TIMOTHY C. FOX
Montana Attorney General
MATTHEW T. COCHENOUR
Acting Solicitor General
215 N. Sanders
P.O. Box 201401
Helena, MT
(406) 444-2026

MARK W. MATTIOLI
Consumer Protection Chief
CHUCK MUNSON
Assistant Attorney General
Office of Consumer Protection
555 Fuller Avenue
P.O. Box 200151
Helena, MT 59620-0151

WILLIAM A. ROSSBACH
Special Assistant Attorney General
Rossbach Law, PC
401 N. Washington Street
P. O. Box 8988
Missoula, MT 59807
(406) 543-5156

LINDA SINGER*
DAVID I. ACKERMAN*
P. GRAHAM MAIDEN
Motley Rice LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
(202) 232-5504

* To be admitted *pro hac vice*

MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

STATE OF MONTANA, Plaintiff, v. McKESSON CORPORATION and CARDINAL HEALTH, INC. Defendants.	Cause No. CDV 2020 131 **COMPLAINT** KATHY SEELEY PRESIDING JUDGE

I. PRELIMINARY STATEMENT

1. The Attorney General brings this action to redress the unfettered and unlawful distribution of opioids into Montana by McKesson Corporation ("McKesson") and Cardinal Health, Inc. ("Cardinal"), the State's largest opioid distributors. McKesson and Cardinal (collectively, "Defendants") were required by statutory and common law to take specific steps designed to protect Montana's citizens from the opioid epidemic that has befallen this State. Instead of detecting, reporting and preventing illegal diversion of opioids, Defendants profited from it—flooding Montana communities for many years with more addictive narcotics than could have been put to legitimate use. Rather than complying with their legal duties, Defendants turned a blind eye to those requirements and the devastating effects that Defendants caused, in favor of their own profits.

2. In the words of the Montana Medical Association, "Prescription drug abuse and diversion is a growing epidemic—it affects everyone, and the statistics are staggering."[1] From 2006 through 2011, Montana consistently ranked in the top 25 states for opioid sales on a grams per capita basis. In 2014, the last year for which such data is available, Montana's opioid sales ranking, per capita, rose to 17th among the 52 states and territories. The numbers for certain specific opioids are even worse, with Montana consistently ranking in the top 10 states per capita for distribution of morphine and hydromorphone (*e.g.*, Dilaudid and Exalgo), and a fentanyl sales ranking that peaked at 7th in the nation.

3. Opioids are highly addictive synthetic drugs derived from opium—pharmacologically similar to heroin. The U.S. Drug Enforcement Administration ("DEA") has

[1] Montana Medical Association, *Know Your Dose*, http://knowyourdosemt.org (last visited Nov. 30, 2017).

categorized opioids as having a "high potential for abuse[.]" The Centers for Disease Control and Prevention ("CDC") declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[2] As the Director of the CDC has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[3]

4. Opioids have created a national and a statewide emergency. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old. Overdoses have been killing people at a pace faster than the HIV epidemic did at its peak. According to the CDC, 130 Americans die every day from opioid overdoses.[4]

5. Opioids have had a particularly acute impact on rural areas throughout the United States, including Montana. According to a recent report by the U.S. Department of Agriculture describing this nationwide trend, "[r]ising rates of prescription medication abuse, especially of opioids, and the related rise in heroin-overdose deaths are contributing to this unprecedented rise in age-specific mortality rates after a century or more of steady declines. This trend, if it continues, will not only lower rural population but will increase what is known as the dependency ratio: the number of people likely to be not working (children and retirees) relative to the number of people likely to be wage earners (working-age adults)."[5]

6. In Montana, the opioid epidemic has caused more than 700 overdose deaths since 2000—parents, spouses, and children who can never be brought back or made whole. In 2011-

[2] CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline") at 2.
[3] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).
[4] Data is of 2017. Available at: https://www.cdc.gov/injury/features/prescription-drug-overdose/index.html#targetText=In%202017%2C%20more%20than%2070%2C000,day%20from%20an%20opioid%20overdose.
[5] U.S. Dept. of Ag., Economic Information Bulletin 182, Rural America at a Glance (Nov. 2017).

2013 alone, prescription drug overdoses were responsible for at least 369 deaths in Montana and more than 7,200 hospital inpatient admissions and emergency department visits; and opioids are the most common substance associated with drug poisoning deaths in Montana. Prescription drug abuse in the State is 15 times more deadly than methamphetamines, heroin and cocaine combined.

7. As Montana's two largest wholesale opioid distributors, McKesson and Cardinal played a key role in fueling the epidemic. The increased volume of opioid prescribing and distribution correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

8. Defendants dominate Montana's wholesale drug distribution market. Depending on the metric used to evaluate the companies' shipments, McKesson and Cardinal alone were responsible for approximately 63-68**%** of the opioids shipped into Montana from 2006 to 2014, the period for which the State has obtained ARCOS data.[6] During this nine-year period, McKesson supplied more than 48% and Cardinal supplied more than 15% of the opioid dosage units to Montana. Measured by Morphine Milligram Equivalents ("MMEs"), a conversion done to compare the amount of opioids containing different dosage strengths, McKesson supplied 51.34% of the prescription opioids in the State, and Cardinal supplied 17.53%. Together, Defendants distributed the equivalent, at 10 mg per pill, of over 432 million opioid pills into Montana between 2006 and 2014. According to the 2010 U.S. Census, Montana's total population was 989,415

[6] The federal DEA maintains a system of records, known as the "Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)," to which all manufacturers and distributors of controlled substances are required to report each transaction in these drugs. The manufacturers and distributors have typically opposed disclosure of the information contained in the system, often referred to as "ARCOS data," arguing that it belongs to them as trade secrets, but has been disclosed in part in a dispute arising *In re Nat'l Prescription Opiate Litig*., No. 1:17-md-2804 (N.D. Ohio) (the "MDL"), and the State also has obtained certain ARCOS data for the years 2006 to 2014.

people. Thus, during the nine-year period from 2006 to 2014, McKesson and Cardinal alone shipped over 400 estimated 10 mg opioid pills for every man, woman and child in the State.

9. Wholesale distributors buy prescription drugs, including narcotics, from manufacturers at enormous volumes and sell them to pharmacies. This allows pharmacies to quickly obtain a full range of prescription drugs from a single source, without having to manage relationships with multiple manufacturers. With distribution centers across the country, Defendants offer "just-in-time delivery," ensuring that pharmacies can provide the drugs their customers need, without the expense and risk of excess inventory. Like other brokers, distributors earn their profits based on the spread between their buy and sell prices, as well as manufacturer chargebacks and a fee that is a percentage of sales.[7] They have financial incentives to keep the volume of controlled substances they distribute high, and to fill orders and supply customers despite seeing the red flags of diversion.

