

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WAYNE

STATE OF MICHIGAN, EX REL.,  
DANA NESSEL, ATTORNEY GENERAL,

Plaintiff,

Case No. 2019-

- NZ

v

HON.

CARDINAL HEALTH, INC., McKESSON  
CORPORATION, AMERISOURCEBERGEN  
DRUG CORPORATION AND WALGREEN CO.,

Defendants.

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There is no other civil action between these parties arising out of the same transaction or occurrence as alleged in this Complaint pending in this Court, nor has any such action been previously filed and dismissed or transferred after having been assigned to a judge, nor do I know of any other civil action not between these parties, arising out of the same transaction or occurrence as alleged in this Complaint that is either pending or was previously filed and dismissed, transferred, or otherwise disposed of after having been assigned to a judge in this Court.

**COMPLAINT AND DEMAND FOR JURY TRIAL**

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## COMPLAINT

Plaintiff, the State of Michigan, by and through its Attorney General, Dana Nessel (hereinafter “Michigan” or “State”), upon personal knowledge as to its own acts and beliefs, and upon information and belief as to all matters, based upon the investigation counsel, alleges as follows against Defendants Cardinal Health, Inc.; McKesson Corporation; AmerisourceBergen Drug Corporation; and Walgreen Co.:

### INTRODUCTION

1. As distributors of controlled substances, Defendants have special responsibilities to ensure that those drugs did not get into the wrong hands, and to protect the Michigan communities those companies purport to serve. Despite having these responsibilities, and despite having unique knowledge of and access to data and other information to help them fulfill those responsibilities, Defendants failed to maintain effective controls over the diversion of prescription opioids. Instead, Defendants distributed and sold far greater quantities of prescription opioids than they knew could be necessary for legitimate medical uses, while failing to report, and to take steps to halt, suspicious orders when they were identified. As a direct result of their conduct, Michigan has experienced both a flood of prescription opioids available for illicit use or sale and a population of patients physically and psychologically dependent on them.

2. Controlled substances, by definition, are highly subject to abuse and diversion. For this reason, the State of Michigan regulates every participant in the chain of distribution which handles controlled substances. To distribute or dispense prescription opioids in the State, companies must maintain effective controls against diversion.

3. Defendants used their licenses to distribute controlled substances in Michigan as a cover for what is essentially a criminal enterprise. They knowingly distributed drugs in Michigan without diversion controls. Such conduct was not only negligent; it was unlawful,

caused a public nuisance, and subjects Defendants to liability under the Drug Dealer Liability Act (DDLA).

4. The Michigan Legislature enacted the DDLA in 1994. As the first act of its kind in any state, the DDLA was based on two principles. First, a defendant's liability is based on entering the illegal drug market in any capacity, not on making a sale to a particular person. Second, the focus of the Act is the ultimate harm to society caused by the illegal drug market—not on the determination of how the harm was caused.

5. Almost immediately after its passage, the DDLA was used by public entities in Michigan to seek the recovery of damages against participants in illegal drug markets. The Wayne County Neighborhood Legal Services' Children's Law Center, along with the Wayne County Sheriff's department, brought a civil action against four drug dealers on behalf of the siblings of a baby girl in Detroit killed by her mother, who was addicted to cocaine. The trial court entered a default judgment in favor of the siblings of \$7.8 million.<sup>1</sup>

6. The DDLA provides the Attorney General authority to pursue such actions, and, as one court recently found, the DDLA is properly brought against defendants who enter an illegal drug market, even if a defendant's business is otherwise "legal":

The DDLA does not confine itself to "street drugs" or "street dealers." What matters under the DDLA is that a person, as defined in the Act, knowingly participates in the illegal drug market. A "person" may be a corporate entity, and a drug's legality depends on the context—that is, whether it is prescribed, whether its sale or distribution conforms to state law, etc. Manufacturer Defendants posit that, by definition, they cannot be drug dealers under the DDLA. They point out that the drugs they produce are FDA-approved and DEA-regulated. That, however, begs the question. ***Drug manufacturers cannot, as is alleged here, knowingly seek out suspect doctors and pharmacies, oversupply them with opioids for the purpose of diversion, benefit from the process, and then cynically invoke their status as otherwise lawful companies to avoid civil liability. The***

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<sup>1</sup> *Ficano v. Clemens*, No. 95-512918 (Cir. Ct. Wayne County Mich. 1995).

*common perception of a drug dealer may be that of the street dealer, but the DDLA does not make that distinction.*<sup>2</sup>

7. Similarly, a public nuisance is defined as “an unreasonable interference with a right common to the general public,” such as the public health or public safety. Restatement (Second) of Torts § 821(B)(1) (1979). Thus, even an otherwise lawful activity can become a nuisance when it unreasonably interferes with the public health or safety. The Attorney General has the right to pursue such an action to protect public rights.

8. The State of Michigan brings this action against Defendants for these very reasons. Although Defendants had licenses to distribute controlled substances in this State, Defendants had duties to : (1) identify suspicious orders of controlled substances; (2) report suspicious orders when discovered; and (3) decline to ship a suspicious order unless and until, through due diligence, the registrant can determine the order is not likely to be diverted into illegal channels. Defendants failed to do any of these things, and thereby created an illegal drug market that devastated the public health and safety of this State.

9. According to the *Washington Post*, between the years 2006 and 2012 alone, there were 2,852,578,277 pills distributed into the State of Michigan. Defendants in this action collectively had over seventy-five percent of that market by morphine milligram equivalents, or MME. McKesson was the number one distributor of oxycodone and hydrocodone in the State, and AmerisourceBergen was second. Cardinal Health and Walgreens round out the third and fourth spots.

10. As a direct and foreseeable result of Defendants’ conduct, the State of Michigan is now swept up in what the Center for Disease Control and Prevention (CDC) has called a “public

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<sup>2</sup> *Effler v. Purdue Pharma L.P.*, No. E201801994COAR3CV, 2019 WL 4303050, at \*10 (Tenn. Ct. App. Sept. 11, 2019).

health epidemic” and what the U.S. Surgeon General has deemed an “urgent health crisis.”<sup>3</sup> The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire – or simply could not afford – prescription opioids.

11. Defendants’ conduct has imposed an enormous toll on the State of Michigan. The Michigan Statewide Opioid Assessment issued on March 29, 2018, which overlaid three years (2013-2015) of well-documented cases of unintentional overdoses with five years (2012-2017) of prescription records in the Michigan Automated Prescription System (MAPS), found that more than 7.5 million patients who had received more than 103 million prescriptions over the last five years were linked to 5,261 overdose deaths in Michigan.<sup>4</sup> These findings are consistent with years of trends in this State. As the chart below reflects, during the years of 1999-2016, the number of overdose deaths in Michigan increased seventeen-fold.<sup>5</sup>

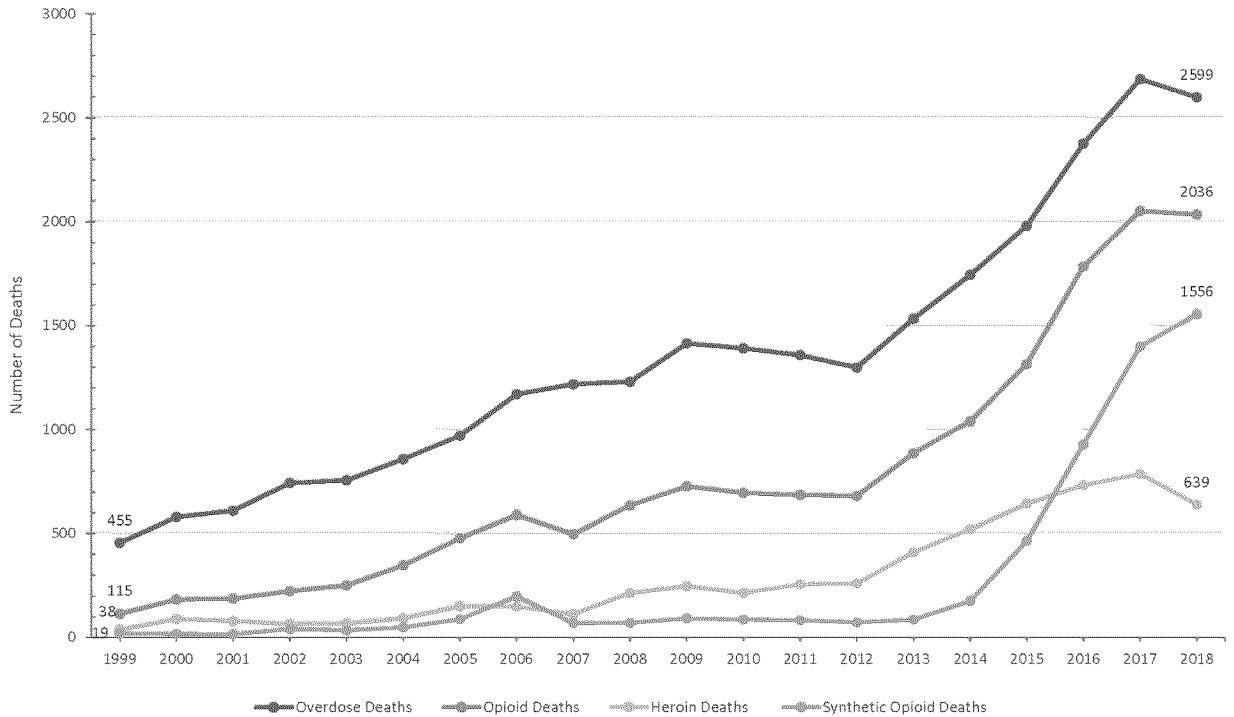
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<sup>3</sup> *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm>; Vivek H. Murthy, Letter from the Surgeon General, August 2016, <http://turnthetidex.org>.

<sup>4</sup> [https://www.michigan.gov/documents/lara/BPL\\_ApprissStatewideOpioidAssesmentMICHIGAN\\_03-29-2018\\_620258\\_7.pdf](https://www.michigan.gov/documents/lara/BPL_ApprissStatewideOpioidAssesmentMICHIGAN_03-29-2018_620258_7.pdf) (last visited Oct. 25, 2019).

<sup>5</sup> <https://www.michigan.gov/opioids/0,9238,7-377-88139---,00.html> (last visited Oct. 25, 2019).





In 2018 alone, 2,036 Michiganders died from an overdose.<sup>6</sup> Prescription opioids accounted for more than twice as many overdose deaths as heroin.<sup>7</sup>

12. The addicts created by the wide availability of prescription opioids turned anywhere they could to feed their addictions. As millions became addicted to opioids, “pill mills,” often styled as “pain clinics,” sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These “pill mills”, typically under the auspices of licensed medical professionals, issued high volumes of opioid prescriptions under the guise of medical treatment.

13. In addition, many opioid users, having become addicted, but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with

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

<sup>7</sup> <https://www.drugabuse.gov/opioid-summaries-by-state/michigan-opioid-summary> (last visited Oct. 25, 2019).

prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

14. But rogue prescribers and the existence of a market for heroin do not absolve Defendants. Had Defendants abided by their obligations to detect, report and stop the shipment of the suspicious orders that rogue prescribers generate, the supply of diverted opioids would have been contained. Instead, Defendants ignored suspicious activity and cynically turned away from a growing population of addicts so that they could make more money distributing pills.

15. Defendants' conduct has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction, overdose, and death. The necessary costs were, and continue to be, borne by the State of Michigan and include providing addiction treatment and treating opioid-addicted newborns in neonatal intensive care units. As one example, Michigan's rate of Neonatal Abstinence Syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS), when babies are born addicted to opioids because their mothers used opioids during pregnancy, has increased eight fold from 2004 to 2014, costing Michigan nearly \$600 million in in-patient hospital costs in 2014.<sup>8</sup> Between 2009 and 2014, Michigan also saw an increase in hospital stays related to opioid use.<sup>9</sup>

16. The burdens imposed on the State of Michigan are not the normal or typical burdens of governmental programs and services. Rather, these are extraordinary costs and losses that are directly related to Defendants' actions as illegal drug dealers in the State. Defendants'

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<sup>8</sup> <https://www.drugabuse.gov/opioid-summaries-by-state/michigan-opioid-summary> (last visited Oct. 25, 2019).

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

conduct has created a public nuisance and a blight. And Defendants have not changed their ways or corrected their past misconduct; but instead are continuing to fuel the crisis.

17. The State of Michigan brings this civil action to eliminate the hazard to public health and safety caused by Defendants' contributions to the opioid epidemic in the State, to abate the nuisance in this State, and to recover damages that resulted from Defendants' unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful and/or negligent actions and omissions.

### **JURISDICTION AND VENUE**

18. Subject matter jurisdiction for this case is conferred upon this Court pursuant to M.C.L.A. 600.601, 600.605 and 600.2940.

19. This Court has personal jurisdiction over Defendants because Defendants do business in Michigan and/or have the requisite minimum contacts with Michigan necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also within the contemplation of M.C.L.A. 600.711 and 600.715.

20. This Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. The State does not bring this action on behalf of a class or any group of persons that can be construed as a class. The claims asserted herein are brought solely by the State of Michigan and are wholly independent of any claims that individual users of opioids may have against Defendants.

21. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does the State plead, expressly or implicitly, any cause of

action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. This Complaint does not implicate any issue important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013) (e.g., federal tax collection seizures, federal government bonds). Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of the State of Michigan. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise of federal jurisdiction is without basis in law or fact.

