 2017. See Letter from Counsel for McKesson to Sen. Claire McCaskill (Mar. 23, 2018); Letter from Counsel for Cardinal Health, Inc., to Sen. Claire McCaskill (Sept. 29, 2017); Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017); Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).
- ⁷⁵ Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (Apr. 2, 2018). These records only reflect electronic reports distributors filed with DEA headquarters subject to a previous memorandum of understanding. In correspondence with the Committee, DEA has noted that "there is no centralized reporting of SORS [suspicious order reports]." See Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Sept. 14, 2017); see also Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (Apr. 2, 2018). The agency, however, "is drafting new regulations which, if promulgated, would require the electronic reporting of SORS to DEA Headquarters in order to remedy this problem." Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Sept. 14, 2017). In the meantime, distributors not subject to memoranda of understanding file suspicious order reports at DEA field offices. Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (Apr. 2, 2018). Recognizing the limits of reliance on self-reporting from distributors and manufacturers, DEA has also stated that "distributors registered with DEA are subject to an unannounced regulatory investigation every three years," during which inspectors compare ARCOS records with source documents, among other activities. According to DEA, the agency conducted 352 regulatory investigations of distributors in the United States during FY 2016. See Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Sept. 14, 2017).
- ⁷⁶ Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (May 30, 2018); Email from Sean R. Mitchell, Drug Enforcement Administration, to Senate Committee on Homeland Security and Governmental Affairs Staff (May 30, 2017).
- ⁷⁷ Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (Apr. 2, 2018).
- ⁷⁸ Letter from Sean R. Mitchell, Drug Enforcement Administration, to Sen. Claire McCaskill (Apr. 2, 2018).
- ⁷⁹ See U.S. Census Bureau, Population Division, *Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2017* (Mar. 2018) (factfinder.census.gov/bkmk/table/1.0/en/PEP/2017/PEPANNRES/0400000US29.05000).
- ⁸⁰ Centers for Medicare and Medicaid Services, *Medicare Part D Opioid Prescribing Mapping Tool* (Nov. 29, 2017) (www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html).
- ⁸¹ Missouri Department of Health and Senior Services, *ER Visits Due to Non-Heroin Opioid Misuse by County of Residence: 2011-2015* (health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-20.pdf).
- ⁸² Missouri Department of Health and Senior Services, *Deaths Due to Non-Heroin Opioid Overdoses: 2012-2016 by County of Residence* (health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-8.pdf).
- ⁸³ *Id.*
- ⁸⁴ Centers for Disease Control and Prevention, *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015* (July 7, 2017) (www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm); see also *These Are the Most Opioid-Soaked Counties in Kansas and Missouri*, Kansas City Star (July 30, 2017) (www.kansascity.com/news/business/health-care/article164307857.html).
- ⁸⁵ Centers for Disease Control and Prevention, *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015* (July 7, 2017) (www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm); Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes: United States, 2017* (Aug. 31, 2017) (www.cdc.gov/drugoverdose/pdfs/pubs/2017-cdc-drug-surveillance-report.pdf).
- ⁸⁶ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017); see also Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0017946-ENDO_HSGAC_0017953; ENDO_HSGAC_0017954-ENDO_HSGAC_0017975).
- ⁸⁷ *Id.*
- ⁸⁸ *Id.*
- ⁸⁹ Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0017946-ENDO_HSGAC_0017953; ENDO_HSGAC_0017954-ENDO_HSGAC_0017975).
- ⁹⁰ *Id.*
- ⁹¹ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).
- ⁹² Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).
- ⁹³ *Id.*
- ⁹⁴ Letter from Counsel for McKesson Corporation to Sen. Claire McCaskill (Oct. 12, 2017).
- ⁹⁵ Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017).
- ⁹⁶ Letter from Counsel for Cardinal Health, Inc., to Sen. Claire McCaskill (Sept. 29, 2017).
- ⁹⁷ Letter from Counsel for McKesson Corporation to Sen. Claire McCaskill (Oct. 12, 2017).

⁹⁸ Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017).

⁹⁹ Letter from Counsel for McKesson Corporation to Sen. Claire McCaskill (Oct. 12, 2017).

¹⁰⁰ *Id.*

¹⁰¹ Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).

¹⁰² Counsel for Cardinal Health, Inc., Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (June 16, 2017).

¹⁰³ Email from Counsel for McKesson Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (July 3, 2018).

¹⁰⁴ Counsel for McKesson, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 19, 2018); Email from Counsel for McKesson Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (July 6, 2018).