10. With their central location in the healthcare marketplace, Defendants also have a treasure trove of information, such as data and services, which they sell upstream to manufacturers and downstream to pharmacies to further leverage their profits. Defendants could have used this information to ensure they were providing opioids only to a legitimate market, but they did not. Because of the addictive nature of these drugs and the existence of a black market for their use, however, wholesale distributors have a long-standing duty under Montana law, as described

[7] Because manufacturers typically negotiate sales prices directly with large buyers, a distributor might initially lose money when it sells prescription drugs to a buyer at a lower, discounted price than its purchase price. The distributor then bills the manufacturer for the difference between the price it paid and the negotiated price, a payment known as a "chargeback." *See* Coleman, John, *The Supply Chain of Medicinal Controlled Substances: Addressing the Achilles Heel of Drug Diversion,* Journal of Pain & Palliative Care Pharmacotherapy, Sept. 13, 2012, at p. 240.

further below, to ensure that the controlled substances they supply, including opioids, are managed and monitored so that they reach only a legitimate market and are not diverted for illicit use.

11. Over a critical decade, each Defendant contributed to the public nuisance that is the opioid epidemic in Montana by breaching its legal duties under Montana's Controlled Substances Act, Mont. Code §§ 50-32-101 through 50-32-611 (the "Montana CSA"), the Montana Wholesale Distributors Act, Mont. Code §§ 37-7-601 through 37-7-612; and the common law duty of reasonable care. Defendants oversupplied opioids into and within Montanaand ignored obvious red flags of diversion. In response to enforcement actions and public attention, recently Defendants have finally begun to improve their compliance efforts in an attempt to meet their legal obligations, but the opioid epidemic was already well underway. Moreover, Defendants' programs still suffered from systemic failures, which existed alongside lucrative financial incentives to ignore their legal obligations. Recent information, including that unveiled through an enforcement action by the DEA that resulted in record-breaking fines against McKesson, as well as Congressional inquiries and Defendants' own internal documents, show that Defendants' widespread systemic failures still continue to devastate Montana.

12. A corporate representative testifying on behalf of McKesson in an MDL deposition acknowledged that failures to investigate, report and prevent the shipment of suspicious orders result in a substantial and detrimental effect on the health and general welfare of the American people. During the same deposition, he further testified that McKesson accepts partial responsibility for the societal costs of the opioid epidemic now facing the nation.

13. The overwhelming increase in and volume of opioids ordered by Montana pharmacies put Defendants on notice that they were meeting more than a predictable and legitimate market demand, including the inflated demand from deceptive marketing, from which the

Defendants profited. Put simply, the volume of opioid pills shipped to Montana could not be explained by any sudden increase in the incidence of pain among Montana residents. Rather than continuing to sell, ship, and profit from these highly dangerous drugs, Defendants' failures to fulfill their legal duties to monitor their shipments, investigate and stop suspicious orders and report the possible diversion, were a substantial factor causing and sustaining the opioid epidemic in Montana. Had Defendants fulfilled their duties, the opioid epidemic in Montana—and its enormous human and financial toll—would not have been as grave.

14. Defendants have reaped substantial revenue from their unfettered distribution of opioids, while the State of Montana and its residents have borne the costs in responding to opioid addiction and overdose, and opioid-related crime. The State has already paid significant sums for services such as prevention and public education programs, treatment, and emergency response, and now it will need to incur significant additional expenses in the future to abate the public nuisance. This will include, but is by no means limited to, the costs of continuing to dispose of unused prescriptions; re-educating doctors and patients about the appropriate use of opioids and about the signs of addiction and the availability of treatment; and treatment for opioid addiction and overdose, including naloxone and medication-assisted addiction treatments, like buprenorphine.

15. Many of those harms cannot be undone or ever adequately compensated, but the financial cost to address this crisis has been, and will be, staggering. The State brings this action to hold Defendants accountable for their conduct and to abate the epidemic, which can be done. Defendants' actions constitute a violation of the Montana Unfair Trade Practices and Consumer Protection Act, a public nuisance, negligence, gross negligence, unjust enrichment, and a civil conspiracy. The State seeks injunctive relief, civil penalties, abatement, compensatory and

punitive damages, disgorgement, and any other relief within this Court's powers to redress and halt these unlawful practices.

16. In addition, and for the sake of clarity, 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 or claim, and 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 Cardinal has or had with the United States Veterans Administration and/or any other federal agencies. Nothing in this Complaint puts at issue in any way any Defendant's distributions under the PPV contract, or any other federal government contract, and nothing in this Complaint challenges in any way, in law or in equity or otherwise, actions of McKesson (or Cardinal) pursuant to a contract it has or ever had with the United States Veterans Administration.

II. PARTIES

17. The Plaintiff State of Montana brings this action, by and through its Attorney General, Tim Fox, in its sovereign capacity in order to protect the interests of the State and its citizens as *parens patriae*. The Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by Mont. Code Ann. §§ 2-15-501 and 502; and the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 through 30-14-144 ("MCPA"). The Attorney General has

constitutional, common law and statutory authority to pursue legal actions in the public interest and has determined that this action on behalf of the State of Montana is in the public interest, including for purposes of Montana Code § 30-14-111.

18. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson, through its various DEA registrant subsidiaries and affiliated entities, is a licensed wholesale distributor of pharmaceutical drugs nationally and in Montana. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

19. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the United States, with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in Montana. Cardinal, including its subsidiaries and affiliated entities, is a licensed wholesale distributor of pharmaceutical drugs in Montana. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio.

III. JURISDICTION AND VENUE

20. Jurisdiction over the subject matter of this cause of action is proper based upon Mont. Code Ann. § 3-5-302.

21. This Court has personal jurisdiction over the Defendants because they each do business in Montana and/or have the requisite minimum contacts with Montana necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Montana's long arm rule. Mont. R. Civ. P. 4. Among other business activities in Montana, the Defendants each take orders for pharmaceutical products from Montana pharmacies and other

customers; they each transport pharmaceutical products into and within Montana, and they each sell such pharmaceutical products to Montana pharmacies and other customers.

22. Venue is appropriate in this Court pursuant to Mont. Code Ann. §§ 25-2-122; 25-2-115; & 30-14-111(3).

23. Because the State of Montana is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case by virtue of diversity of citizenship. The Attorney General does not represent or seek relief on behalf of consumers, either individually or as a class, but acts pursuant to his constitutional, common law, and statutory authority to protect the interests of the State.