22. This Complaint cites federal statutes and regulations. The State does so to state the duties owed under Michigan law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question under *Gunn v. Minton*. Thus, the removal of this complaint based on an imagined federal cause of action or substantial question is without merit.

23. In addition, notwithstanding anything to the contrary, under no circumstance is the State bringing this action against, or bringing an action or claim of any kind directed to, any federal officer or person acting under any officer of the United States for or relating to any act under color of such office; nothing in this Complaint raises such an action, and to the extent that anything in the Complaint could be interpreted as potentially bringing an action against or directed to any federal officer or person acting under any officer of the United States for or relating to any act under color of such office, then all such claims, actions, or liability, in law or in equity, are denied and disavowed in their entirety. Specifically and without limitation, nothing in the State's Complaint seeks to bind the McKesson Corporation, or any other

Defendant, in law or in equity, or to otherwise impose any liability or injunction, related to any United States government contract, including without limitation any Pharmaceutical Prime Vendor (PPV) contract that the McKesson Corporation (or any affiliated entity) or any other Defendant has or had with the United States Veterans Administration. Specifically and without limitation, nothing in this Complaint challenges in any way, in law or in equity or otherwise, actions of McKesson pursuant to a contract it has or ever had with the United States Veterans Administration.

24. Venue is proper in this Court pursuant to M.C.L.A. 600.1629, because the claims for relief asserted herein arose in large part in the County of Wayne, and under M.C.L.A. 600.1621, because Defendants all conduct business in the County of Wayne.

### **PARTIES**

#### **A. PLAINTIFF**

25. The State of Michigan is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought by the State, by and through Dana Nessel, the Attorney General of the State of Michigan, in its sovereign capacity, in order to protect the interests of the State of Michigan and under its *parens patriae* authority to protect the health and well-being of the State's citizens. Attorney General Nessel is acting pursuant to her authority under Mich. Comp. Laws §§ 14.28, 691.1604(4), and 691.1605(1).

#### **B. DEFENDANTS**

26. At all relevant times, Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs.

27. Defendant Cardinal Health, Inc. (Cardinal or Cardinal Health) describes itself as a “global, integrated health care services and products company,” and is the sixteenth largest

company by revenue in the U.S., with annual revenue of \$121 billion in 2016. Through its various DEA registered subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country including in the State of Michigan. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

28. Defendant McKesson Corporation (McKesson) is seventh on the list of Fortune 500 companies, ranking immediately after Amazon and UnitedHealth Group, with annual revenue of \$191 billion in 2016. McKesson, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in Irving, Texas.

29. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (DOJ) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Michigan, as well as Ohio, Florida, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

30. AmerisourceBergen Drug Corporation (AmerisourceBergen or ABDC), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Michigan.

AmerisourceBergen is the tenth largest company by revenue in the United States, with annual

revenue of \$147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

31. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens. Walgreen Co. is sometimes referred to herein as "Walgreens." Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed and dispensed prescription opioids throughout the United States, including in Michigan. At all relevant times, Walgreens operated both as a licensed pharmacy wholesaler and operated multiple pharmacies through which it distributed prescription opioids in the State of Michigan.

32. "Defendants" include the above referenced entities, as well as their predecessors, successors, affiliates, subsidiaries, partnerships, and divisions, to the extent that they are engaged in the manufacture, promotion, distribution sale and/or dispensing of opioids.

33. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

## **FACTUAL ALLEGATIONS**

### **A. Opioids and Their Effects**

34. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived

from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

35. The medicinal properties of opioids have been recognized for millennia—as has their potential for abuse and addiction. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

36. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances since 1970.

37. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents, or MME. According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME.

**B. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders**

38. Through a marketing campaign premised on over a decade of false and incomplete information, manufacturers of prescription opioids engineered a shift in how and when opioids are prescribed by the medical community and used by patients. While opioids had long been reserved for acute pain and cancer pain, where the substantial risk of addiction is less pronounced, manufacturers of opioids changed that long-standing medical practice by misrepresenting the safety and efficacy of their products, asserting that the risk of addiction was



low when opioids were used to treat chronic pain, overstating the benefits and trivializing the risk of long-term use of opioids.

39. After manufacturers of opioids engineered a marketing scheme that successfully changed the way the medical and scientific communities viewed the risks and benefits of using opioids for chronic pain, as distributors of prescription opioids, Defendants could have stopped—or at least mitigated the effects of—the opioid epidemic in Michigan. Instead, they stood by and raked in profits from selling far more opioids than could have been justified to serve the legal and appropriate market.

40. The reason Defendants stood by, even when they had substantial reason to know that the drug manufacturers had used fraud to convince the public that the risks of using opioids for chronic pain were outweighed by the benefits of doing so, is because Defendants worked together with those manufacturers to continue to increase the market for prescription opioids. Defendants had financial incentives from opioid manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. For example, distributors like Defendants acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits. Also, opioid manufacturers paid rebates and/or chargebacks to the Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts.

41. In addition, in order to distribute opioids, Defendants are required to maintain certain security protocols and storage facilities. The manufacturers negotiated agreements whereby they installed security vaults for the Defendants in exchange for agreements to maintain minimum sales performance thresholds.

42. For these and other reasons, Defendants worked together with manufacturers to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (PCF) and the Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HDA).

43. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”<sup>10</sup> Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.<sup>11</sup>

44. Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.<sup>12</sup> Defendants actively participated, and continue to

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<sup>10</sup> Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

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

<sup>12</sup> *PAIN CARE FORUM 2012 Meetings Schedule* (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>

participate, in the PCF, at a minimum, through their trade organization, the HDA.<sup>13</sup> Defendants participated directly in the PCF as well.

45. McKesson, Cardinal and AmerisourceBergen were all members of the HDA. Although Walgreens was not a member of the Alliance, it was closely involved with it. For example, Walgreens is a member of the HDA Pharmaceutical Cargo Security Coalition (PCSC)<sup>14</sup> and Walgreens' David Brandt sits on the HDA PCSC Advisory Board.<sup>15</sup>

46. By its own account, HDA provides Defendants with a forum for “networking” and building “alliances.”<sup>16</sup> HDA openly encourages members to participate in working groups to provide “guidance” and “leadership” across the membership on a variety of issues affecting the industry, including “DEA regulation of distribution” and “supply chain issues.”<sup>17</sup>

47. In 2007, in response to heightened DEA scrutiny, HDA's membership began “developing a comprehensive DEA strategy,” related to the identification of “suspicious orders.”<sup>18</sup> HDA's internal documents show that members were specifically concerned about the “surge in DEA enforcement around suspicious shipments” and felt the industry needed “to quickly develop a plan to deal with and work with the DEA as necessary.”<sup>19</sup> HDA members considered plans to “challenge the DEA” and “develop business practices” in response to the

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<sup>13</sup> *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance (accessed on Sept. 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

<sup>14</sup> <https://www.hdapcsc.org/membership/member-organizations>

<sup>15</sup> <https://www.hdapcsc.org/about/advisory-board>

<sup>16</sup> See [https://www.hda.org/~media/pdfs/membership/manufacturing-membership-benefits.ashx?la=en](https://www.hda.org/~/media/pdfs/membership/manufacturing-membership-benefits.ashx?la=en).

<sup>17</sup> See <https://www.hda.org/about/councils-and-committees#Committees>.

<sup>18</sup> *In Re: National Prescription Opiate Litigation*, 17-md-2804 (N.D. Ohio), Dkt. No. 1979-7, at 61-62 (HDA 30(b)(6) deposition).

<sup>19</sup> *Id.* at 68.

DEA's heightened scrutiny of suspicious shipments.<sup>20</sup> As part of this effort, HDA collected copies of its "member companies' suspicious order policies and procedures."<sup>21</sup> HDA members then convened privately to discuss "best practices" in response to DEA enforcement and brainstorm "next steps."<sup>22</sup> In January 2008, as part of a monthly meeting with PCF, the HDA apprised PCF members—including opioid manufacturers and pharmacies—of the DEA's enforcement actions and the steps HDA was taking in response.<sup>23</sup> Thus, Defendants had multiple avenues to coordinate among themselves and with manufacturers in their dealings with the DEA.

48. Further, Defendants knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other and with manufacturers about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

49. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded. Indeed, as described below, even though Defendants were required to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, Defendants, in a breach of both statutory and common law duties, failed to maintain effective controls against diversion, thereby facilitating the flood of pills that went into Michigan communities, including Wayne County.

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<sup>20</sup> *Id.* at 75-6.

<sup>21</sup> *Id.* at 121.

<sup>22</sup> *Id.* at 137.

<sup>23</sup> *Id.* at 139-40.

1. **Defendants have a duty to report suspicious orders and not to ship those orders unless due diligence disproves their suspicions**

50. Several sources impose duties on Defendants to maintain effective controls against diversion. First, under the common law, Defendants had a duty to exercise reasonable care in manufacturing and distributing dangerous narcotic substances. By flooding the State of Michigan with opioids and failing to effectively prevent diversion, including failing to monitor for red flags, Defendants breached those duties. By filling and failing to report or halt orders that they knew or should have realized were likely being diverted for illicit uses, Defendants further breached their duties. Defendants' breaches created and failed to prevent a foreseeable risk of harm to Michigan and its communities. Second, as described more fully below, under regulations adopted under the Controlled Substances Act and Michigan state law, each of the Defendants was required to maintain effective controls and procedures against diversion. Defendants have violated their duties arising under the law. By failing to comply with their common law and statutory duties, Defendants entered an illegal drug market.

a. **Federal law**

51. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, Congress enacted the Controlled Substances Act (CSA) in 1970. The CSA and its implementing regulations<sup>24</sup> created a closed system of distribution for all controlled substances and listed chemicals.

52. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed system was specifically

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<sup>24</sup> See 21 U.S.C. 801–971 (2006); 21 C.F.R. 1300–1321 (2009).

designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.

53. Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.<sup>25</sup> All registrants—which includes all manufacturers, distributors, and dispensers of controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.

54. Regulations implementing the CSA also make very clear that registrants, including Defendants, owe a regulatory duty to “provide effective controls and procedures to guard against theft and diversion of controlled substances.”<sup>26</sup> Accordingly, Defendants must design and operate a system to disclose to the registrant suspicious orders of controlled substances. When suspicious orders are discovered, a registrant must inform the Field Division Office of the Administration in its area.<sup>27</sup>

55. Suspicious orders include orders of “unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>28</sup> These criteria for identifying suspicious orders are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over

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<sup>25</sup> 21 U.S.C. 822; 21 C.F.R. 1301.11.

<sup>26</sup> 21 C.F.R. 1301.71(a).

<sup>27</sup> Judge Polster, presiding over the federal MDL in the United States District Court for the Northern District of Ohio, recently granted the plaintiffs’ motion for summary judgment on these issues, holding as a matter of law that, to maintain effective controls against diversion under the CSA and its regulatory scheme (which South Dakota law mirrors), registrants must: (1) design and operate a system to identify suspicious orders; (2) report suspicious orders to the DEA upon discovery; and (3) stop shipment of suspicious orders pending investigation, and not ship them if suspicion remains. *See* Order, Dkt No. 2483, Case No. 17-MD-2804 (Aug. 19, 2019).

<sup>28</sup> 21 U.S.C. 802; 21 C.F.R. 1301.74(b) [1971].

time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

56. This regulatory duty has been defined to include the following obligations:

The “security requirement” at the heart of this case mandates that distributors “design and operate a system” to identify “suspicious orders of controlled substances” and report those orders to DEA (the Reporting Requirement). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor [or other registrant] provide basic information about certain orders to DEA, so that DEA “investigators in the field” can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out “potential illegal activity.” *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007). Once a distributor [or other registrant] has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement).<sup>29</sup>

57. Of course, a registrant’s due diligence efforts must be thorough: “the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order nonsuspicious and exempt it from the requirement that the distributor ‘inform’ the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed.”<sup>30</sup>

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<sup>29</sup> *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017).

<sup>30</sup> *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at \*55477 (DEA Sept. 15, 2015).

**b. Michigan law**

58. Michigan law also provides that distributors must be licensed because they “distribute[] ... a controlled substance in” the state. Mich. Comp. Laws § 333.7303. Moreover, distributors operating in Michigan are required to “operate in compliance with applicable federal, state, and local laws.” Mich. Admin. Code R. 338.493c(i).

59. Michigan law expressly provides that a distributor’s failure to comply with applicable federal law regarding distribution of controlled substances can result in revocation of the distributor’s Michigan license. *See* Mich. Comp. Laws § 333.7311(1)(f) (providing for the revocation of a license for any distributor “not in compliance with applicable federal, state, and local laws”). Among the federal laws thereby incorporated into Michigan law, then, is the CSA.

60. Michigan regulations required distributors, as licensees, to “provide effective controls against theft and diversion of controlled substances” (Mich. Admin. Code R. 338.3141(1)), to “make and maintain a complete and accurate inventory of all stocks of controlled substances” (*Id.* at 338.3151(1)), and “keep and make available for inspection all records for controlled substances, including invoices and other acquisition records.” *Id.* at 338.3153(1), *accord* 21 U.S.C. § 823 (mandating that registration be consistent with the public interest, which, in turn, requires “maintenance of effective controls against diversion . . . into other than legitimate medical, scientific, or industrial channels” and “compliance with applicable State and local law”); 21 C.F.R. §§ 1301.11, 1301.74.