¹⁰⁵ Email from Counsel for AmerisourceBergen Corporation to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).

¹⁰⁶ Counsel for Cardinal Health, Inc., Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (June 16, 2017).

¹⁰⁷ Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017).

¹⁰⁸ *Id.*

¹⁰⁹ Letter from Counsel for McKesson Corporation to Sen. Claire McCaskill (Oct. 12, 2017).

¹¹⁰ *DEA Responds to Explosive "60 Minutes"/Washington Post Report About Opioid Crisis*, CBS News (Oct. 16, 2017) (www.cbsnews.com/news/opioid-crisis-dea-responds-60-minutes-report/); see also LinkedIn, D. Linden Barber (www.linkedin.com/in/d-linden-barber-41061314) (accessed Apr. 12, 2018).

¹¹¹ Letter from Counsel for McKesson Corporation to Sen. Claire McCaskill (Oct. 12, 2017).

¹¹² *Id.*

¹¹³ Letter from Counsel for Cardinal Health, Inc., to Sen. Claire McCaskill (Sept. 29, 2017).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ Letter from Counsel for AmerisourceBergen Corporation to Sen. Claire McCaskill (Sept. 29, 2017).

¹¹⁷ *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, Charleston Gazette-Mail (Dec. 17, 2016) (www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses).

¹¹⁸ Verified Shareholder Derivative Complaint for Breaches of Fiduciary Duty Owed to the Company (Oct. 20, 2017), *Steinberg v. McKesson Corporation, et al. Del. Ch. (No. 2017-0736-SG)*; see also *Big McKesson Shareholder, Governance Experts Say the Opioid Crisis Should Have Cost the CEO Some Bonus Pay*, Fortune (July 10, 2017) (fortune.com/2017/07/10/mckesson-ceo-pay-opioid-teamsters/).

¹¹⁹ These totals include salary, cash awards, exercised options, vested stock, and the cash value of other perks. See Securities and Exchange Commission, *Proxy Statement Pursuant to Section 14(a) Submitted by McKesson Corporation* (Commission File Number: 1-13252) (July 27, 2017) (www.sec.gov/Archives/edgar/data/927653/000119312517205237/d341720ddef14a.htm); Securities and Exchange Commission, *Proxy Statement Pursuant to Section 14(a) Submitted by AmerisourceBergen Corporation* (Commission File Number: 1-16671) (Jan. 19, 2018) (www.sec.gov/Archives/edgar/data/1140859/000104746918000269/a2234204zdef14a.htm); Securities and Exchange Commission, *Proxy Statement Pursuant to Section 14(a) Submitted by Cardinal Health, Inc.* (Commission File Number: 1-11373) (Sep. 21, 2017) (www.sec.gov/Archives/edgar/data/721371/000072137117000124/cah-2017xdef14a.htm).

¹²⁰ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹²¹ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).

¹²² Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹²³ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).

¹²⁴ *Id.*

¹²⁵ Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0002755-ENDO_HSGAC_0017945).

¹²⁶ Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0002813).

¹²⁷ *Id.*

¹²⁸ See, e.g., Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0009504-05).

¹²⁹ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹³⁰ *Id.*

¹³¹ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Email from General Counsel for Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017).

¹³⁷ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).

¹³⁸ *Id.*

¹³⁹ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Aug. 30, 2017) (MNK 000017-002537); Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (MNK 003297-508).

¹⁴⁰ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Aug. 30, 2017) (MNK 000362-63).

¹⁴¹ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Aug. 30, 2017) (MNK 000363).

¹⁴² Department of Justice: *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017) (www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

¹⁴³ *Id.*

¹⁴⁴ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹⁴⁵ *Id.*

¹⁴⁶ Letter from Counsel for Endo to Sen. Claire McCaskill (Sept. 20, 2017).

¹⁴⁷ Importantly, Mallinckrodt has noted that with the exception of methadone, the company “does not sell its dosage opioid products directly to dispensing entities like independent retail pharmacies. The vast majority of Mallinckrodt’s dosage opioid products are sold to distributors and central distribution centers of large retail chains.” Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹⁴⁸ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (MNK 003296).

¹⁴⁹ *Id.*

¹⁵⁰ Endo International plc, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (July 13, 2017).

¹⁵¹ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (MNK 003296).

¹⁵² Advanced Pain Centers, *Doctor to Pay \$820,000 for Medicare Fraud*, St. Louis Business Journal (Mar. 9, 2010) (www.bizjournals.com/stlouis/stories/2010/03/08/daily23.html).