24. The State of Montana does not allege any federal cause of action, and to the extent that any pleading allegedly can be interpreted as stating any claim arising under federal law, any and all such federal claims are expressly disavowed. No federal question, substantial or otherwise, arises from or is stated in the State's pleadings.

FACTUAL ALLEGATIONS

A. Opioid Volumes Soar in the State

24. As explained above, Defendants facilitated the supply of far more opioids than could have been justified. Their failure to maintain effective controls, and to investigate, report, and halt orders that they knew, or should have known, were suspicious, breached both their statutory and common law duties and worsened the opioid epidemic in Montana.

25. Together, Defendants delivered over 63% of the more than 292 million dosage units[8] and 68.7% of the 3 million grams (equating to more than 432,250,222 estimated 10 mg equivalent pills) of opioids shipped to Montana, from 2006 to 2014.

[8] Dosage units refers to the unit of dose delivery (e.g., tablet or capsule at a defined dose).

26. Available ARCOS data reveals that the volume of opioids sold in Montana was generally above national averages as measured by grams per capita. Further, while opioid purchases per capita began to decline nationally in 2011, Montana did not see a decline, but sales instead continued to increase. Within the State, both grams per capita and MMEs per capita generally increased from 2006 to 2012.

27. Out of this extraordinary volume, Defendants, as discussed below, systematically and repeatedly failed in their obligations to maintain effective controls against diversion. Their failure to detect, halt and report suspicious orders of opioids and continued shipments of such orders into Montana resulted in a gross, and too often fatal, oversupply of pills.

B. Defendants Neglected Compliance in Pursuit of Profits

28. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. Through the Montana CSA (Mont. Code Ann. §§ 50-32-101 through 50-32-611) and the Montana Wholesale Drug Distributors Act (Mont. Code Ann. §§ 37-7-601 through 37-7-612), Defendants are subject to statutory obligations enacted to prevent oversupply and diversion into the illicit market — legal duties specifically designed to protect the public health and safety.[9] Together, these laws set standards of care that make clear that wholesalers of controlled substances 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 distribution chain is not properly controlled.

[9] *See, e.g.*, Montana CSA, Mont. Code Ann. § 50—32-306(1) ("The board shall register an applicant to manufacture or distribute dangerous drugs . . . unless it determines that the issuance of that registration would be inconsistent with the public interest."). Licensure requires that distributors "abide by federal and state law and . . . comply with the rules adopted by the board[.]" Mont. Code Ann. § 37-7-604(2)(a).

29. Further, these laws set standards of care that make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, with the deeply tragic and entirely foreseeable — and avoidable — consequences that Montana has experienced.

30. As explained below, Defendants are obligated to prevent diversion, to report suspicious orders and not to fill those orders unless due diligence disproves those suspicions. Defendants' obligations to maintain effective controls against diversion stem from multiple sources, including the common law, the Montana CSA, the Montana Wholesale Distributors Act and the MCPA.

31. First, under the common law, Defendants have a duty to exercise reasonable care and to avoid creating a public nuisance. Because opioids are dangerous, addictive drugs, the standard of care Defendants must meet in distributing and selling them is appropriately high.

32. Second, Defendants are required under the Montana CSA to obtain an annual registration that requires a determination that registration is in the public interest, including a demonstration that the applicant has maintained "effective controls against diversion of dangerous drugs into other than legitimate medical, scientific, or industrial channels.". Mont. Code Ann. §§ 50-32-306(1), (2)(a); 50-32-301..

33. Third, the Montana Wholesale Distributors Act, Mont. Code Ann. §§ 37-7-601 through 37-7-612, which also regulates distribution and sale of controlled substances, incorporates by reference federal law regarding the distribution and sale of prescription opioids. *See* Mont. Code Ann. § 37-7-604(2) ("A license may not be issued or renewed for a wholesale distributor . . . unless

the applicant: (a) agrees to abide by federal and state law and to comply with the rules adopted by the FDA and the board[.]").

34. Fourth, Defendants are prohibited under the MCPA from engaging in unfair acts or practices. *See* Mont. Code Ann. § 30-14-103. An "unfair act or practice is one which offends established public policy and which is either immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." *Rohrer v. Knudson*, 2009 MT 35, ¶ 31, 349 Mont. 197, 203 P.3d 759. To that end, Defendants' conduct in flooding the market with opioids, failing to maintain effective controls against diversion, and fueling an illicit black market injures consumers and is an unfair practice under the MCPA.

35. This is particularly true given that, at the same time, Defendants voluntarily represented, through their statements to the media, regulators, and the public at large, that they had taken all reasonable precautions to prevent drug diversion. Defendants publicly touted their corporate responsibility with references to their purportedly state-of-the-art suspicious order monitoring systems and processes, as well as professed commitment to legal compliance. These statements were false.

36. Montana law expressly incorporates the requirements of federal law. *See, e.g.*, Mont. Code Ann. § 50-32-306(3) (entitling manufacturers and distributors compliant with federal registration requirements to obtain state licensure); ARM § 24.174.1201 (6) ("Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale drug distributors who deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.") These legal requirements are clear and exacting. Defendants are required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious

orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. This includes a duty to monitor, detect, report, investigate, and refuse to fill suspicious orders. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74.[10] To allow for action by law enforcement, the duty must be carried out without delay; distributors "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered* by the registrant."[11]

37. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74(b). These criteria are not exclusive; any one of them can trigger the duty to report and stop shipment, and other factors not listed in the regulations also may point to suspicious orders. A volume of orders of a controlled substance disproportionate to the population or historic use in an area, for example, may provide reason for suspicion. In addition, orders skewed toward high-dose pills or drugs valued for abuse should alert distributors to potential diversion.

38. Of course, 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 non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA] 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."[12] Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of

[10] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter, "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter, "2007 Rannazzisi Letter").

[11] *Id*. (emphasis added); *see also* https://www.deadiversion.usdoj.gov/ pubs/manuals/sec/other_sec.htm#good_faith (registrant must inform the DEA of suspicious orders "immediately upon discovery").

[12] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).

controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[13]

39. According to the DEA: a) DEA registrants are required to block all suspicious orders of prescription opioids; b) shipping a suspicious order is a per se violation; and c) if a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.

40. To comply with their obligations under Montana law, distributors must know their customers and the communities they serve. Each distributor must "perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017). This includes a "reasonable investigation to determine the nature of a potential customer's business before it sells to the customer, and the distributor cannot ignore information which raises serious doubt as to the legality of a potential or existing customer's business practices." *Id*. (alterations and internal quotation marks omitted) (quoting *Southwood Pharms.*, Inc., 72 Fed. Reg. 36,487, 36,498 (DEA July 3, 2007)).