61. In sum, Defendants have many responsibilities under Michigan law with respect to control of the supply chain of opioids. They must set up a system to prevent diversion, including excessive volume and other suspicious orders by reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities.



Defendants must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

2. **Defendants also have a duty to apply their specialized knowledge of the market to prevent diversion**

62. Defendants possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

63. Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Drug manufacturers engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled.

64. In addition, Distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances.

65. Defendants McKesson, Cardinal and ABDC also developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the

DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.<sup>31</sup> The “Know Your Customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders. Because Walgreens distributed prescription opioids to its own stores, it likewise had such information.

66. These information points give Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA and Michigan law.

67. In addition to the substantial data Defendants possessed, their on-the-ground sales forces allow Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. Sales representatives were aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences – so some patient gets Rx’d the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got “sold” on the 80mg) and their teen son/daughter/child’s teen friend finds the pill bottle and takes out a few 80’s... next they’re at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don’t wake up (because they don’t understand

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<sup>31</sup> *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Admin. Diversion Control Div., <https://www.dea.gov/diversion-control/diversion-control-division/industry/14th-pharm/levinl-ques.pdf>; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC (Oct. 2010), [https://www.mcguirewoods.com/news-resources/publications/lifesciences/product\\_diversion\\_beyond\\_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

68. Of course, Walgreens didn't need sales representatives to monitor signs of suspicious prescribing and dispensing at its own stores. Perhaps more than any other defendant, Walgreens had an unimpeded view of how and where the pills it distributed were ultimately dispensed.

69. Moreover, Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). In addition to the actual distribution of pharmaceuticals, as wholesalers, Defendants also offer their pharmacy customers a broad range of added services, such as sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

3. **Defendants were aware of and have acknowledged their obligations to prevent diversion and to report and take steps to halt suspicious orders**

70. The reason Defendants are required to report suspicious orders is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors’ obligation to maintain effective controls to prevent diversion of controlled substances is critical. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

71. The DEA has repeatedly reminded Defendants of their regulatory obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Defendants attended at least one of these conferences.

72. In a September 27, 2006 letter, the DEA also reminded every commercial entity registered to distribute controlled substances that they are “one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the

American people.” The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The same letter reminds distributors of the importance of their obligation to “be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes,” and warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

73. The DEA sent another letter to all entities registered to distribute or manufacture controlled substances on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). The letter explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an

unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.

74. Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

75. In addition, trade organizations to which Defendants belong or are closely allied have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The HDA, the trade association described above, has long taken the position that distributors have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.” Guidelines established by the HDA also explain that distributors, “[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

4. **Defendants failed to report suspicious orders or otherwise act to prevent diversion**

76. Defendants failed to prevent diversion, or otherwise control the supply of opioids flowing into communities across the United States, including in the State of Michigan. Defendants further failed to report and halt shipment of suspicious orders. In disregard of their known duties, Defendants continued to pump massive quantities of opioids into the State of Michigan.

77. Data from the DEA’s ARCOS database shows that Defendants placed a huge volume of prescription opioids into the State of Michigan.<sup>32</sup> Between the years 2006 and 2012 alone, there were 2,852,578,277 pills distributed into the State.<sup>33</sup> The highest number of pills, 514,258,850, were distributed by McKesson, with Walgreens not far behind. Moreover, two Walgreens pharmacies were within the top five recipients of prescription opioids in the State. This high volume of opioids alone should have alerted Defendants to the fact that suspicious

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<sup>32</sup> *Drilling into the DEA’s pain pill database*, The Washington Post, (originally published July 16, 2019, updated July 21, 2019), at [https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/?utm\\_term=.f0cebd69c859](https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/?utm_term=.f0cebd69c859).

<sup>33</sup> *Id.*

orders were being placed, as the amount of opioids that were sent into Michigan far exceeded what could be consumed for medically legitimate purposes; yet, Defendants failed to report and halt those orders.

78. Michigan's analysis of ARCOS data further confirms that Defendants are responsible for a large number of shipments that deviated—often substantially—in size, pattern, or frequency from shipments in preceding months. Although the State's analysis is ongoing, the pattern of suspicious shipments is immediately apparent. Thousands of shipments of Defendants' drugs were of a quantity or frequency that exceeded the range established over the preceding six months, or otherwise deviated substantially from normal patterns. Shipments exhibiting such deviation from historic baselines are presumptively suspicious under the CSA.

79. Exercising reasonable care, Defendants should have taken reasonable steps to monitor, investigate, and, where warranted, report and halt suspicious orders to prevent diversion. Consistent with their prolonged failure to implement anti-diversion controls, Defendants did not take these steps.

80. Defendants' failure to monitor, investigate, report, and halt suspicious orders of prescription opioids are a direct and proximate cause of the widespread diversion of prescription of opioids for non-medical uses in Michigan. This unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic and prescription opioid abuse, addiction, and death in the State of Michigan.

81. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against three of the four Defendants in



178 registrant actions between 2008 and 2012<sup>34</sup> and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.<sup>35</sup> Governmental agencies and regulators have confirmed (and in some cases these Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing. This failure has materially contributed to the opioid crisis by flooding Michigan with large quantities of opioids.

82. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, inter alia, failure to identify and report suspicious orders at several of its facilities. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

83. McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers.” Due to these violations, McKesson agreed to a partial suspension of its

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<sup>34</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

<sup>35</sup> *Id.*

authority to distribute controlled substances from certain of its facilities some of which investigators found “were supplying pharmacies that sold to criminal drug rings.”

84. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in three states by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
- “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”;
- “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

85. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance.

Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal Health settled for \$20 million.

**a. McKesson**

86. McKesson breached its duties under federal and state law.

87. McKesson distributed an extraordinary amount of prescription opioids into Michigan's communities. McKesson's excessive distribution was made possible by, and is evidence of, McKesson's failures to comply with its duties under state and federal law.

88. McKesson entered the illegal drug market and failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the State of Michigan.

89. McKesson is a sophisticated pharmaceutical distributor that has amassed great wealth from the delivery of pharmaceutical products, including prescription opioids. In fact, McKesson touts the fact that it delivers 1 out of every 3 prescriptions in the United States.<sup>36</sup> This prowess in the pharmaceutical arena currently has McKesson seated at number 7 on the Fortune 500 list. However, as the company acknowledges, its size and infiltration into various aspects of the pharmaceutical industry have also provided the company with a unique national perspective on the diversion of controlled substances, including opioids.<sup>37</sup>

90. McKesson has admitted its well-established duties to prevent diversion through its monitoring of controlled substances, which has been consistent since 1970.<sup>38</sup> As part of this suspicious order monitoring system, McKesson has a duty to report suspicious orders and to halt shipment of any orders that are deemed suspicious.<sup>39</sup> Further, McKesson has conceded that

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<sup>36</sup> MCKMDL00336768 at MCKMDL00336776.

<sup>37</sup> MCKMDL00452353 at MCKMDL00452357.

<sup>38</sup> See 7/31/18 Hartle Depo. at 78:4-10; 85:2-9.

<sup>39</sup> See 7/31/18 Hartle Depo. at 36:14-37:4; 38:5-19.

violations of these CSA requirements result in a substantial and detrimental effect on the health and general welfare of the American people.<sup>40</sup>

91. Importantly, McKesson has also known since it began distributing opioids that this class of drugs has a high potential for abuse, and can lead to severe psychological and physical dependence.<sup>41</sup> In fact, McKesson has acknowledged in internal presentations that the opioid epidemic is the deadliest drug epidemic this country has ever faced.<sup>42</sup> Unfortunately, opioid addiction is also a direct gateway to the initiation of illicit heroin use.<sup>43</sup>

92. McKesson admits that the societal costs of the opioid epidemic have been massive. McKesson internally has estimated the financial impact to cost this country in the range of \$57 billion annually.<sup>44</sup> McKesson has further conceded that McKesson is partially responsible for the societal costs of the opioid epidemic this country faces today.<sup>45</sup>

93. McKesson has consistently failed to comply with its obligations to prevent diversion. McKesson has had SOM policies in place dating at least back to 1997.<sup>46</sup> Under the 1997 version of its policy, which remained in effect until 2007, a daily and monthly Controlled Substance Suspicious Order Warning Report was generated at the distribution center. To qualify for placement on this report the controlled substance order had to be 3 times the rolling 12 month average for that drug at that distribution center.<sup>47</sup> While McKesson claims that these reports

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<sup>40</sup> See 7/31/18 Hartle Depo. at 43:22-44:5.

<sup>41</sup> See 7/31/18 Hartle Depo. at 50:3-7; 50:22-51:3.

<sup>42</sup> MCKMDL00448596 at MCKMDL00448598.

<sup>43</sup> See 8/1/18 Hartle Depo. at 37:4-38:17.

<sup>44</sup> MCKMDL00336833 at MCKMDL00336856.

<sup>45</sup> See 7/31/18 Hartle Depo. at 285:6-286:15.

<sup>46</sup> MCKMDL00651873.

<sup>47</sup> MCKMDL00346554 at MCKMDL00346582; See also Gary Hilliard Depo. at 163:21-169:7.

were provided to the DEA, McKesson has not yet provided any evidence that this claim is true. Further, orders listed on this report were not held or halted, but were shipped without review. McKesson's own regulatory employees have conceded that these reports did not satisfy the requirements of the CSA to report suspicious orders.<sup>48</sup>

94. In late 2005, DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for internet pharmacies. In January 2006, DEA notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several internet pharmacies during a 3 week period.<sup>49</sup> During discussions with DEA, McKesson conceded that these extremely large orders were not flagged, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes.<sup>50</sup> These excessive and suspicious purchases ultimately led to DEA seeking a show cause order against the distribution center supplying these pills. McKesson ultimately resolved these violations as part of the 2008 settlement.<sup>51</sup>

95. Due in large part to the violations referenced above, in May 2007 McKesson created the Lifestyle Drug Monitoring Program (LDMP). The LDMP set thresholds of 8,000 doses a month for oxycodone and hydrocodone containing products.<sup>52</sup> However, these thresholds were only "soft caps," and orders exceeding these levels would not be blocked and were not reported to DEA.<sup>53</sup> Additional problems with the LDMP were uncovered during routine auditing of the program. First, it was noted that "it is possible not all of the products containing

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<sup>48</sup> MCKMDL00510747; See also Gary Hilliard Depo. at 176:8-22.

<sup>49</sup> MCKMDL00496876 at MCKMDL00496877.

<sup>50</sup> MCKMDL00496876 at MCKMDL00496877-MCKMDL00496878.

<sup>51</sup> MCKMDL00337001 at MCKMDL00337013.

<sup>52</sup> MCKMDL00330211.

<sup>53</sup> MCKMDL00540033.

one of the generic ingredients are included” in the reports generated as part of the LDMP.<sup>54</sup> The second flaw noted was that the Daily Dosage Summary Report generated under the LDMP was organized by distribution center, and therefore a customer could both exceed the monthly 8,000 dosage unit threshold and avoid detection by spreading its purchases across multiple distribution centers.<sup>55</sup> McKesson employees have alleged the company continued using the DU45 reports during this time period to report excessive orders as defined above.

96. While McKesson’s first written policy aimed at preventing diversion dates back to at least 1997, the company has shown an unwillingness to comply with that policy and those that followed it. By 2008, the DEA and DOJ felt compelled to punish McKesson for its flagrant noncompliance with the law. On May 2, 2008, McKesson entered into a settlement agreement with the DEA and DOJ and paid \$13,250,000 in fines for numerous violations concerning the distribution of opioids.<sup>56</sup>

97. The violations at issue were as egregious as they were widespread. For example, from January 2005 to October 2006 McKesson delivered over 3 million doses of hydrocodone to a single small pharmacy in Baltimore, Maryland while also failing to report any of the orders from that pharmacy as suspicious.<sup>57</sup> In a single month, McKesson delivered more than 2 million doses of hydrocodone to seven pharmacies in the Tampa area and failed to report any orders from those pharmacies as suspicious.<sup>58</sup> Over a several month period in 2007 McKesson delivered 2.6 million doses of hydrocodone to two Texas pharmacies while failing to report any

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<sup>54</sup> MCKMDL00591949 at MCKMDL00591951.

<sup>55</sup> *Id.*

<sup>56</sup> MCKMDL00337001.

<sup>57</sup> MCKMDL00337001 at MCKMDL00337013.

<sup>58</sup> *Id.*

orders from those pharmacies as suspicious.<sup>59</sup> These violations only scratch the surface of the conduct at issue in the 2008 settlement agreement.

98. In May 2008, McKesson launched the Controlled Substances Monitoring Program (CSMP), which has remained in effect in some form since 2008. Given that the CSMP was created as a result of the DOJ settlement, it would be expected that the program would serve to make it more difficult for customers to improperly obtain opioids. However, when the program was launched, McKesson made sure to notify all of its pharmacy customers that it would remain “business as usual” as it pertained to those customers’ ability to obtain controlled substances, including opioids.<sup>60</sup>

99. Thresholds were set under the CSMP utilizing the customer’s last 12 months of orders for a given product and adding a buffer to that amount. Specifically, McKesson took the highest of the preceding 12 months orders for a given product and added a 10% buffer to that number and set that as the running threshold for the customer.<sup>61</sup> Retail national accounts received even more leeway on their thresholds, generally being given a 20-25% buffer, rather than 10%.<sup>62</sup> Thresholds were also routinely increased with little or no justification given to support the increase.<sup>63</sup> Customers were also notified as they approached their threshold, so they could request an increase without any interruption in receiving the product.