¹⁵³ Pain Center Remains Open Following Raid, Daily Journal (June 28, 2013) (dailyjournalonline.com/news/local/pain-center-remains-open-following-raid/article_ccc2ac30-de9e-11e2-b8a0-001a4bcf887a.html).

¹⁵⁴ Amendment to Settlement Agreement (Oct. 17, 2016), *In the Matter of Abdul N. Naushad*, State of Missouri Board of Registration for the Healing Arts (Case No.: 2013-004004); Settlement Agreement (Nov. 23, 2015), *In the Matter of Abdul N. Naushad*, State of Missouri Board of Registration for the Healing Arts (Case No.: 2013-004004).

¹⁵⁵ Joint Stipulation of Facts, Waiver of Hearing before the Administrative Hearing Commission, and Consent Order with Joint Conclusions of Law (Aug. 25, 2014), *Department of Health and Senior Services Bureau of Narcotics and Dangerous Drugs v. Naushad*, Administrative Hearing Commission (Case No.: 14-0214DH).

¹⁵⁶ Production from Mallinckrodt to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (MNK 002538-MNK 003295).

¹⁵⁷ *Id.*

¹⁵⁸ Production from Endo International plc to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Sept. 20, 2017) (ENDO_HSGAC_0000001-ENDO_HSGAC_0002754).

¹⁵⁹ *Id.*

¹⁶⁰ Letter from John M. Gray, President and CEO, Healthcare Distribution Alliance to Sen. Claire McCaskill (Nov. 28, 2017).

¹⁶¹ Healthcare Distribution Alliance, *What The Washington Post Won’t Say About Distributors and Regulation of Controlled Substances in the Supply Chain* (Oct. 15, 2017) (www.hda.org/news/2017-10-15-correcting-the-record). Similarly, the Government Accountability Office (GAO) concluded, based in part on a survey of distributors, that “better communication and guidance from DEA could help registrants make business decisions that balance ensuring access for patients with legitimate needs with controlling abuse and diversion.” Government Accountability Office, *More DEA Information About Registrants’ Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access* (GAO-15-471) (June 2015). In response, “DEA stated that short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers. Instead, DEA highlighted regulations that require distributors to design and operate systems to disclose suspicious orders.” *Id.*

¹⁶² House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Testimony of Robert W. Patterson, Acting Administrator, Drug Enforcement Administration, *Hearing on the Drug Enforcement Administration’s Role in Combating the Opioid Epidemic*, 115th Cong. (Mar. 20, 2017) (S. Hrg. 115-XX) (docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf).

¹⁶³ Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, *Minority Roundtable: Restoring DEA Enforcement Power Over Drug Distributors*, 115th Cong. (Nov. 28, 2017).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*; see also remarks from Mr. Novak (“One of the best cases that has ever come out of DEA came out during this slowdown, Masters Pharmaceutical. It provides case law clarifying the obligations on the distributors, in terms of due diligence and reporting suspicious orders.”); and Mr. Rannazzisi (“I have sent two letters to all registrants in 2007—in 2006 and 2007—stating that Southwood, which was a case we did, basically buttressed those letters.”).

¹⁶⁶ See Southwood Pharm., Inc., 72 Fed. Reg. 36,487 (July 3, 2007); Masters Pharmaceuticals, Inc., 80 Fed. Reg. 55,418 (Sept. 15, 2015). See also Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, *Minority Roundtable: Restoring DEA Enforcement Power over Drug Distributors*, 115th Cong. (Nov. 28, 2017).

¹⁶⁷ Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration, No. 15-1335 (D.C. Cir. 2017).

¹⁶⁸ See Masters Pharmaceuticals, Inc., 80 Fed. Reg. 55,418 (Sept. 15, 2015).

¹⁶⁹ Letter from John M. Gray, President and CEO, Healthcare Distribution Alliance to Sen. Claire McCaskill (Nov. 28, 2017).

¹⁷⁰ *Id.*

¹⁷¹ Senate Committee on the Judiciary, Statement Submitted for the Record of John M. Gray, President and CEO, Healthcare Distribution Alliance, Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act, 115th Cong. (Dec. 12, 2017) (S. Hrg. 115-XX) (www.judiciary.senate.gov/imo/media/doc/12-12-17%20Gray%20Testimony.pdf).

¹⁷² Drug Enforcement Administration: DEA Creates New Resource to Help Distributors Avoid Oversupplying Opioids (Feb. 14, 2018) (www.dea.gov/divisions/hq/2018/hq021418.shtml).