41. A customer's order data and the data of other similar customers provide detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion.

13 *Masters Pharmaceuticals*, 861 F.3d at 212. "The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

42. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under Montana law with respect to preventing diversion. First, they must set up a system designed to detect and reject suspicious orders. Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill orders that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and other customers, and following up on reports or concerns of potential diversion. All suspicious conduct must be reported to relevant enforcement authorities. Further, Defendants must not ship any suspicious order unless they have conducted an adequate investigation and determined that the order is not likely to be diverted into illegal channels.[14] Reasonably prudent distributors would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

C. Defendants Failed to Maintain Effective Controls Against Diversion and Oversupplied Opioids into Montana

43. In its 2017 investigation of wholesale distributors, the U.S. House of Representatives Committee on Energy and Commerce ("Energy and Commerce Committee") noted that distributors, including Defendants, despite "settlement agreements and the subsequent policy enhancements" and "[d]espite efforts by DEA to educate distributors about their responsibility to report suspicious orders," "failed to address suspicious order monitoring in critical ways" and in many instances "appeared to turn a blind eye to red flags of possible drug diversion." These systemic failures are evident in Montana.

[14] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Montana); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same)

44. Despite their compliance obligations, Defendants shipped far more opioids into Montana than could have been expected to serve legitimate uses, ignored other red flags of diversion, failed to investigate their customers and to detect suspicious orders, and chose not to report or reject even those suspicious orders that were, or should have been, evident.

45. Given the volume and pattern of opioids distributed in the State, Defendants were, or should have been, aware that opioids were being oversupplied into the State and should have detected, reported, and rejected suspicious orders. They did not.

46. According to data from the ARCOS database, between 2006 and 2014, McKesson supplied over 322 million estimated 10 mg equivalent opioid pills in the State and Cardinal supplied over 110 million estimated 10 mg equivalent opioid pills in Montana. This volume grew dramatically from 2006 to 2012. During that period, Montana's total population was 989,409 people, according to the 2010 U.S. Census.

47. This deluge of opioids and its increase after 2006 *per se* demonstrates that Defendants were significantly oversupplying opioids into the State. The massive volumes of opioids Defendants distributed in and of themselves should have raised "red flags" that not all of the prescription opioids Defendants distributed into Montana could be used for legitimate medical uses. Per capita opioid sales in Montana, for years, exceeded the national average, and increased in ways that should have alerted Defendants to potential misuse and diversion and that the volume of opioids they were distributing was contributing substantially to causing and sustaining a public health crisis.

48. Also as described above, Defendants had specific and detailed information giving them insight into diversion in Montana. Additionally, other sources were available to show systemic failures and red flags relating to pharmacies, orders, prescribers, and patients in Montana.

49. The information on the supply of opioids distributed in Montana, along with the information known only to Defendants, including their analysis of individual order data and other data sources described above, should have alerted them to potential diversion of opioids in Montana.

1. McKesson

50. McKesson's policies and procedures for the distribution of controlled substances nationally and in Montana were recorded in its Drug Operations Manual, known as Section 55, as early as 1997. The Manual also underscores the fact that McKesson has long understood its obligation to report and prevent "unusual or suspicious purchases of controlled substances by [its] customers." For example, Sec. IV.6 of the Manual emphasizes that "[c]ontrolled substance order fillers must be aware of our responsibilities. They are expected to report to management any unusual purchase request before orders are filled." The Manual also explains that "reports of controlled substance diversion are not only a necessary part of an overall security program, but also serve the public interest at large."

51. In 1993, the DEA contacted McKesson to emphasize that the registrant – not the DEA – was responsible for determining if an order was suspicious, explaining: "A registrant, whose own personnel are in the best position to determine what is excessive or unusual based on knowledge of their customers and usual purchasing practices, may not abrogate its responsibility to identify suspicious orders and to determine whether to ship or refuse to ship, the controlled substance order. The registrant must also report any suspicious order as soon as possible to DEA."

52. However, despite being well aware of its obligations, McKesson consistently failed to design and implement a system that effectively identified suspicious orders for many years. Moreover, even when McKesson's system finally *did* identify suspicious orders, McKesson

nevertheless continued to ship many of the orders and failed to report suspicious orders to the DEA. McKesson's practices in Montana reflect these systemic failures.

a. McKesson Failed to Maintain Effective Controls Against Diversion in Montana

53. McKesson was the largest distributor in Montana from 2006 to 2014, the last year for which ARCOS data is available, responsible for approximately 51% of opioid distribution measured by grams and for approximately 48% of opioid distribution measured by dosage units in the State during that time. More specifically, over that time, McKesson shipped the equivalent of 322,211,070 estimated ten mg pills into Montana.

54. According to McKesson's own data, from May 2008 – November 2017, McKesson identified [redacted] from Montana pharmacies and other customers. [redacted]

Failing to report each one of these [redacted] constitutes prima facie evidence that McKesson failed to maintain effective controls to prevent diversion in continuing violation of Montana law.

55. Moreover, McKesson failed to report other customers or even to identify their orders as suspicious, despite its knowledge of alarming facts and orders that clearly should have been reported. For example, in 2007, McKesson noted in an internal review of the PharmCare in Hardin, Montana that "[t]his is an Indian reservation area and oxycodone is prescribed a lot." Rather than reporting the abnormally high number of oxycodone prescriptions in this Indian reservation area as suspicious, or further investigation of the orders, McKesson merely raised its threshold for PharmCare's oxycodone purchases and continued to ship the addictive drugs to an area in Montana known to have a dangerous oversupply.

56. In April 2009, McKesson uncovered an alarming fact regarding Western Drug pharmacy in Livingston, Montana. According to McKesson's review, McKesson had been supplying the Western Drug with more than 3.5 times the amount of hydrocodone than the pharmacy reported dispensing. Yet McKesson took no action in response to this information. Upon information and belief, McKesson did not report these pharmacy orders as suspicious to the DEA, local law enforcement, or any State regulatory board.

57. In May 2009, McKesson twice increased its threshold for the Pamida Pharmacy in Eureka, Montana to purchase significantly greater quantities of hydrocodone, relying on the patently inadequate justification: "Local doctor prescribes a lot." With two separate Threshold Change Requests submitted on 5/15/09 and 5/29/09, McKesson increased this pharmacy's allowable purchases of hydrocodone from 10,000 dosage units to 15,000 dosage units, a 50% increase. Upon information and belief, McKesson did not report these pharmacy orders or the local doctor as suspicious to the DEA, local law enforcement, or any State regulatory board.