100. While customers rarely reached their thresholds under the CSMP, if they did, the orders would be blocked until a threshold increase was approved. Once the orders were blocked

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<sup>59</sup> *Id.*

<sup>60</sup> MCKMDL00543554 at MCKMDL00543558.

<sup>61</sup> MCKMDL00267223 at MCKMDL00267225.

<sup>62</sup> MCKMDL00430124.

<sup>63</sup> MCKMDL00476776.

under the CSMP, a three-level review was also triggered.<sup>64</sup> This three-level review was designed to assess whether the order was suspicious and whether further orders from the customer should be blocked. Orders were only reported as suspicious if the review made it to level 3.

101. The settlement with DEA and DOJ in 2008 and the implementation of the CSMP program did nothing to curb McKesson's flagrant violations of the CSA. The DEA has testified that McKesson "blatantly" violated the terms of its 2008 MOU with the DEA.<sup>65</sup> 1

102. The DEA and DOJ began investigating McKesson again in 2013 and quickly discovered that McKesson had developed a policy of not reporting suspicious orders. In fact, the CSMP, in effect, actually instructed McKesson employees to avoid using the word suspicious so as to avoid the requirement to report suspicious orders to the DEA.<sup>66</sup> This policy, and others, ensured that McKesson reported almost no suspicious orders of opioids nationally from 2008 to 2013.

103. McKesson also manipulated the threshold system it established to ensure that it would not have to block customer orders or engage in any due diligence involving customer orders. First, McKesson set thresholds so high that they would never be exceeded, thus ensuring that no higher level due diligence would be required by McKesson.<sup>67</sup> Second, McKesson would routinely increase opioid thresholds preemptively despite a well-established policy that threshold increases should always be customer generated.<sup>68</sup> Third, McKesson would also increase thresholds for the flimsiest of reasons or for no reason at all. For example, in November 2008,

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<sup>64</sup> MCKMDL00000021 at MCKMDL00000029 - MCKMDL00000031.

<sup>65</sup> See Prevosnik Dep. Vol. II, 621:5 to 621:16, 624:13 to 624:18, April 18, 2019 (DEA 30(b)(6) designee).

<sup>66</sup> MCKMDL00002509 at MCKMDL00002531.

<sup>67</sup> MCKMDL00409224 at MCKMDL00409234.

<sup>68</sup> MCKMDL00409224 at MCKMDL00409235.



employees of McKesson permanently increased opioid thresholds for 200 customers by 30% for no reason other than it was around the Thanksgiving holiday.<sup>69</sup>

104. McKesson also deferred completely to retail national account customers to dictate when their thresholds would be increased. McKesson's Senior Director of Distribution Operations, Donald Walker, readily acknowledged that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.<sup>70</sup> For example, as seen in a January 2009 presentation, McKesson outlined its plan for automatic threshold increases for CVS stores when they approached their threshold and to only seek a justification for thresholds increases from CVS if the increases were "extraordinary" and without "further CVS explanation."<sup>71</sup> McKesson's erroneous reasoning for such automatic threshold increases was to "minimize disruption of business," and to ignore reviewing "routine" threshold increases.<sup>72</sup>

105. Ultimately, DEA and DOJ concluded that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders and jeopardized the health and safety of people around the country.<sup>73</sup> DEA and DOJ described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic"<sup>74</sup> As a result of these broad sweeping due diligence failures, McKesson agreed to a \$150,000,000 settlement with the DEA and DOJ.<sup>75</sup> Additionally, McKesson accepted responsibility for nationwide failures of due

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<sup>69</sup> MCKMDL00000520.

<sup>70</sup> See Donald Walker Depo. at 190-193.

<sup>71</sup> MCKMDL00574488.

<sup>72</sup> *Id.*

<sup>73</sup> MCKMDL00409224 at MCKMDL00409234.

<sup>74</sup> MCKMDL00409453 at MCKMDL00409454.

diligence as to opioid distribution spanning 2009 to 2017.<sup>76</sup> It would be expected that such a harsh financial penalty would have dramatically altered McKesson's practices. However, before the ink of the settlement agreement was even dry, McKesson was already re-assuring customers who were concerned that the flow of opioids would be curtailed that it would be "business as usual" at McKesson.<sup>77</sup>

106. After renewed investigations by the DEA and DOJ beginning in late 2013, McKesson began to try and tighten up its SOM policies. Included within those efforts was the threshold reduction initiative wherein McKesson reduced the oxycodone thresholds for most customers, which ultimately resulted in a total threshold reduction for oxycodone of 42 million doses per month.<sup>78</sup>

107. McKesson also began working with a consulting company named Analysis Group (AGI) in 2014. AGI was tasked with creating a new SOM policy for McKesson. AGI and McKesson tinkered around with some advanced analytics over the next couple of years until finally settling into a new analytics-based program in 2017. Under this new system, McKesson established two separate thresholds – the benchmark threshold and the same-customer threshold. The lower of these two thresholds was binding on the customer as their operative threshold.<sup>79</sup> The same customer threshold is simply a threshold created based on the customer order history

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<sup>75</sup> MCKMDL00355349.

<sup>76</sup> MCKMDL00355349 at MCKMDL00355352.

<sup>77</sup> MCKMDL00418094.

<sup>78</sup> MCKMDL00410744 & MCKMDL00402184.

<sup>79</sup> MCKMDL00336634 at MCKMDL00336679.

for the product in question. That threshold changes monthly as a new average is established for the customer.<sup>80</sup> The benchmark threshold is established by inputting factors such as size of the pharmacy and typical usage for the geographic region whether the pharmacy is located.<sup>81</sup> Orders exceeding these thresholds are blocked and reported to DEA.<sup>82</sup>

108. On January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.” McKesson further admitted that, during this time period, it:

“[F]ailed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers” throughout the United States. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which, investigators found “were supplying pharmacies that sold to criminal drug rings.”

**b. Cardinal Health**

109. Defendant Cardinal Health breached its duties under federal and state law.

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<sup>80</sup> MCKMDL00336634 at MCKMDL00336687.

<sup>81</sup> MCKMDL00336634 at MCKMDL00336683.

<sup>82</sup> MCKMDL00336634 at MCKMDL00336682.

110. Cardinal Health distributed an extraordinary amount of prescription opioids into Michigan communities. Cardinal Health's excessive distribution was made possible by, and is evidence of, Cardinal Health's failures to comply with its duties under state and federal law.

111. Cardinal Health entered the illegal drug market and failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms the State of Michigan.

112. Cardinal Health did not have anything resembling an adequate suspicious order monitoring system until at least 2008. Despite having nearly unlimited resources and sources of data and information to assist it in preventing diversion, Cardinal Health only made improvements to its suspicious order monitoring system as a result of the investigations and fines levied by the DEA and state attorneys general.

113. As a DEA registrant and wholesale distributor, Cardinal Health was required to maintain effective controls against the diversion of prescription opiates. Cardinal Health was further required to identify, block and report suspicious orders from pharmacies. Cardinal Health failed to do this, resulting in the widespread diversion of prescription opioids in the State of Michigan.

114. From 1996 to 2008, Cardinal Health did not have an anti-diversion program that could adequately monitor and detect suspicious orders of opioids or timely report any suspicious orders.

115. Cardinal Health adopted a DEA Compliance Manual<sup>83</sup> as early as April 4, 2000,

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<sup>83</sup> CAH\_MDL\_PRIORPROD\_DEA07\_01176559.

which contained a corporate policy on suspicious order reporting.<sup>84</sup> The policy provided for after-the-fact reporting and a cage vault rule placing a cap on individual sales. The policy was in effect at least through June 15, 2006.<sup>85</sup>

116. According to its policies and procedures, Cardinal identified suspicious orders prior to shipment via each distribution center's "pickers and checkers" - distribution center cage/vault personnel responsible for physically "picking" customers' orders from warehouse shelves for packaging and "checking" the contents of the package to ensure the order was filled correctly. According to Cardinal's DEA Compliance Manual, the "pickers and checkers" were responsible for policing individual orders that appeared excessive in relation to other customers' ordering patterns or that customer's order history. Cardinal developed and posted in the distribution centers' cage/vault areas an "Excessive Purchases Schedule" for pickers and checkers to use to identify suspicious orders.<sup>86</sup>

117. Cardinal implemented daily limits that the pickers and checkers were to use for identifying suspicious orders. Schedules of these limits were implemented across the entire United States in the late 1990s. The charts identify daily limits for multiple drugs including several categories of opioids for Cardinal Health customers.

118. According to Cardinal Health's top regulatory employee from 1996 to 2007, Steve Reardon, any orders exceeding these limits should have been stopped, reported to the DEA, and due diligence should have been conducted and documented to dispel suspicion of diversion before the order was allowed to ship.<sup>87</sup>

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<sup>84</sup> CAH\_MDL\_PRIORPROD\_DEA07\_01384040; CAH\_MDL\_PRIORPROD\_DEA07\_01176607.

<sup>85</sup> CAH\_MDL\_PRIORPROD\_DEA07\_01188147.

<sup>86</sup> CAH\_MDL\_PRIORPROD\_DEA07\_01383895.

<sup>87</sup> Depo. of Reardon, 421:4-16; 493:1-18.

119. The warehouse employees at each distribution center had the impossible task of monitoring the millions of orders received each month by Cardinal, comparing those orders to the Dosage Limit Chart, and reporting any excessive orders to the DEA. Cardinal documents show that in a single month in 2009, for example, Cardinal shipped more than 146 million dosage units of fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone dosage units across United States.<sup>88</sup> This procedure simply was not followed at Cardinal Health to any meaningful degree.

120. From at least 1996 to 2008, Cardinal's other method for reporting suspicious orders was through the submission of Ingredient Limit Reports (ILR) to the DEA. These were retrospective monthly summaries for the prior month related to all controlled substances, including opioids. These reports showed which orders of controlled substances Cardinal received that exceeded a pre-determined average that had been multiplied by 4. Cardinal's submission of ILRs did not satisfy its obligation to report suspicious orders under 21 C.F.R. 1301.74(b), adopted into Michigan law, as they were only submitted after the orders had already shipped. Cardinal knew the reports did not satisfy Cardinal's suspicious order reporting obligations because both the DEA and the National Wholesale Druggists Association – predecessor of the Healthcare Distribution Alliance – had made it clear as early as 1984 that they did not. In an April 27, 1984 letter to NWDA Vice President of Government Affairs, Ronald Streck, Acting Chief of the Diversion Operations Section of the DEA, G. Thomas Gitchell, advised Streck that an “after-the-fact computer printout of sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered.”<sup>310</sup> The NWDA's Suspicious Order Monitoring System guidelines, issued to all its members including Cardinal

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<sup>88</sup> CAH\_MDL2804\_03248526.

Health in June of 1993, re-states the DEA's position, advising distributors that the "submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders."<sup>89</sup> In other words, it was Cardinal's policy to ship orders it knew were suspicious without conducting any due diligence or investigation. Further, the ILR system failed because it did not account for orders of unusual frequency or orders deviating from a normal pattern. Despite having around 30,000 employees, Cardinal Health had only 3 employees that were responsible for reviewing Ingredient Limit Reports.<sup>90</sup> Even Cardinal Health's former Vice President of Quality and Regulatory Affairs, Steve Reardon, testified that three individuals was insufficient to review all Ingredient Limit Reports.<sup>91</sup>

121. Cardinal Health has been in possession of the *NWDA Suspicious Order Monitoring System* (v.1984), including the "Letters from the DEA Approving the Format" since 1993.<sup>92</sup> Cardinal Health was on notice that "after-the-fact computer printout of sales data" is not sufficient to comply with its obligations. Nonetheless, Cardinal Health continued to report suspicious orders after-the-fact.

122. Cardinal Health has been in possession of Section 5126 of the DEA's Diversion Investigators Manual (v.1996) since at least 2003.<sup>93</sup> The Manual states:

The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to

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<sup>89</sup> *Id.* at 01465730.

<sup>90</sup> Depo. of Reardon, 71:16-72:5; 147:14-21.

<sup>91</sup> *Id.* at 464:4-20.

<sup>92</sup> CAH\_MDL2804\_01465723.

<sup>93</sup> CAH\_MDL2804\_02203353.

believe that controlled substances possibly are being diverted.

123. Cardinal was therefore on notice that shipping a suspicious order, rather than blocking the order, expressed an “attitude of irresponsibility that is a detriment to public health and safety.” Nonetheless, it continued to ship suspicious orders.

124. Cardinal met with the DEA on August 22, 2005, as part of the DEA’s Distributor Initiative.<sup>94</sup> It was reminded to “report suspicious orders when discovered” and that “reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective control against diversion.” Nonetheless, Cardinal continued to ship suspicious orders and report after-the-fact.

125. In 2008, for the first time, Cardinal implemented a written policy to stop shipment of orders suspected of diversion. The policy was implemented more than a year following the receipt of Joseph Rannazzisi’s September 27, 2006 letter reminding Cardinal of its obligation to stop shipments of suspicious orders. As Cardinal Health’s own employee Steve Reardon testified, suspicious orders must not be shipped without first conducting due diligence to dispel the suspicion of diversion.<sup>95</sup>

126. Prior to 2012, Cardinal Health’s approach to reporting suspicious orders was to only report customers that appeared suspicious enough to warrant Cardinal terminating the customer as an unreasonable risk for diversion.<sup>96</sup>

127. In 2007, the DEA initiated a prosecution of multiple Cardinal Health distribution centers due to their failure to operate an adequate suspicious order monitoring systems (SOMS) and violations of the CSA. The DEA found that Cardinal Health failed to “maintain adequate

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<sup>94</sup> US-DEA-00000352.