¹⁷³ *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Washington Post (Apr. 2, 2017).

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ Letter from General Counsel for Mallinckrodt to Sen. Claire McCaskill (Aug. 30, 2017).

¹⁷⁷ As of May 2018, DEA was unable to provide a breakdown of ISOs by registrant for FY 2018. See Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (May 15, 2018). The same month, DEA issued a suspension order against the distributor Morris & Dickson, alleging the company had failed to "properly identify large suspicious orders for controlled substances sold to independent pharmacies." The Washington Post noted that this was "the first time in six years the DEA had taken such drastic measures against a distributor." *Justice Department Revives Order Stopping Opioid Sales by Louisiana Distributor*, Washington Post (May 18, 2018). Weeks later, however, DEA rescinded the order after Morris & Dickson disputed agency data and methodology in federal court. *Id.*

¹⁷⁸ Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, *Minority Roundtable: Restoring DEA Enforcement Power Over Drug Distributors*, 115th Cong. (Nov. 28, 2017).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ Office of Administrative Law Judges, FY 2014 Third Quarter Status Report (June 24, 2014); see also *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Washington Post (Oct. 22, 2016).

¹⁸² Office of Administrative Law Judges, FY 2014 Year End and Fourth Quarter Status Report (Sept. 23, 2014).

¹⁸³ Office of Administrative Law Judges, FY 2017 Year End and Fourth Quarter Status Report (Oct. 5, 2017).

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (May 15, 2018).

¹⁸⁸ See Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Oct. 6, 2017); Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (May 15, 2018).

¹⁸⁹ Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Oct. 6, 2017).

¹⁹⁰ 'We Feel Like Our System was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017) (www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html).

¹⁹¹ See Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (May 15, 2018); Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (May 16, 2018).

¹⁹² *Id.*

¹⁹³ Frank Younker, Former Diversion Group Supervisor, DEA Cincinnati Resident Office, Interview with Senate Committee on Homeland and Governmental Affairs (Nov. 8, 2017).

¹⁹⁴ Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, *Minority Roundtable: Restoring DEA Enforcement Power Over Drug Distributors*, 115th Cong. (Nov. 28, 2017).

¹⁹⁵ Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Oct. 6, 2017).

¹⁹⁶ Email from Sean R. Mitchell, Drug Enforcement Administration, to Senate Committee on Homeland Security and Governmental Affairs Staff (Dec. 18, 2017).

¹⁹⁷ Senate Committee on Homeland Security and Governmental Affairs, Interview of Joseph Rannazzisi (Nov. 2, 2017).

¹⁹⁸ Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, *Minority Roundtable: Restoring DEA Enforcement Power Over Drug Distributors*, 115th Cong. (Nov. 28, 2017).

¹⁹⁹ Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Oct. 6, 2017).

²⁰⁰ House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Testimony of Robert W. Patterson, Acting Administrator, Drug Enforcement Administration, Hearing on the Drug Enforcement Administration's Role in Combating the Opioid Epidemic, 115th Cong. (Mar. 20, 2017) (S. Hrg. 115-XX) (docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Transcript-20180320.pdf).

²⁰¹ Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic, ProPublica (Jan. 27, 2017) (www.propublica.org/article/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic).

²⁰² How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Washington Post (Oct. 22, 2016); U.S. Department 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) (www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html).

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Securities and Exchange Commission, Form 10-K Submitted by McKesson Corporation (Commission File Number: 1-13252) (May 22, 2017) (www.sec.gov/Archives/edgar/data/927653/000092765317000007/mck_10kx3312017.htm).

²⁰⁶ Securities and Exchange Commission, Form 10-K Submitted by Cardinal Health, Inc. (Commission File Number: 1-11373) (Aug. 10, 2017) (www.sec.gov/Archives/edgar/data/721371/000072137117000083/a17q4_10kx63017xform10-k.htm).

²⁰⁷ The Government's Struggle to Hold Opioid Manufacturers Accountable, Washington Post (Apr. 2, 2017); Securities and Exchange Commission, Form 10-K Submitted by Mallinckrodt PLC (Commission File Number: 1-35803) (Feb. 27, 2018) (www.sec.gov/Archives/edgar/data/1567892/000156789218000010/mnk10-k122917.htm).