58. ARCOS data reveals that the Big Sky Pharmacy in Miles City, Montana—population of about 8,100—purchased over 200,000 dosage units (mostly pills) of opioids every year from 2006-2014, the overwhelming majority of which were supplied by McKesson. During the full nine-year period for which ARCOS data is now available, Big Sky consistently purchased more opioids than the average pharmacy in Montana and the United States—sometimes much more. For example, in 2014, the Big Sky Pharmacy purchased over 50,000 more opioid dosage units than the averages for both State and national pharmacies. [redacted] Even more alarming, on the same day, McKesson shipped 700 of the same pills to Big

Sky. The following day, it shipped 100 more. The next month, McKesson filled 16 orders for the same hydrocodone product, shipping 2,700 of the hydrocodone pills to Big Sky Pharmacy. [redacted]

59. In Cut Bank, Montana—population about 3,000—the Osco Pharmacy (owned by Albertsons) purchased 15,274,427 MMEs of opioids in 2012—enough opioids in one year to give every man, woman and child in Cut Bank the equivalent of more than 500 morphine pills (10 mg). Its opioid purchases first skyrocketed in 2010, with a 195% increase in total dosage units to a level that was about 50% higher than the average U.S. pharmacy. McKesson supplies the Osco Pharmacy with nearly half of its opioids, as measured by MMEs. [redacted]

60. Based on documents and data provided to the State of Montana, [redacted] evidences the magnitude of McKesson's failure to adequately report suspicious orders. This is particularly true given that overall sales of opioids did not experience a marked increase in 2013 as compared to years prior, [redacted]

b. McKesson's Monitoring Program was, on its Face, Ineffective because it Improperly Relied on Thresholds

61. From 1997 to 2007, McKesson's suspicious order monitoring policy, including in Montana, consisted of retrospective reports documenting previous sales of controlled substances to customers whose sales exceeded three times the customer's annual average for that drug code. Although the Manual clearly recognized the importance of requiring review of suspicious orders prior to shipment, it contained no requirement that orders flagged by the system be reported to the DEA or that such orders be investigated and cleared prior to shipment.

62. McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders as required by law. In particular, McKesson's Regulatory Affairs Director, David Gustin, stated in an internal email that "the previous reports were not the exclusive and proper response to this regulation," as the company has an "obligation to report 'suspicious orders" and "[s]imply reporting larger than usual orders does not [meet the spirit and letter of the regulation] when there are so many plausible and routine reasons for orders to be 'larger than normal.'"

63. McKesson then created what it characterized as an "improved" monitoring program, which it called the Lifestyle Drug Monitoring Program ("LDMP"), in 2007. However, rather than monitor orders for all controlled substances, the LDMP only monitored four specific controlled substances. For these four drugs, McKesson set an 8,000 monthly dosage unit threshold for every McKesson customer nationwide, with a review process triggered only if that threshold was met. Moreover, McKesson ignored the dosage unit thresholds set by the LDMP and nevertheless continued to ship large quantities of oxycodone and hydrocodone to its customers. Nationwide, McKesson's threshold was only a soft cap, so that orders of oxycodone and hydrocodone exceeding 8,000 units were not blocked, but instead investigated after McKesson had

already made the sale. This failure illustrates systemic flaws, from which operations in Montana would not have been exempt. Deposition testimony by a former McKesson employee confirmed the LDMP had no mechanism to block orders once the 8,000 unit threshold was met and while an investigation was ongoing. Further, internal documentation shows that pharmacy customers were routinely permitted to exceed the monthly dosage thresholds before McKesson completed a due diligence review.

64. [redacted]

65. The investigation of orders triggered by McKesson's threshold system was also patently insufficient. McKesson undertook no investigation of the legitimacy of such orders, other than confirming whether McKesson's systems accurately reflected certain orders as requested by McKesson's customers.

66. In 2008, McKesson entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with the DEA. The 2008 McKesson MOA settled allegations made by six U.S. Attorneys that the company failed to report suspicious orders of hydrocodone (and another

[15] [redacted]
The DEA had previously identified these drugs as controlled substances that had an especially high likelihood for abuse and were commonly found in illegal internet pharmacies.

controlled substance, alprazolam). The federal government found that three of McKesson's distribution centers filled hundreds of suspicious orders by pharmacies that were involved in the illegal online prescription scheme about which the DEA warned McKesson in their 2005 meeting. In addition to paying $13.25 million in fines, McKesson temporarily suspended the distribution of the two drugs from two of its distribution centers. In addressing McKesson's wrongdoing, DEA Administrator Leonhart stated that "[b]y failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country."[16] The national scope of McKesson's centralized suspicious orders monitoring system ("SOMS") and the systemic nature of the CSA violations reflect on McKesson's conduct nationwide, including in Montana.

67. The 2008 McKesson MOA 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." The Controlled Substances Monitoring Program ("CSMP"), a new, national monitoring program that McKesson launched as part of the settlement, applied to shipments to Montana. It was not until development of the CSMP that McKesson began making any effort to block suspicious orders. However, like its LDMP, this monitoring program was also woefully inadequate.

68. In an April 24, 2018 letter to the Energy and Commerce Committee, McKesson asserted that one of the key elements of its revised CSMP is its controlled substances threshold management program, which McKesson describes as "a cutting-edge controlled substances threshold management program." The letter continued: "McKesson's model analyzes each

[16] Shannon Henson, Law360, *McKesson Ponies Up $13M To Settle Drug Claims* (May 5, 2008), https://www.law360.com/articles/55133/mckesson-ponies-up-13m-to-settle-drug-claims.

customer order against established monthly thresholds to determine whether that order should be filled. If a customer's order exceeds the monthly threshold, that order is required to be blocked and not filled. McKesson reports each blocked order to DEA pursuant to 21 C.F.R. § 1301.74 and to State monitoring agencies pursuant to applicable state reporting regulations . . . "

69. There are at least three deficiencies in this approach. First, a threshold-based compliance system is both under- and over-inclusive. Even an order that is within a customer's threshold may be suspicious because, for example, it includes a disproportionate share of high-dose opioids. Conversely, an order that exceeds threshold may not be suspicious. Orders, for example, frequently exceed threshold at the end of the month, and are filled at the start of the next month, when the threshold re-sets. Yet, McKesson still reports those orders, burying orders that it believes may actually be suspicious among those McKesson believes are no more than typical inventory management issues. (If, of course, McKesson regards such orders as suspicious, there would be no better reason to ship them on the first day of a new month than on the 25th day of the prior month.)