<sup>95</sup> Depo. of Steve Reardon, 451:15-23.

<sup>96</sup> CAH\_MDL\_PRIORPROD\_HOUSE\_0003331.



controls against the diversion of controlled substances on or prior to September 30, 2008, at all distribution facilities” operated, owned, or controlled by Cardinal Health in the United States.

This encompassed all 27 of Cardinal Health’s distribution facilities.

128. Cardinal Health knew its suspicious order monitoring system (SOMS) was defective. In the face of sanctions from the DEA, Cardinal Health commissioned Cegedim Dendrite to perform an investigation into its suspicious order monitoring system (SOMS). The report, dated January 23, 2008, found that Cardinal Health’s SOMS was not compliant with federal law and made several recommendations. Cardinal Health did not timely implement many of the recommendations.<sup>97</sup>

129. Cardinal Health then entered into an Administrative Memorandum of Agreement, following the DEA’s issuance of immediate suspension orders or orders to show cause (“ISO” or “OSC”) on Cardinal distribution centers in Washington, Florida, New Jersey, and Texas.<sup>98</sup> Cardinal distributed massive amounts of opioids to pharmacies across the country that Cardinal knew or should have known were diverting opioids. The DEA found that Cardinal failed to maintain effective controls to detect and prevent diversion of controlled substances at each distribution center.

130. Cardinal paid \$34 million to the U.S. government to resolve the investigation and was also required to implement a suspicious order monitoring program wherein it would determine whether a suspicious order should either not be filled and reported to the DEA or

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<sup>97</sup> CAH\_MDL2804\_03309960. Cardinal Health failed to disclose this external investigation and/or its findings in its “confidential” written response to Congress despite a specific directive from the Chief Counsel of Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives. CAH\_MDL\_PRIORPROD\_HOUSE\_0004068.

<sup>98</sup> CAH\_MDL\_PRIORPROD\_DEA12\_00013056.

based on a detailed review the order is for a legitimate purpose and not likely to be diverted— obligations with which Cardinal Health did not comply.

131. In light of the DEA crackdown in 2007, Cardinal hired Deloitte to create a threshold system, which set thresholds for each base code for each customer based on 1) the customer's designation as small, medium, or large (based on the customer's sales), 2) the average orders for the prior year of all customers in that size designation, and 3) multiplied by a factor of three. Deloitte's calculation of initial thresholds was based on the previous twelve months' worth of ordering data. These numbers were significantly inflated due to the fact the United States was in the middle of a deadly opioid epidemic. Almost immediately, Cardinal began increasing thresholds far and above the levels established by Deloitte. Cardinal Health took no steps to consider the opioid epidemic when setting or increasing these thresholds.

132. Due in part to Cardinal's history of failing to monitor, detect, and report suspicious orders, average distribution of opioids had increased dramatically across the country over the previous decade. Cardinal calculated the thresholds amid the opioid epidemic, benefiting from an artificially high average upon which to base its calculations. These thresholds, which would become the centerpiece of Cardinal's anti-diversion program going forward, were premised on faulty reasoning.

133. Under Cardinal's threshold system after 2008, according to its Standard Operating Procedures, if, for a given month, a customer ordered more than its established threshold, Cardinal would be notified, the order would be held, and a due diligence review of the customer's profile and order history was triggered. Cardinal employees have testified that if an order tripped a pharmacy's threshold, a review of the circumstances surrounding the order should be documented and maintained in that pharmacy's "due diligence file." According to Cardinal's

policies, neither the orders triggering the pharmacy's threshold nor any other orders for drugs from the same drug family should have been shipped to the pharmacy without first conducting due diligence to verify that the orders were not suspicious. Cardinal documents show that in spite of its policies, Cardinal continued to fill orders for the same controlled substances without regard to the prior threshold breaches. Cardinal failed to conduct due diligence in response to these threshold events. Cardinal also continued to ship the customer the same drug that triggered a threshold event without any evidence that the order had been investigated or that the suspicion had been dispelled.

134. Cardinal had a policy and practice of providing preferential treatment to chain pharmacies differently than retail-independent pharmacies in many respects, including setting thresholds and conducting due diligence. Cardinal refused to impose the same requirements on chain customers because, as stated in Cardinal's June 27, 2006 letter to the New York Attorney General, large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."<sup>99</sup> Cardinal did not calculate thresholds for chain pharmacies in the same manner as described above; instead, this was a process that was conducted outside the Anti-Diversion Department at Cardinal Health. Cardinal also failed to conduct due diligence on its retail pharmacy chain customers, and instead, relied on the chains to report this information. Former Cardinal Health Director of Supply Chain Integrity, Steve Morse, confirmed this practice, particularly with respect to CVS.<sup>100</sup> Morse testified that despite Cardinal's written policy of requiring pharmacies to provide drug utilization reports, sales of controlled substances, sales of non-controlled substances, or prescriber information, and that a pharmacy's refusal to provide such information would be a red flag, CVS failed to provide this information to

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<sup>99</sup> 89(5) FOIL Appeal G000804 000006.

<sup>100</sup> Deposition of Steve Morse, 113:8-13.

Cardinal. Despite the clear violation of Cardinal’s own policies, Cardinal continued to supply CVS stores with large volumes of opioids.

135. After 2008, Cardinal ceased submitting Ingredient Limit Reports as its suspicious order reports but continued to manually submit suspicious order reports. Cardinal documents indicate that, nationwide, Cardinal reported a few dozen suspicious orders per year from 2008 to 2011.<sup>101</sup>

136. In 2012, the DEA began another prosecution of Cardinal Health for “blatantly” violating the terms of its 2008 MOU and shipping suspicious orders.<sup>102</sup> The DEA served another ISO on Cardinal’s distribution facility in Lakeland, Florida – one of the facilities at issue in the 2008 action – for distributing excessive amounts of oxycodone to retail pharmacies. Steve Morse, who Cardinal hired following the 2008 DEA action, was demoted for failing to timely terminate the pharmacies despite finding evidence of suspected diversion. Morse was removed from his position as a Director of Investigations to a position in regulatory management. A 2013 report of the Special Demand Committee of Cardinal Health’s Board of Directors cited his questionable judgment as part of the reason for this demotion, as well as the fact that Morse failed to review pharmacy site visit reports as required by Cardinal’s 2008 SOPs.<sup>103</sup> Similar to Steve Morse, as a result of the 2012 ISO and DEA investigation, Michael A. Moné was moved from his position as Vice President of Anti-Diversion into a position as an attorney with the company’s regulatory group where he remains today as a VP Associate General Counsel. The Special Demand Committee report states that Mr. Moné was moved as part of Cardinal’s

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<sup>101</sup> CAH\_MDL2804\_03262274, 03262438, CAH\_MDL2804\_00228327 and 00228364.

<sup>102</sup> Prevoznik Dep. (DEA 30(b)(6) designee), Vol. II, p.193 (April 19, 2019).

<sup>103</sup> CAH\_MDL\_PRIORPROD\_HOUSE\_00003331, 0003367.

transition to “assessing customers based more on objective criteria;” where Moné evaluated customers under a subjective standard.<sup>104</sup>

137. The 2012 DEA investigation resulted in Cardinal Health admitting that it failed to ensure proper due diligence for its customers and in complying with the 2008 MOA. The DEA has testified, through Thomas Prevoznik, that the DEA is “in fact frustrated that registrants were blatantly violating the MOUs from prior administrative actions” including “Cardinal Health’s 2008 MOU and settlement which resulted in a second DEA fine.”<sup>105</sup> It is this type of blatant disregard for regulatory obligations that has made the current volume of pills available to the public at large.

138. Cardinal Health entered a second MOA with the DEA in 2012 (2012 MOA) and again assured the DEA that they would come into compliance and operate within the confines of the CSA. Cardinal Health indicated that this time it was going to get it right and remove all subjectivity from the process to prevent poor decision making.

139. While Cardinal Health again attempted to make changes to its SOMS systems, it still did not ensure that it was maintaining effective controls to prevent the diversion of controlled substances. Cardinal Health continued to operate with the same threshold system that was previously in operation, with several changes.

140. Around the same time Cardinal Health entered into the 2012 MOA with the DEA, it moved Todd Cameron into the position of Senior Vice-President of Supply Chain Integrity. Mr. Cameron has testified that Cardinal Health’s new threshold system focused on prescription volume of each specific customer to determine its threshold. The significant problem with this

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<sup>104</sup> CAH\_MDL\_PRIORPROD\_HOUSE\_0003331, 0003367.

<sup>105</sup> See Prevoznik Dep. Vol. II, 621:5 to 621:20, April 18, 2019 (DEA 30(b)(6) designee).

approach was that Cardinal Health no longer considered population or comparison to similarly situated customers when setting thresholds.

141. While that lack of ensuring proper due diligence on chains such as CVS and Walgreens was a significant issue related to the 2012 MOA, Cardinal Health continued to refuse to require the same due diligence from national chains as they did retail independents.<sup>106</sup>

Additionally, Cardinal Health's failure to ensure its chain customers were conducting due diligence was further aggravated by the fact that Cardinal Health failed to sufficiently evaluate the national chains' SOMS to determine if such programs were effective to prevent diversion.<sup>107</sup>

142. Cardinal Health also devised a system where pharmacy customers were provided buffers above their previously set thresholds and used a coding scheme to identify which pharmacies had this built-in buffering system. However, Cardinal Health made no mention of any such buffering system in its SOP's that were the policies Cardinal Health indicated to regulators, including the DEA, it was operating by.

143. Even after the 2012 DEA investigation, Cardinal Health continued to fail to report suspicious orders. Cardinal Health Director of Quality and Regulatory Affairs Chris Forst testified that, after 2012, Cardinal Health only reported orders that the company believed to present a "high potential for diversion" instead of orders of unusual size, of unusual frequency, or deviating substantially from a normal pattern.<sup>108</sup>

144. From 2012 through 2015, Cardinal Health admittedly failed to report approximately 14,000 suspicious orders from "across the country" to the DEA.<sup>109</sup> The "vast

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<sup>106</sup> CAH\_MDL2804\_02953715.

<sup>107</sup> CAH\_MDL2804\_02953716.

<sup>108</sup> Depo. of Chris Forst, 192:15-193:4.

<sup>109</sup> Depo. of Todd Cameron, 269:12-270:13.

majority” of those orders involved opioids. Cardinal Health “uncovered” the unreported suspicious orders retrospectively through an audit process in 2015.<sup>110</sup>

**c. AmerisourceBergen**

145. Defendant AmerisourceBergen breached its duties under federal and state law. AmerisourceBergen distributed an extraordinary amount of prescription opioids into Michigan communities. Its excessive distribution was made possible by, and is evidence of, its failures to comply with its duties under state and federal law.

146. AmerisourceBergen failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms in the State of Michigan.

147. AmerisourceBergen’s breaches of its duties have persisted for many years, dating back to before 2007, when the DEA shut down one of AmerisourceBergen’s distribution centers as part of an enforcement action. AmerisourceBergen’s pre-2007 policies constituted a failure to design and operate a system to identify suspicious orders because they only identified “excessive” orders that exceeded a three times threshold, which only took into consideration prior orders of that specific pharmacy. AmerisourceBergen’s system did not take into consideration other relevant factors such as order frequency patterns, order averages of similar pharmacies, or comparisons of sales of Schedule II or III controlled substances with the sales of other controlled substances. AmerisourceBergen also specifically failed to identify suspicious orders from internet pharmacies that the DEA concluded should have been identified.

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<sup>110</sup> *Id.* at 271:18-22.

148. AmerisourceBergen further failed to report suspicious orders, shipped orders that were suspicious, and failed to perform meaningful due diligence. Pre-2007, while certain orders that exceeded the three times threshold were reported to the DEA, they were only reported *after* being shipped. AmerisourceBergen had no meaningful due diligence process in place to investigate whether “excessive” orders otherwise qualified as suspicious, other than an effort to make sure a customer was licensed with the state and registered with the DEA.

149. AmerisourceBergen’s official national policy from 1990 until the 2007 DEA Settlement was to ship *all* orders of controlled substances, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or whether that order was determined to be suspicious.

150. The 2007 enforcement action by the DEA was based on AmerisourceBergen filling and shipping orders from pharmacies, which, according to the DEA, AmerisourceBergen knew to be suspicious.<sup>111</sup> The enforcement action shut down AmerisourceBergen’s Orlando distribution center. On June 22, 2007, AmerisourceBergen and the DEA reached a settlement agreement in which AmerisourceBergen acknowledged it had “failed to maintain effective controls at the Orlando Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of AmerisourceBergen.”<sup>112</sup> According to the April 19, 2007 Order to Show Cause and Immediate Suspension of Registration issued by the DEA, AmerisourceBergen distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers and it distributed hydrocodone to pharmacies even though they ordered small amounts of other drug products relative to those purchases. According to that same Order,

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<sup>111</sup> See ABDCMDL00269383-84.

<sup>112</sup> See ABDCMDL00279854.