²⁰⁸ Securities and Exchange Commission, Form 10-K submitted by McKesson Corporation (Commission File Number: 1-13252) (May 22, 2017) (www.sec.gov/Archives/edgar/data/927653/000092765317000007/mck_10kx3312017.htm); see also Securities and Exchange Commission, Form 10-K submitted by Cardinal Health, Inc. (Commission File Number: 1-11373) (Aug. 10, 2017) (www.sec.gov/Archives/edgar/data/721371/000072137117000083/a17q4_10kx63017xform10-k.htm).

²⁰⁹ Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Washington Post (Dec. 22, 2016).

²¹⁰ How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Washington Post (Oct. 22, 2016).

²¹¹ Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Washington Post (Oct. 22, 2016); see also Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Washington Post (Dec. 22, 2016).

²¹² The Drug Industry's Triumph Over the DEA, Washington Post (Oct. 15, 2017).

²¹³ Senate Committee on Homeland Security and Governmental Affairs, Roundtable Transcript, Minority Roundtable: Restoring DEA Enforcement Power Over Drug Distributors, 115th Cong. (Nov. 28, 2017).

²¹⁴ *Id.*

²¹⁵ Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Washington Post (Oct. 22, 2016).

²¹⁶ Production from the Drug Enforcement Administration to the Senate Committee on Homeland Security and Governmental Affairs (Aug. 3, 2017).

²¹⁷ *Id.* See also House of Representatives Committee on Energy and Commerce, Testimony of Neil Doherty, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Hearing on Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives, 115th Cong. (Oct. 25, 2017) (H. Hrg. 115-XX).

²¹⁸ See, e.g., Senate Committee on Homeland Security and Governmental Affairs, Interview of Joseph Rannazzisi (Nov. 2, 2017); Senate Committee on Homeland Security and Governmental Affairs, Interview of Jonathan Novak (Oct. 31, 2017).

²¹⁹ Letter from Sen. Claire McCaskill to Inspector General Michael E. Horowitz, Department of Justice Office of Inspector General (Mar. 6, 2017).

²²⁰ Department of Justice Office of the Inspector General, Ongoing Work, Review of the Drug Enforcement Administration's Opioid Enforcement Efforts (June 1, 2017) (oig.justice.gov/ongoing/all.htm).

²²¹ Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145.

²²² *Id.*

²²³ *Id.*

²²⁴ The Drug Industry's Triumph over the DEA, Washington Post (Oct. 15, 2017).

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Washington Post (Oct. 22, 2016).

²²⁸ See Minority Staff, Senate Committee on Homeland Security and Governmental Affairs, Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Feb. 12, 2018).

²²⁹ Letter from Alliance for Patient Access, et al., to Sens. Orrin Hatch and Sheldon Whitehouse (Mar. 4, 2015).

²³⁰ Letter from Academy of Integrative Pain Management, et al., to Sens. Orrin Hatch and Sheldon Whitehouse (Nov. 16, 2017).

²³¹ Senate Committee on the Judiciary, Statement Submitted for the Record of John M. Gray, President and CEO, Healthcare Distribution Alliance, Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement

Act, 115th Cong. (Dec. 12, 2017) (S. Hrg. 115-XX) (www.judiciary.senate.gov/imo/media/doc/12-12-17%20Gray%20Testimony.pdf).

²³² Minority Staff, Senate Committee on Homeland Security and Governmental Affairs, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018).

²³³ S.1960, 115th Cong. (2017).

²³⁴ See *44 State Attorneys General Want Repeal of Law That Curbed DEA Powers*, Washington Post (Nov. 14, 2017) (www.washingtonpost.com/national/health-science/44-state-attorneys-general-want-repeal-of-law-that-curbed-dea-powers/2017/11/14/4f746f4a-c975-11e7-b0cf-7689a9f2d84e_story.html).

²³⁵ Letter from the National Association of Attorneys General to Speaker Paul Ryan, et al. (Nov. 13, 2017).

²³⁶ *Id.*

²³⁷ Senate Committee on the Judiciary, Testimony Submitted for the Record of Demetra Ashley, Acting Assistant Administrator, Drug Enforcement Administration, *Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act*, 115th Cong. (Dec. 12, 2017) (S. Hrg. 115-XX).

²³⁸ Senate Committee on the Judiciary, *Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act*, 115th Cong. (Dec. 12, 2017) (S. Hrg. 115-XX).

²³⁹ Letter from Stephen E. Boyd, Assistant Attorney General, Department of Justice, to Chairman Greg Walden, House Committee on Energy and Commerce (Feb. 28, 2018).

²⁴⁰ *Id.*