70. Second, McKesson's thresholds are based on the already too high baseline for opioid distribution. Because thresholds are set based on pharmacies' historic patterns, a pharmacy that received a volume of opioids that is too high for the expected use in its area, for example, would continue to receive orders at that too-high threshold. Notably, McKesson set thresholds based on purchases from the 2007-2008 time period, a year that the Department of Justice has noted was a one "in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies." Internal documents show that thresholds were initially set under the CSMP by reviewing the customer's 12 month purchase history for each drug base code, taking the highest month of purchases in that 12 month period, and adding, without any compliance justification, a further 10% buffer to that purchase amount.

71. [redacted]

72. Internally, McKesson recognized that thresholds for many customers were too high. David Gustin (Director of Regulatory Affairs), stated in August 2011 that: "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."' Despite these concerns, no serious efforts were undertaken to systematically reduce thresholds until 2015, a full four years later.

73. Third, McKesson does not apply any metric that assesses an area's population to determine whether orders are suspicious. A small pharmacy serving a town of 10,000 people could order 25,000 opioid tablets month after month without being flagged or reported. Nor does McKesson add up the volume of orders for a particular city or across the State to determine whether the overall supply is reasonable or suspicious.[18] A volume of orders of a controlled substance

[17] [redacted]

[18] Energy and Commerce Report from 2018 which notes this as an issue for each distributor

disproportionate to the population or historic use in an area, however, may provide reason for suspicion.

74. These flaws are particularly problematic because McKesson's compliance system depends upon thresholds. The only other circumstance in which a customer will be investigated is if McKesson receives an enforcement tip or if it is assessing a new customer.

75. With a compliance system that was still fundamentally flawed, McKesson was "neither rehabilitated nor deterred" by the 2008 settlement, as a DEA official working on the case that lead to the subsequent 2017 settlement noted.[19] 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," "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.[20] Instead, the DEA officials said, the company raised its own thresholds on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[21]

c. Orders that exceeded thresholds merely prompted threshold increases

76. Another systemic deficiency, repeated in Montana, was that McKesson's threshold change request process created additional incentives to inflate thresholds. McKesson responded to threshold exceedances not by stopping orders and conducting due diligence as it should have done, but by raising the customers' thresholds. In theory, customers that have a legitimate reason to purchase additional controlled substances (e.g., the closure of an alternate pharmacy or the opening

[19] Lenny Bernstein and Scott Higham, "*We Feel Like Our System Was Hijacked": DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post, December 17, 2017, *available at* https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html
[20] *Id.*
[21] *Id.*

of a new nearby doctor's office) should be allowed to request an increase in their thresholds. In practice, many orders that McKesson flagged for exceeding the pharmacy's threshold merely led to McKesson increasing that pharmacy's threshold.

77. Not only did McKesson raise thresholds after an order was flagged as suspicious, it often raised them even before an order was likely to go over a customer's allotted threshold. Sales representatives were given a "threshold warning report" of customers that were nearing thresholds for them to call, which was used for years, to great effect, as a preemptive tool to increase thresholds before orders had to be blocked or reported. In discussing these reports in an October 2006 internal email, an employee noted that this practice allowed work to begin on justifying an increase before any "lost sales" occurred from imposing a limit, and emphasizing that McKesson was "in the business to sell product."[22]

78. Internal documents reflect that, as of 2011, McKesson knew that it needed to "tighten up" both its due diligence on accounts that had undergone significant changes in controlled substances purchasing, as well as its "process regarding granting [threshold] increases." Even though McKesson's Standard Operating Procedure made clear that threshold increases should not be granted without supporting data, as a practical matter, McKesson had "gotten to a point where certain % of increase [we]re almost automatic" and it "too easily accept[ed]" what its own correspondence described as "'reasons' like 'business increase' for raising thresholds by small amounts." These increases, cumulatively and incrementally, could make a big difference, yet

[22] MCKMDL00543971. McKesson would later effectively acknowledge the impropriety of this practice in a November 2013 announcement to its employees of new policy pertaining to threshold warning reports. This presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time." MCKMDL00476786 at 00476791. And announcing a policy, of course, does not mean that McKesson actually abided by it or reformed its systemic failures.

McKesson effectively admitted it was not requiring submission of supporting data to justify the increase.

79. In April 2011, a McKesson official was concerned enough with the state of affairs to comment to his colleagues that "[w]e as DRAs [Directors of Regulatory Affairs] need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time." Another Regulatory Affairs Director responded: "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up."

80. In August 2014, the Department of Justice noted in connection with its investigation of McKesson's Aurora, Colorado distribution center, which serves Montana, that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons. The same letter advised that McKesson, which should have been particularly aware of its obligations given its 2008 settlement, had caused "significant public harm." It also highlighted "a disturbing pattern," in which the Colorado distribution center's "desire for increased sales and retaining its customers overrode its obligations to report suspicious orders," a "trend" the DEA identified "across several different areas." As explained above and further below, the investigation of this and other distribution centers confirmed systemic failures in McKesson's suspicious order monitoring, reporting, and due diligence obligations. Moreover, McKesson established its thresholds using a national average, failing to factor in an area's population or provide any comparison to similar pharmacies in the region.

d. McKesson Systemically Failed to Identify and Report Suspicious Orders

81. Despite its professed commitments to reform in 2008, McKesson continued to be deficient in its compliance, both nationally and in Montana.

82. Based on records produced by the DEA and McKesson, McKesson supplied Montana pharmacies with opioids from well before 2006 until mid-2013 without reporting a single suspicious order to the DEA. Upon information and belief, McKesson has never reported any suspicious order or possible unlawful activity of any Montana pharmacy or Montana physician to a Montana law enforcement official or Montana regulatory body.

83. According to McKesson's own data, from May 2008 to November 2017, McKesson identified [redacted] evidence that McKesson did not maintain sufficient controls to protect against diversion, in violation of Montana law.

84. A 2014 letter to McKesson from the U.S. Attorney's office concerning McKesson's distribution center in Aurora, Colorado—which serves pharmacies in Montana—outlined McKesson's failures, noting that "time and time again, McKesson-Aurora received information about orders that were unusual or exceeded even generous thresholds, but failed to report those orders." The letter further noted that rather than encourage its employees to report suspicious orders to the DEA, McKesson's CSMP Operations Manual "contains a troubling directive to McKesson employees to communicate in a manner that will not require the company to report suspicious orders to the DEA. The Operations Manual directs McKesson employees to "'[w]rite information as if it were being viewed by the DEA,'" and "specifically instructs employees to 'refrain from using the word 'suspicious' in communications' describing customer orders."