AmerisourceBergen distributed hydrocodone to pharmacies much more frequently than AmerisourceBergen's other customers and shipped to pharmacies that AmerisourceBergen knew or should have known were dispensing opioids prescribed by physicians who did not conduct medical examinations of their customers, and instead wrote prescriptions for controlled substances ordered by customers over the internet.<sup>113</sup>

151. In order to obtain authorization from the DEA to re-open the Orlando facility, AmerisourceBergen was required to update its diversion control program, including adding (1) a more in-depth due diligence process; and (2) a requirement to stop shipping suspicious orders to customers.<sup>114</sup> However, despite these requirements, AmerisourceBergen still failed to comply with its obligations under the CSA.

152. Post-2007, AmerisourceBergen still failed to design and operate an adequate system to identify suspicious orders because it continued to employ a "threshold-based system," which was based on an arbitrary three times multiplier among drug families and, which continued to ignore other relevant information. AmerisourceBergen also left critical discretion to identify suspicious orders with its distribution center employees, without putting in place any concrete rules or criteria on how suspicious orders should be identified. Accordingly, AmerisourceBergen failed to identify and grossly underreported suspicious orders.

153. Further, while AmerisourceBergen purported to change its system in 2007 pursuant to its settlement agreement with the DEA, it still did not fully comply with the requirement not to ship suspicious orders after that date. In certain cases, even orders reported to the DEA were shipped anyway, rather than being held or cancelled.

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<sup>113</sup> See ABDCMDL00269383-387.

<sup>114</sup> See Zimmerman Deposition, 139:20-140:8; see also Settlement and Release Agreement, ABDCMDL00279854-00279865.

154. An Audit Report performed of AmerisourceBergen's SOM system in 2015 cited numerous problems with AmerisourceBergen's SOM system, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies and communications break-downs, which contributed to "gaps and risks" in AmerisourceBergen's ability to identify orders as suspicious and prevent diversion.

155. AmerisourceBergen's efforts of due diligence in identifying suspicious orders at this time were also ineffective. Specifically, AmerisourceBergen's "Know Your Customer" due diligence policy was based on a form filled out by AmerisourceBergen's own sales representatives in conjunction with AmerisourceBergen's pharmacy customers, creating a conflict of interest in identifying accurate information. As AmerisourceBergen acknowledged internally regarding its targeted pharmacy visits, its true goal "is always to maintain the entity as an ABC customer."<sup>115</sup> Additionally, AmerisourceBergen's chain retail pharmacy customers were exempt from the requirement to provide certain "Know Your Customer" information, which improperly abdicated AmerisourceBergen's duty to identify suspicious orders to the customers themselves. Further, AmerisourceBergen's due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible. Internally, AmerisourceBergen admitted to having only "about 10% of the required customer due diligence documents," acknowledging that such a failure put AmerisourceBergen "at risk with regulators."<sup>116</sup>

156. Rather than focusing on putting effective controls to prevent diversion in place and designing and operating a system to detect suspicious orders and stopping those orders,

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<sup>115</sup> ABDCMDL00364844.

<sup>116</sup> ABDCMDL00159415.

AmerisourceBergen circumvented the requirements and coached customers on how to avoid being detected by the system and being the subject of an enforcement action by the DEA. For example, a July 2013 AmerisourceBergen document entitled “Sales Talking Points” warned an AmerisourceBergen customer that its “overall volume” and “percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. *This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions.* Every day, we read about another independent pharmacy under investigation. *I want to make sure that doesn’t happen to you.*” AmerisourceBergen then counseled the customer not to order fewer controlled substances, but to strategically format their ordering patterns so that they would not get flagged by SOMs programs or regulators.<sup>117</sup>

157. AmerisourceBergen well knew the consequence of failing to meet its obligations under the CSA. AmerisourceBergen’s chief compliance officer admitted that if AmerisourceBergen did not adhere to “our effective controls to prevent diversion, yes, diversion could occur.”<sup>118</sup> As discussed above, however, the evidence shows that AmerisourceBergen consistently ignored critical red flags and warning signs from its customers in what amounts to a structural break-down of its diversion prevention obligations under the CSA, which had real consequences in the communities where AmerisourceBergen shipped dangers drugs, like prescription opioids.

**d. Walgreens**

158. Despite its legal obligations as registrants under Michigan law, Walgreens entered an illegal drug market and allowed widespread diversion to occur—and did so knowingly. Walgreens knew that its SOM system did not comply with its obligations. In May 2006, the DEA

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<sup>117</sup> ABDCMDL00278212 (emphasis added).

<sup>118</sup> See Zimmerman Deposition, 104:14-17.

sent Walgreens a Letter of Admonition citing Walgreens for controlled substances violations at its Perrysburg Distribution Center. Specifically, the DEA informed Walgreens that the “formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient,”<sup>119</sup> and “inadequate.” The DEA reminded Walgreens that its suspicious ordering “formula should be based on (size, pattern, frequency).”<sup>120</sup>

159. After receiving the Letter of Admonishment, Walgreens decided to utilize to generate and send the DEA a monthly report of post-shipment “Suspicious Control Drug Orders” that Walgreens had filled for its stores, and did so from 2007 through 2012.<sup>121</sup> Despite the orders being flagged as “suspicious,” Walgreens did not halt these orders or perform any due diligence on them before shipment.<sup>122</sup>

160. Walgreens knew that this type of post-shipment “excessive purchase report” did not satisfy the requirements in the CSA and its implementing regulations. In September 2007, three Walgreens’ senior employees attended the DEA Office of Diversion Control’s 13th Pharmaceutical Industry Conference in Houston, Texas.<sup>123</sup> Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA “requirement is to report suspicious orders, not suspicious sales after the fact.”<sup>124</sup> Participant notes from this meeting indicate that Mr. Mapes advised the

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<sup>119</sup>CAH\_MDL\_PRIORPROD\_DEA12\_00011836,CAH\_MDL\_PRIORPROD\_DEA12\_00011853, CAH\_MDL\_PRIORPROD\_DEA07\_00159466, CAH\_MDL\_PRIORPROD\_DEA12\_00004383.

<sup>120</sup> WAGMDL00709508.

<sup>121</sup> WAGMDL00400357.

<sup>122</sup> See Errata to E. Bratton 30(b)(6) deposition.

<sup>123</sup>CAH\_MDL\_PRIORPROD\_DEA07\_01185382 at CAH\_MDL\_PRIORPROD\_DEA07\_01185404-5.

<sup>124</sup> CAH\_MDL\_PRIORPROD\_DEA12\_00011059; HDS\_MDL\_00002032 at 2040.

audience not to “confuse suspicious order report with an excessive purchase report. They are two different things.”<sup>125</sup>

161. Despite knowing as early as 2006 that its SOM policies were inadequate, being admonished by the DEA, and receiving specific instruction that the post-shipment excessive purchase reports did not satisfy its duties, Walgreens still did not institute a SOM program.<sup>126</sup>

162. It was not until March 2008, in response to three of Cardinal Health’s facilities being shut down by the DEA for suspicious drug ordering violations, that Walgreens finally took action to “begin creating” a SOM program.<sup>127</sup>

163. In December 2008, Walgreens conducted an internal audit of its Perrysburg, OH Distribution Center. That audit found that issues related to Walgreens suspicious controlled drug order processing and reporting system were still open from DEA’s May 2006 inspection, but Walgreens did not begin to address these issues until five months later.<sup>128</sup>

164. Though Walgreens developed a SOMS algorithm in June 2008,<sup>129</sup> Walgreens did not practically begin to implement its SOM program until August 2009, when it began to pilot the algorithm with respect to orders from seven (7) Walgreens stores.<sup>130</sup> Until September 2010, the SOM program flagged certain orders that exceeded the tolerance or frequency thresholds as

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<sup>125</sup> Acquired\_Actavis\_00441354 at 441355.

<sup>126</sup> WAGMDL00757193 (“internal controls that ensure compliance with DEA regulations ... pertain[ing] to all company DCs ... should be addressed to void potential DEA sanctions”, noting that these issues had been pending and “un-remediated” since audits in 2005 and 2006, and included “suspicious controlled drug order processing and reporting” and “lack of formalized CII controlled substance policies and procedures.”); *See also* WAGMDL00709508 (““suspicious ordering report is inadequate”); WAGMDL00709510 (“formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient”).

<sup>127</sup> WAGMDL00659801 at 818; WAGMDL00709395.

<sup>128</sup> WAGMDL00757193.

<sup>129</sup> WAGMDL00624527.

<sup>130</sup> WAGMDL00667936, at 938 and 940; *see also* WAGMDL00658227.

“suspicious,” but did not reduce, block, or report the orders. In September 2010, the program began to reduce orders that exceeded the tolerance threshold set by Walgreens to an amount below the threshold, but still did not halt the orders for evaluation or report the orders as suspicious. In November 2012, the program began to automatically reduce orders that violated ceiling thresholds.<sup>131</sup> Still, the program did not halt the orders for due diligence evaluation or report the orders as suspicious.

165. Not only did Walgreens’s SOM program not halt or report the orders its SOM program flagged as being suspicious, but there were other loopholes that limited the program’s effectiveness. First, the program only monitored orders Walgreens stores placed to Walgreens’ own distribution centers, so that even if a store hit its ceiling with Walgreens, the store could order more controlled substances through outside vendors such as Cardinal Health.<sup>132</sup> Second, even though a Walgreens store had hit its ceiling limit, the SOM program permitted stores to place PDQ (“pretty darn quick”) orders for controlled substances outside of those limits.<sup>133</sup> Additionally, stores had the ability to “interstore,” which means they simply transferred product from another store outside of the visibility of the SOM program.<sup>134</sup>

166. Beginning in 2013, Walgreens finally implemented a process which, in theory, permitted stores to order controlled substances in excess of the thresholds only if such orders could be justified. However, the review process was nominal, as such requests were almost always approved, as evidenced by the 95%+ approval rate for FY 2014 and 2015.<sup>135</sup>

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<sup>131</sup> WAGMDL00667938.

<sup>132</sup> See N. Polster Deposition at 250:1-253:7.

<sup>133</sup> WAGMDL00705321.

<sup>134</sup> See N. Polster Deposition at 257:14-258:2.

<sup>135</sup> WAGMDL00010887.

167. Walgreens admits that, since at least 2009, the DEA instructed Walgreens to “stop what was considered suspicious drug shipments to any of our stores.”<sup>136</sup> However, until the end of 2012 Walgreens continued to ship all flagged orders without due diligence review and continued to merely send a report to the DEA.

168. Thus, though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information from indicating red flags in order to more effectively prevent diversion. Notably, because of its vertically integrated structure, Walgreens has access to complete information regarding red flags of diversion across its pharmacies in and around Michigan, but, upon information and belief, Walgreens failed to utilize this information to effectively prevent diversion, both as a distributor and as a pharmacy.

169. Upon information and belief, Walgreens adopted “performance” metrics and prescription quotas that made it nearly, if not actually, impossible for its pharmacists to comply with Walgreens’ duties under Michigan law.

170. Upon information and belief, this problem was compounded by Walgreens’ failure to adequately train its pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

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<sup>136</sup> WAGMDL00660331.

171. Upon information and belief, Walgreens also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

172. Upon information and belief, Walgreens failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

173. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

174. Upon information and belief, Walgreens failed to conduct adequate internal or external audits of its opioid sales to identify patterns regarding prescriptions that should not have



been filled and to create policies accordingly, or, if they conducted such audits, they failed to take any meaningful action as a result.

175. Upon information and belief, Walgreens also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

176. Walgreens was, or should have been, fully aware that the quantity of opioids being distributed and dispensed by its stores was untenable, and in many areas was so high that illegal diversion was the only logical explanation; yet it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations under the law with regard to controlled substances.

177. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by pharmacies, including Defendant Walgreens, themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

178. According to industry standards, if a pharmacy finds evidence of prescription diversion, it has a duty to report to the Michigan Board of Pharmacy, and DEA also must be contacted.

179. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$130 billion. According to its website, Walgreens operates more than 8,000 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

180. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black-market sales.<sup>137</sup>

181. The settlement resolved investigations into and allegations of CSA violations in Michigan, as well as Florida, New York, and Colorado, that resulted in the diversion of millions of opioids into illicit channels.

182. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.<sup>138</sup>

183. Walgreens increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,”

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<sup>137</sup> Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

<sup>138</sup> Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.<sup>139</sup>

184. Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.<sup>140</sup>

185. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).<sup>141</sup>

186. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

187. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite

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<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.<sup>142</sup>

188. Walgreens routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

189. Throughout the country, and in Michigan in particular, Walgreens was or should have been aware of numerous red flags of potential suspicious activity and diversion.

190. On information and belief, Defendant Walgreens knew or reasonably should have known about the disproportionate flow of opioids into Michigan and the operation of “pill mills”. These “pill mills” generated opioid prescriptions that, by their quantity or nature, were red flags and/or direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

191. On information and belief, Defendant Walgreens knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Michigan.

192. On information and belief, because of regulatory and other actions taken against Defendant Walgreens directly, actions taken against others pertaining to prescription opioids obtained from its retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sales data that it developed and monitored, Defendant Walgreens was well aware that its distribution and dispensing activities fell far short of legal requirements.

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<sup>142</sup> *Id.*

193. Defendant Walgreens' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

**C. By Failing to Prevent Diversion of Highly Addictive Prescription Opioids, Defendants Have Fueled the Opioid Epidemic in Michigan**

194. Defendants' failures to prevent the diversion of prescription opioids in Michigan has created an unprecedented public health epidemic. In announcing a six-step plan to combat the opioid crisis in the State, Governor Whitmer called the opioid crisis the "greatest health crisis of our lifetime," and characterized the crisis as one that has "ravaged communities and families across the State."

195. According to the *Washington Post*, between the years 2006 and 2012 alone, there were 2,852,578,277 pills distributed into the State of Michigan. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."<sup>143</sup> As a direct result of Defendants' failure to stop the flood of opioids into Michigan communities, the State of Michigan has experienced a substantial increase in rates of opiate-related substance abuse, hospitalization and death. Defendants' failures to implement controls to prevent diversion has contributed to the opioid epidemic in Michigan.

196. According to a June 26, 2017 *mLive* article, opioid overdose deaths in Michigan nearly doubled from 2010 to 2015, from 639 opioid-related overdose deaths in 2010 to 1,271 deaths in 2015.<sup>144</sup> This number only includes overdose deaths which specify opioid and/or

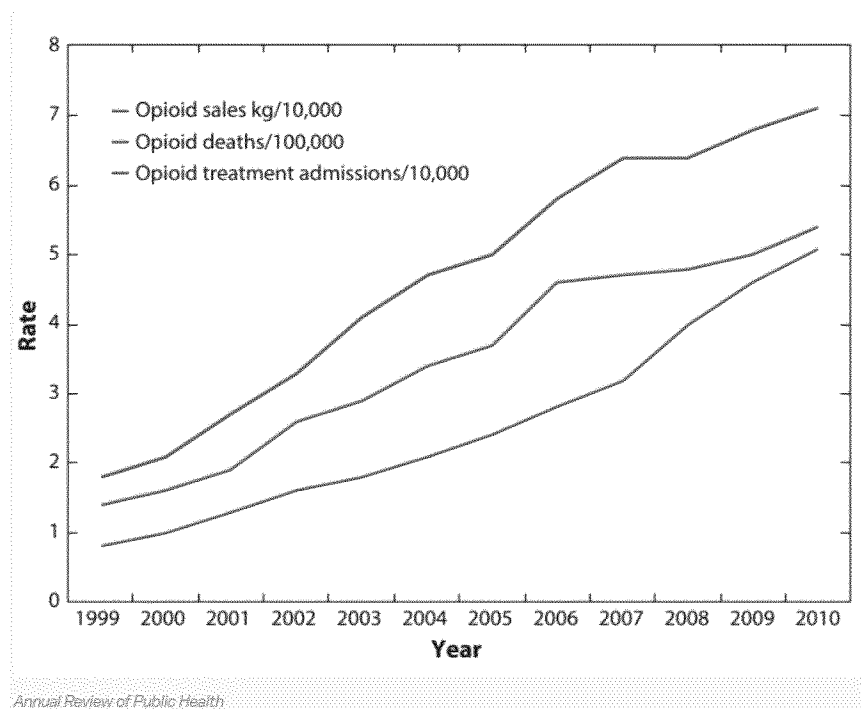
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<sup>143</sup> See Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

<sup>144</sup> Julie Mack, *See trend of opioid/heroin deaths in your Michigan county*, *mLive* (June 26, 2017), [http://www.mlive.com/news/index.ssf/2017/06/see\\_trend\\_of\\_opioidheroin\\_deat.html?app](http://www.mlive.com/news/index.ssf/2017/06/see_trend_of_opioidheroin_deat.html?app)

heroin as a factor, which understates the actual number of opioid-related deaths, because a significant number of death certificates for overdose deaths do not list the specific drugs at fault.<sup>145</sup> According to the CDC, Michigan ranks eighteenth in the nation for overdose deaths: there were nearly 2,000 drug overdose deaths in Michigan in 2015, and 2,347 in 2016.<sup>146</sup>

197. As prescription opioid sales increased in Michigan, so did treatment admissions and deaths, as demonstrated below:



As staggering as these numbers are, they understate the extent of the problem in Michigan, as 81.7% of Michiganders suffering from substance abuse go untreated.<sup>147</sup>

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<sup>145</sup> *Id.*

<sup>146</sup> *Drug Overdose Mortality by State*, Centers for Disease Control and Prevention, [https://www.cdc.gov/nchs/pressroom/sosmap/drug\\_poisoning\\_mortality/drug\\_poisoning.htm](https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm) (last visited April 4, 2019).

<sup>147</sup> *See* [https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid\\_fs\\_michigan.pdf](https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid_fs_michigan.pdf) (last visited Oct. 25, 2019).

198. Since 2014, the State has also increased spending on Medication Assisted Treatments (MATs) to address opioid addiction. This expense is in addition to treatment and counseling services.

199. Defendants' conduct has also had a devastating effect on children in Michigan. In 2016, 6,380 children were placed into foster care in Michigan. In 33% of those placements, parental substance abuse was a factor.<sup>148</sup> Of the placements involving parental substance abuse, 21% of those children were infants.<sup>149</sup> Children dealing with traumatic experiences can face social, emotional, physical, and mental health challenges that last into adulthood. Left unaddressed, early childhood adversity can lead to school failure, risky behaviors like alcohol and drug use, and increased chance of health conditions like obesity and heart disease.<sup>150</sup>

200. Defendants' conduct has further resulted in a dramatic rise in the number of infants in Michigan who are both addicted to opioids due to prenatal exposure to opioids and suffer from neonatal abstinence syndrome (NAS). Babies born with NAS typically require extensive hospital stays as they withdraw. Notably, in 2012 alone, Michigan Medicaid paid 81% of the \$1.5 billion that hospitals billed for treating babies suffering from opioid withdrawal.<sup>151</sup>

201. Defendants' conduct has also contributed to increased law enforcement costs in Michigan. In June 2017, the Michigan State Police launched the "Angel Program," a diversion program that "enables addicts to seek treatment," in an effort to battle the opioid epidemic.<sup>152</sup>

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<sup>148</sup> See [https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid\\_fs\\_michigan.pdf](https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid_fs_michigan.pdf) (last visited Oct. 25, 2019).

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

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

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

<sup>152</sup> Brad Devereaux, *Michigan State Police Offers Drug Treatment Instead of Arrest*, MLive (Dec. 18, 2017), [http://www.mlive.com/news/index.ssf/2017/12/michigan\\_state\\_police\\_offers\\_d.html](http://www.mlive.com/news/index.ssf/2017/12/michigan_state_police_offers_d.html).

The State Police have likewise sponsored numerous drug takeback events in an attempt to get the flood of opioids off Michigan streets.<sup>153</sup>

202. The rise in opioid addiction caused by Defendants' conduct has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past previously abused prescription opioids. In 2014, 568 people in Michigan died related to opioid overdose, while 433 people died related to heroin overdose. According to numbers from the Michigan Department of Health and Human Services, those numbers are on the rise over 15 years, increasing from 99 heroin or opioid overdose deaths in 1999 to 1,001 in 2014.<sup>154</sup>

203. Having profited enormously through the irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the State of Michigan. Defendants' role in these costs is not broken by the criminal actions of third parties. The express purpose of Michigan regulations, which follow federal law, is to prevent diversion of controlled substances. Defendants knew this, and knew that their failures to implement effective controls would result in opioids being diverted. As such, the flood of opioids caused by Defendants' misconduct was not only foreseeable by Defendants, but known by them directly. In many cases, Defendants were the first entities to know of the existence of the opioid crisis in the State but, rather than attempting to avert the crisis, or simply report it, Defendants did nothing.

204. The State seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the public nuisance.

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<sup>153</sup> See, e.g., <https://www.dailypress.net/opinion/editorial/2019/10/michigan-state-police-drug-take-back-day-is-october-26/> (last visited Oct. 25, 2019).

<sup>154</sup> See [https://www.mlive.com/news/2016/07/10\\_things\\_about\\_michigans\\_dead.html](https://www.mlive.com/news/2016/07/10_things_about_michigans_dead.html) (last visited Mar. 25, 2019).



**D. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations as Defenses**

**1. Continuing Conduct**

205. Up to and including the date of this Complaint, the State of Michigan continues to suffer harm from the unlawful actions by Defendants.

206. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

**2. Equitable Estoppel and Fraudulent Concealment**

207. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the State of Michigan and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of Michigan, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor status in Michigan and to continue generating profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, including the State of Michigan, that they were and are working to curb the opioid epidemic.

208. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and assured the public it was being “as effective and

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”<sup>155</sup>

209. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”<sup>156</sup>

210. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, HDMA and NACDS, made the following statements:<sup>157</sup>

- “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

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<sup>155</sup> Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\\_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html).

<sup>156</sup> Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse,* Wash. Post, Dec. 22, 2016, [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e\\_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html).

<sup>157</sup> Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at \*3-4, \*25.

- “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”
- “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

Through the above statements made on their behalf by their trade associations, Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

211. When a distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

212. After being caught failing to comply with particular obligations at particular facilities, Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson’s 2008 Settlement with the DEA, McKesson claimed to have “taken steps to prevent such conduct from occurring in the future,” including specific measures delineated in a “Compliance Addendum” to the Settlement. Yet, as outlined above, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had

specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

213. More generally, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

214. Along the same lines, Defendant McKesson publicly claims that its “customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process,” creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

215. Defendant AmerisourceBergen, too, has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

216. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and the National Association of Chain Drug Stores (NACDS), of which Defendant Walgreens is a member, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:<sup>158</sup>

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

217. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

218. Public statements by Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression

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<sup>158</sup> Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf’t Admin.*, Case No 15-1335, 2016 WL 1321983, (D.C. Cir. April 4, 2016) at \*3-4, \*25.

that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

219. Defendants were deliberate in taking steps to conceal their behavior and active role in the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

220. Defendants also concealed from the State of Michigan the existence of the State's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the State of Michigan, and deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims. The State's claims were fraudulently concealed and are thus subject to MCL § 600.5855 and common law fraud.

221. The State of Michigan did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Michigan, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

222. Further, Defendants also concealed and, for years, prevented discovery of information, including data from the ARCOS database, that confirmed their identities and the extent of their wrongful and illegal activities. It wasn't until April 11, 2018, that the Northern District of Ohio ordered the transactional ARCOS data be produced, over Defendants' strenuous

objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, entities like the State of Michigan *could not identify* the potential defendants in this litigation, and further held that such information was “critical”:

This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation . . . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiffs’ claims, but also to the Court’s understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

223. Defendants intended that their actions and omissions would be relied upon, including by the State of Michigan. The State did not know and did not have the means to know the truth, due to Defendants’ actions and omissions.

224. The State of Michigan reasonably relied on Defendants’ affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

**E. The State of Michigan Is Entitled to Exemplary Damages**

225. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs.

226. Defendants knew that large and suspicious quantities of opioids were pouring into communities throughout the United States, yet, despite this knowledge, took no steps to report

suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

227. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country.

228. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a high probability of causing substantial harm.

229. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

230. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.



[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

231. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

232. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also

referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

233. McKesson’s deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 McKesson MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.”

234. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

235. As noted, above, on January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Livonia, MI and in several other places. McKesson’s 2017 agreement

with DEA documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”

236. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”<sup>159</sup> Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”<sup>160</sup> McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels” at certain McKesson Distribution Centers including the McKesson Distribution Center located in “Washington Courthouse, Ohio.”<sup>161</sup> Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.<sup>162</sup>

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<sup>159</sup> See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

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

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

<sup>162</sup> *Id.* at 6.

237. As *The Washington Post* and *60 Minutes* reported in late 2017, DEA staff recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

238. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.

\* \* \*

They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?<sup>163</sup>

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<sup>163</sup> Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), <https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/>.

239. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

240. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

241. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements

of “DEA investigators, agents and supervisors who worked on the McKesson case”, as reported in *The Washington Post*, “the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.” “Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”

242. As all of the governmental actions against Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

243. Meanwhile, the opioid epidemic rages unabated in Michigan. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. They pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

244. Defendants have knowingly abandoned their duties imposed under Michigan law and federal law that is incorporated therein, taken advantage of a lack of DEA law enforcement in Michigan, and abused the privilege of distributing controlled substances in this State.

## **CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF**

#### **Public Nuisance M.C.L.A. § 600.3801 and Common Law**

245. The State of Michigan incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, unless inconsistent with the allegations in this Count, and further alleges:

246. The Attorney General may bring an action to abate a public nuisance in the name of the State. Mich. Comp. Laws § 14.28.

247. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health of thousands of Michigan residents and which interferes with the enjoyment of life, in violation of Michigan law.

248. Prescription opioid abuse, addiction, morbidity, and mortality are a public nuisance in Michigan, which remains unabated. The unlawful conduct by the Defendants, as described herein, has created these hazards to public health and safety.

249. The health and safety of the citizens of the State, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State's citizens and residents.

250. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit.

251. Defendants knew, or should have known, that their promotion and irresponsible distribution of opioids (in violation of their monitoring and reporting obligations) would create a public nuisance.

252. Defendants are liable for a public nuisance because they acted without lawful authority in knowingly creating and maintaining opioid use at such volumes and degree as to create an epidemic, which clearly affects a number of citizens, is injurious to public health, safety, morals and welfare, and interferes with the exercise and enjoyment of public rights.