85. On the heels of renewed investigations by the DEA beginning in mid-2013, McKesson finally began to tighten up its suspicious order monitoring policies. Part of this effort included a threshold reduction initiative, through which McKesson reduced the oxycodone thresholds for most of its customers. The total threshold reduction of oxycodone was 42 million doses per month, reflecting just how inflated these levels were in the preceding years.

86. In connection with the investigation of McKesson that led to the 2017 settlement, the DEA and DOJ concluded that McKesson's desire for increased sales and customer retention had overridden its obligations to report suspicious orders and jeopardized the health and safety of people around the country. The DEA and DOJ also described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic."

87. Ultimately, on January 5, 2017, despite having notice and nearly nine years to improve its compliance since its 2008 settlement, McKesson entered into another Administrative Memorandum Agreement ("AMA") with DEA and agreed to pay a $150 million civil penalty—the largest penalty leveled in DEA's history against a distributor. A DEA memo outlining the investigative findings, stated that McKesson "[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."

88. In the AMA, McKesson admitted that, from January 1, 2009 through January 17, 2017, at 12 of its distribution facilities (including Aurora, Colorado), 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 [2006 and 2007] DEA Letters." McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion . . . in violation of the CSA and the CSA's implementing regulations . . . ."

89. As part of the AMA, 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."[23] As the DEA wrote to McKesson in November 2014 in connection with the investigation, McKesson's failures "were as systemic as they were serious." The Department of Justice likewise recognized as part of its investigation in 2013 and 2014 that there was a "nationwide" and "systemic" failure on McKesson's part to report suspicious orders and otherwise maintain effective controls against diversion. McKesson's compliance failures were an issue across all of its distribution centers, including those that distributed to Montana.

e. McKesson Lacked Adequate Due Diligence Policies and Prioritized Sales Over Safety.

90. McKesson's due diligence policies for both its new and existing customers were also inadequate to satisfy its legal obligations and to guard against diversion in Montana.

91. Under McKesson's CSMP, the process for evaluating new customers to determine whether to supply them with controlled substances consisted of questionnaires, which were filled out by the pharmacy or by sales representatives (who have financial incentives based on new customers and, as explained below, opioid sales). The information supplied in these questionnaires (which were only required in some instances) was rarely verified by compliance staff, who depend upon pharmacies to self-disclose, for example, their cash payment rates or employees with criminal records. McKesson's investigation of new customers consisted only of internet searches on the pharmacy, a check of the pharmacy's licensing status, review of the pharmacy's unverified

[23] Lenny Bernstein & Scott Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper*, The Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.bb606509a764

questionnaire, photos of the pharmacy's building, and reviews of the pharmacy's ordering history. Seldom did McKesson conduct a site visit or even call the pharmacy. This surface-level review falls short of the DEA's suggested "know your customer" guidance. It also stands in sharp contrast to McKesson's willingness, as described above, to make frequent sales calls on and contact with existing customers, both for its own benefit and complimenting the marketing efforts of opioids manufacturers, which overinflated both the demand for addictive opioids and McKesson's own profits.

92. McKesson also lacked adequate policies for conducting due diligence investigations of its chain store pharmacy customers.

93. For example, in a January 9, 2009 policy entitled "CVS CSMP: Threshold Review," McKesson directed its employees to approve automatic threshold increases for CVS "without further CVS explanation," and to only seek justification for increases deemed "extraordinary" in order to "minimize disruption of business." In other words, McKesson's procedures were driven not by its obligation to report "unusual" (not "extraordinary") orders, but by its business interests to maintain a customer relationship and to maximize its profits from the sale of addictive, controlled substances in the midst of the opioid crisis.

94. Further, in January 2019 in the Federal Multidistrict Litigation consolidated in Ohio, in which city and county suits against Opioid manufactures, distributors and pharmacies have been consolidated (the "MDL"), McKesson's Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for its national chain pharmacy customers; instead, it generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.

95. McKesson's legal obligations to prevent diversion extend equally to chain pharmacies and small, independent pharmacies. However, McKesson's CSMP, its sole program for tracking and reporting suspicious orders, applied only to independent and small to medium chain retail pharmacies ("ISMC customers") until April 2018, when McKesson adopted an Operating Manual for Retail National Accounts ("RNA").

96. Upon information and belief, McKesson continues to work with chain pharmacies at the corporate level, rather than on a pharmacy-by-pharmacy basis. For example, Section 11.5, Documentation for a RNA Chain Onboarding, states that "Rather than completing an Investigative Report for each individual Customer within the Chain, a Chain-level Investigative Report will be documented in the RNA Chain's R:Drive folder." It is only the "small subset of Customers within the RNA segment that does not have internal and centralized compliance/ oversight related to controlled substances" that are reviewed using the due diligence procedures outlined in the ISMC Operating Manual. However, as the DEA has made clear, "due diligence must be performed on all customers, chain pharmacies included."

2. Cardinal

a. Cardinal Failed to Maintain Effective Controls Against Diversion in Montana

97. Between 2006 and 2014, Cardinal was the second largest distributor shipping opioids to and within Montana. Cardinal shipped more than 16% of all estimated 10 mg equivalent opioid pills in the State – a total of 110,039,152 estimated 10 mg equivalent pills. Yet based on records produced by the DEA, [redacted] This was true even though information available to Cardinal should have raised red flags.

98. [redacted]

99. Broadway Pharmacy in Missoula was Cardinal's top customer in Montana. It purchased almost 4 million dosage units (mostly pills) of opioids from 2006 to 2014, about 90% of which were supplied by Cardinal. These transactions included over 21,000 dosage units of fentanyl, an extremely powerful opioid that is 50-180 times more potent than morphine. [redacted]

100. The Kmart Pharmacy in Butte was Cardinal's second largest customer in Montana. From 2006-2014 (the period for which DEA data is available), Cardinal supplied nearly all of the Kmart Pharmacy's opioids, including nearly 1.6 million dosage units of hydrocodone and 23,680 dosage units of fentanyl. [redacted]

101. In sworn testimony taken during the Montana Attorney General's investigation, a Cardinal Senior Vice President who is responsible for anti-diversion compliance confirmed that it is not Cardinal's policy always to report to DEA or state law enforcement when Cardinal refuses to accept a new customer or terminates an existing customer because of concerns regarding possible diversion, and he could not recall Cardinal ever making any such reports in Montana.