253. Each Defendant is liable for public nuisance because each Defendant's conduct at issue has caused or contributed to an unreasonable interference with a right common to the general public. *Adkins v Thomas Solvent Co*, 440 Mich 293, 303-305; 487 NW2d 715, 720 (1992). The Defendants' conduct described herein significantly interferes with public health, safety, peace, comfort, and convenience. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

254. In addition and independently, Defendants' conduct invades a legally protected interest. Defendants' conduct constitutes an unreasonable interference because, *inter alia*, each Defendant has violated Michigan law. Mich. Comp. Laws §§ 333.7303; 333.7311; Mich. Admin Code R. 338.493c(i); 338.3141(1); 338.3151(1); 338.3153(1); *accord* 21 U.S.C. § 823. Defendants have permitted dangerous drugs under their control to be diverted for illicit purposes so as to injure the State and its residents.

255. Specifically, Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and



- g. Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”

256. All Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

257. Because Defendants have maintained their opioid drug selling activities contrary to law, and because Defendants’ conduct has unreasonably interfered with a right common to the general public, Defendants are liable for public nuisance per se.

258. Defendants’ unreasonable interference with a right common to the public is of a continuing nature.

259. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference with public rights that their conduct has caused in the State of Michigan. Defendants created an absolute nuisance. Defendants’ actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

260. The public nuisance created by Defendants’ actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from Defendants’ abdication of their gate-keeping duties have caused harm to the entire State of Michigan that includes, but is not limited to:

- The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries and deaths.
- Easy access to prescription opioids, making opioids a recreational drug of choice among Michigan teenagers. In addition, children have not escaped the opioid epidemic unscathed. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- State residents who have never taken opioids. These residents have suffered from the public nuisance arising from Defendants’ abdication of their gate-keeper duties.

Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by, opioids.

- Increased health care costs as a result of the opioid epidemic.
- The lost the value of productive and healthy employees to employers.
- The abundance of drugs available for criminal use that has fueled a new wave of addiction, abuse and injury created directly by Defendants' conduct.
- A diverted supply of narcotics to sell and the ensuing demand of addicts to buy them. More pills sold by Defendants led to more addiction, with many addicts turning from prescription pills to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin. This was a foreseeable result of Defendants' conduct and the dereliction of their duties.
- The diversion of opioids into the secondary criminal market which has increased number of individuals who abuse or are addicted to opioids. This, in turn, further increased the demands on health care services and law enforcement in the State.
- The significant and unreasonable interference with the public rights caused by Defendants' conduct which has taxed the human, medical, public health, law enforcement and financial resources of the State.
- Defendants' interference with the comfortable enjoyment of life in Michigan. This interference is unreasonable because there is no social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

261. The State has sustained specific and special injuries because its damages include, *inter alia*, health services and law enforcement expenditures, as described in this Complaint.

262. Plaintiff, the State of Michigan, seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, abatement of the public nuisance, payment to the State of monies necessary to abate the public nuisance, all damages as allowed by law, attorney fees and costs and pre- and post-judgment interest.

## SECOND CLAIM FOR RELIEF

### **Drug Dealer Liability Act (DDLA)**

263. The State of Michigan incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

264. The Attorney General may bring an action under Michigan’s Drug Dealer Liability Act (DDLA) pursuant to Mich. Comp. Laws § 691.1613(1).

265. The purpose of the DDLA, Mich. Comp. Laws §§ 691.1601, *et seq.*, “is to provide actions for civil damages against persons who participated in illegal marketing of controlled substances for injuries caused by illegal use of controlled substances in order to . . . [c]ompensate persons injured as a result of illegal marketing of controlled substances; . . . [and to] [a]ssess the cost of illegal marketing of controlled substances against persons who profit from that market.” *Id.* § 691.1601(2).

266. Michigan’s DDLA imposes liability on those, like Defendants, who unlawfully distribute controlled substances that causes injuries or damages.

267. The DDLA defines “person” to include “governmental entit[ies]” and “corporation[s]” and other “incorporated or unincorporated association[s].” *Id.* § 691.1604(4). An “individual abuser” is “an individual who uses a controlled substance that is not obtained directly from, or pursuant to a valid prescription or order of, a practitioner who is acting in the course of the practitioner’s professional practice, or which use is not otherwise authorized under article 7 of the public health code . . . .” *Id.* § 691.1603(2). To “participate in illegal marketing” means “[m]anufacturing or delivering, or attempting to manufacture or deliver, a controlled substance . . . in violation of state or federal law.” *Id.* § 691.1604(3)(a). Opioids are “controlled substances” under the DDLA. *Id.* § 691.1603(1); Mich. Comp. Laws §§ 333.7104(3); 333.7212(a). A “market area” for purposes of the DDLA includes “the area in which a person is

presumed to have participated in illegal marketing of a market area controlled substance . . . .” DDLA, § 691.1604(1). And a “market area controlled substance” is defined as “a specific controlled substance” [*Id.* § 691.1604(2)], which, by definition, includes opioids.

268. Section 691.1605 provides that “[a] person injured by an individual abuser may bring an action under [the DDLA] for damages against a person who participated in illegal marketing of the controlled substance actually used by the individual abuser.” *Id.* § 691.1605(1). “If a plaintiff in an action under this section proves that the defendant participated in the illegal marketing of the controlled substance actually used by the individual abuser who injured the plaintiff, the defendant is presumed to have injured the plaintiff and to have acted wantonly and willfully.” *Id.* § 691.1605(2).

269. Section 691.1607 provides that “a person injured by an individual abuser may bring an action for damages against a person who participated in illegal marketing of the market area controlled substance used by the individual abuser.” *Id.* § 691.1607(1). “If the plaintiff in an action under this section proves a defendant’s participation in the illegal marketing of a market area controlled substance and the plaintiff is [any] of the following [including a “governmental entity” that “financially supports a drug treatment or other assistance program for, or that otherwise expends money or provides unreimbursed service on behalf of, the individual abuser”], the defendant is presumed to have injured the plaintiff and to have acted willfully and wantonly.” *Id.* §§ 691.1607(2), 691.1607(2)(d).

270. For a market area claim under the DDLA, the relevant market area depends on the volume of the illegal drug that was distributed. *Id.* § 691.1608. Where the volume of illegal drugs distributed is 650 grams or more, the relevant market area is the entire State of Michigan. *Id.* §§ 691.1603(3), 691.1608(1), 691.1608(2)(d).

271. The State of Michigan is a governmental entity that funds drug treatment and other assistance programs for opioid abusers in Michigan, and otherwise expends significant sums of money and provides unreimbursed services as a result of the illegal distribution of opioids in the Michigan.

272. Accordingly, under the DDLA, the State “may recover economic, noneconomic, and exemplary damages and reasonable attorney fees and costs, including, but not limited to, reasonable expenses for expert testimony.” *Id.* § 691.1610(1).

273. Residents of Michigan who acquired opioid drugs from unlicensed drug dealers illegally distributing prescription opioids in Michigan are “individual abusers” under the DDLA. Under Michigan laws and regulations, opioids are illegal drugs if possessed, sold, and/or distributed without a valid prescription.

274. The DDLA imposes liability on those, like Defendants, who participate in the distribution of an illegal drug that causes damages. *Id.* § 691.1605(1).

275. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in an area where illegal drugs cause damages. *Id.* § 691.1607(1).

Defendants knowingly participated in the distribution of prescription opioids in a total volume far in excess of 650 grams and, therefore, the relevant market area is the entire State of Michigan. *Id.* §§ 691.1603(3), 691.1608(1), 691.1608(2)(d).

276. Defendants all recognized that they had a responsibility not to procure or fill suspicious orders and not to supply channels of distribution that they knew or should reasonably have expected would result in diversion. Nevertheless, they violated these responsibilities through the various acts described in this Complaint.

277. Accordingly, and for all the reasons set forth in this Complaint, Defendants did not lawfully distribute and/or sell illegal drugs into or within the State of Michigan, and otherwise exceeded their lawful authority by violating requirements or guidance from the FDA, DEA, Michigan law and regulations, and/or Michigan licensing authorities.

278. As described throughout this Complaint, Defendants all committed acts intended to facilitate the distribution of illegal opioids in the State of Michigan.

279. Among other things, Defendants knowingly disseminated massive quantities of prescription opioids to physicians, pharmacies, and/or patients and into the criminal market. Defendants also knowingly facilitated the illegal distribution and sale of prescription opioids into the criminal market, knowing that such opioids would be illegally trafficked and abused.

280. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals in Michigan who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement and financial resources of the State.

281. Having knowingly participated in the illegal distribution of the prescription opioids purchased by residents in the “market area” of Michigan, Defendants are liable to the State of Michigan under the DDLA for damages caused by opioids in Michigan that were acquired from distribution channels in which Defendants were a market participant.

282. Recoverable damages attributable to Defendants’ violations of the DDLA include, but are not limited to, costs that have been or will be incurred for:

- Increased law enforcement costs;
- Health care costs;
- Costs borne by the State to care for, house, rehabilitate and/or foster opioid addicts and opioid-dependent infants and children;

- Costs associated with early childhood intervention;
- Special needs education costs borne by the State with respect to infants born with NAS because of opioid abuse, who require special education costs when they attend local schools;
- Prosecution-related costs, including hiring additional prosecutors, investigators, and/or staff, as well as additional courtroom-related expenses borne by prosecutors' offices, the State and local courts;
- Costs for additional jail space and other costs associated with incarceration;
- Drug treatment program costs; and
- Any other pecuniary loss proximately caused by the illegal drug use at issue.

283. The State of Michigan brings this action under the DDLA to hold Defendants civilly liable for the devastation that their facilitation of the illegal opioids market in Michigan has wrought. In so doing, the State is vindicating the stated purpose of the DDLA to assess the costs of illegal distribution of controlled substances against the entities that have profited therefrom.

### **THIRD CLAIM FOR RELIEF**

#### **Negligence**

284. The State of Michigan incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

285. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustains an injury or loss proximately caused by the defendant's breach.

286. Where the defendant violates a statutory duty and where the statute is intended to protect against the result of the violation, the plaintiff is within the class intended to be protected

by the statute and the statutory violation is a proximate cause of the plaintiff's injury, it is presumed that the defendant was negligent.

287. Defendants owed and continue to owe the State of Michigan, acting on its own behalf and on behalf of its inhabitants, *inter alia*, common law and statutory duties to prevent diversion, to monitor and report suspicious orders, to not fill suspicious orders, to abide by any government agreements entered regarding the same, and to comply with the federal CSA, 21 C.F.R. §1301.74(b), as incorporated by Mich. Admin. Code R. 338.493c(i), which required the design and operation of a system to detect and disclose suspicious orders of controlled substances. Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances, by failing to report such suspicious orders to the appropriate regulators as required by state and federal law, and by filling or failing to halt those suspicious orders. In so doing, the Defendants acted with actual malice.

288. Defendants have breached, and continue to breach, their statutory and common law duties to the State of Michigan by, *inter alia*:

- Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- Choosing not to effectively monitor for suspicious orders;
- Choosing not to investigate suspicious orders;
- Choosing not to report suspicious orders;
- Choosing not to stop or suspend shipments of suspicious orders; and
- Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”



289. It was, and remains, reasonably foreseeable that Defendants' actions and omissions would result in the harm to the State of Michigan as described herein.

290. Plaintiff, the State of Michigan, acting on its own behalf and on behalf of its inhabitants, has suffered and continues to suffer both injuries and pecuniary losses and damages proximately caused by the Defendants' breaches. Among other things, and as discussed further herein, the State has experienced an unprecedented opioid addiction and overdose epidemic costing millions, including, but not limited to, health benefit expenditures, treatment services, emergency visits, medical care, treatment for related illnesses and accidents, lost productivity to the State's workforce, increased law enforcement and judicial expenditures, increased prison and public works expenditures, increased substance abuse treatment and diversion plan expenditures, lost economic activity, and lost reputation and good will. Defendants' breaches of the statutory and common-law duties they each owed to the State of Michigan and its citizens are the proximate cause of this crisis and its resultant harm to the State and its residents.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff the State of Michigan prays that the Court grant the following relief:

A. Enjoin Defendants from failing to monitor, report and halt suspicious orders as required by common law and the federal CSA, as incorporated by Mich. Admin. Code R. 338.493c(i);

B. Order Defendants to pay costs, losses and damages, in excess of \$25,000, for injuries sustained by the State of Michigan, as a result Defendants' unlawful conduct as set forth herein;

C. Order that Defendants be ordered to abate the public nuisance that they created in violation of Michigan law;

D. Order that Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

E. Order that Defendants be ordered to pay exemplary damages provided by law;  
and

F. Such other and further relief as the Court deems just, necessary and appropriate.

DATED: December 17, 2019

Respectfully submitted,

/s/ D. J. Pascoe  
D.J. PASCOE (P54041)

/s/ Joseph Potchen  
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/s/ David Tanay  
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STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WAYNE

STATE OF MICHIGAN, EX REL.,  
DANA NESSEL, ATTORNEY GENERAL,

Plaintiff,

Case No. 2019 -

-NZ

v

HON.

CARDINAL HEALTH, INC., McKESSON  
CORPORATION, AMERISOURCEBERGEN  
DRUG CORPORATION AND WALGREEN CO.,

Defendants.

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**JURY DEMAND**

NOW COMES Plaintiff, the State of Michigan, by and through its Attorney General, Dana Nessel, and hereby respectfully demands a Trial by Jury in the above-entitled cause of action.

DATED: December 17, 2019

Respectfully submitted,

/s/ D. J. Pascoe

D.J. PASCOE (P54041)

/s/ Joseph Potchen

JOSEPH POTCHEN (P49501)

/s/ David Tanay

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