102. The same official testified that in monitoring the orders of its pharmacy customers, Cardinal makes no effort to factor in local information such as the population of the town, overdose data from the area, opioid-related hospitalization numbers, or even statewide opioid statistics. In short, Cardinal makes no effort to give special attention or use tighter controls for pharmacies in places that are known to be suffering from especially severe opioid addiction. In addition, Cardinal's opioid monitoring is drug-specific, so that a pharmacy that places a suspicious order of oxycodone will still receive its orders of hydrocodone, fentanyl and other opioids. Even worse, however, is the fact that it is "not uncommon" for Cardinal to hold a shipment of oxycodone or another opioid as a suspicious order and then ship the same amount of the same drug to the same pharmacy in a matter of days or weeks after that pharmacy's monthly thresholds reset.

103. Finally, the Cardinal official testified that in the past, Cardinal used a DEA algorithm to identify customers to include in "Excessive Purchase Reports" to the DEA, but Cardinal did not stop the customers' orders because the shipments were already made by the time Cardinal ran the algorithm. More recently, from 2012-2015, Cardinal experienced an "IT glitch" that caused about 14,000 suspicious orders from across the nation, the vast majority of which were opioids, to go unreported to the DEA.

104. These examples illustrate Cardinal's systemic failures to maintain effective controls against diversion of opioids in Montana.

b. Cardinal Knowingly Failed to Design a Suspicious Order Monitoring System that Would Have Allowed it to Properly Identify Suspicious Orders

105. Cardinal knowingly failed to design and operate an effective system to identify suspicious orders in Montana. Prior to 2008, Cardinal tasked its distribution center's cage vault personnel (i.e. personnel who work in secure areas in which the DEA requires that controlled substances be stored and who assist with picking orders) with its suspicious order monitoring and had no electronic system for analyzing orders.

106. [redacted]

[redacted]

107. Further, employees could easily override the system's limits, even though, as Cardinal's then Quality Assurance & Compliance Manager noted in a November 2006 e-mail, "[t]his is not supposed to happen without authorization."

108. In an earlier 2005 e-mail, a Cardinal employee reported being asked about the existence, or lack thereof, of a specific protocol to monitor possible drug diversion by internet pharmacies or wholesale accounts. He explained that none of the three wholesalers asked, including Cardinal, volunteered an answer, and to his knowledge, Cardinal had no such program. Rather, its practice was that "[if] a distributor or internet pharmacy customer is properly licensed and a legal entity to purchase from us, we typically do not monitor what they purchase, or track who they sell to." Moreover, as described further below, until 2008, Cardinal primarily reported suspicious orders to the DEA after they had already been shipped, in the form of monthly summaries called

Ingredient Limit Reports (ILRs). ILRs not only did not promptly report suspicious orders, upon discovery, as required, but accounted only for the volume of a drug purchased and were not able to track unusual patterns or frequency.

109. The DEA repeatedly took action against Cardinal in 2007 and 2008 for failing to report suspicious orders and prevent diversion, demonstrating both Cardinal's awareness of its obligations and its failure to meet them.

110. These actions include:

- 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 entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA ("2008 MOA") related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The Agreement also referenced allegations by DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado. As part of the Agreement, Cardinal agreed "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Cardinal also agreed to pay $34 million in civil penalties.

The 2008 MOA not only covered the Lakeland, Florida facility, it resolved allegations of Cardinal's "alleged failure . . . to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, *at all distribution facilities* ... operated, owned, or controlled by it."

111. Only after the DEA actions in 2007/2008 did Cardinal take steps to implement an electronic suspicious order monitoring system. From late 2007 to 2008, Cardinal hired an outside consultant, Deloitte Consulting, to develop an algorithm to establish thresholds for its customers based on the customer's size (small, medium, or large, as determined by sales) and using the average annual sales of customers, grouped by trade (e.g., retail independents, chains, hospitals, and long-term care), multiplied by three. Notably, in setting these thresholds, Cardinal made no effort to determine whether the average sales it was using to determine future thresholds were themselves appropriate for its customers. It also ignored that the baseline calculation used to set the threshold was significantly inflated, as the United States was already in the midst of an opioid epidemic. The system was not implemented immediately, as reflected in a January 2008 internal email with the subject line "Possible Suspect Pharmacy," which explained, among other things, that "Cardinal does not yet have a system for detecting all suspicious orders.

112. Additionally, according to a former employee of Cardinal's subsidiary ParMed, it was well-known that sales representatives called customers from their cell phones to avoid recorded lines in order to coach the customers on how to order in a way that would allow them to circumvent the thresholds.

113. Although Cardinal's Standard Operating Procedures set thresholds based on the type or size of a pharmacy, they wholly failed to account for other important facts, such as the

population of an area that a particular pharmacy was serving, which would provide information about the expected legitimate prescription needs.

114. In 2018, Cardinal Health's Senior Vice President of Supply Chain Integrity, Todd Cameron, testified that Cardinal did not take the population of an area into consideration when evaluating whether a particular order was suspicious, agreeing that there was "no volume" of opioids that would be a red flag on its own, even a hypothetical "billion pills" to a town of 7,000.

115. Cardinal's 2010 process to establish threshold limits was identical to its 2008 policy and continued to rely on customer segments. As before, thresholds could be increased "if the customer has a documented diversion or loss prevention program. In essence, Cardinal's role in the customer's anti-diversion decreases as the customer ability increases." This policy did not take into account whether the customers' diversion program was legally sufficient or actually implemented. Cardinal's failure to determine these facts compounded its own compliance deficiencies.

116. Another deficiency in Cardinal's system was the monitoring of thresholds by the company's sales force. From 2008 to 2010, sales representatives were expected to monitor thresholds through "Highlight Reports," monthly reports that identified "Red Flag" or "Yellow Flag" customers, based on a percentage increase in a pharmacy's controlled substance orders. Salespeople were required to visit their Red Flag customers within ten working days to look for signs of diversion and contact their Yellow Flag customers as soon as possible (presumably, more than 10 days) to understand the reason for the increased ordering. Orders that triggered a customer's classification as Red or Yellow were not stopped—a facial violation of law.

117. During a May 2018 hearing before the House of Representatives' Energy and Commerce Subcommittee on Oversight and Investigations, Cardinal's Chairman George Barrett

denied that "volume in relation to size of population" should be a "determining factor" in identifying potentially suspicious orders. Barrett was also asked during the hearing about an instance in 2008 when a Cardinal employee flagged an especially prolific pharmacy as a potential pill mill. In that case, the Committee found no evidence that Cardinal took any action in response. Cardinal increased another pharmacy's threshold twelve times, but, once again, Barrett could not explain what factors it applied or how it made decisions to increase thresholds.

118. While Cardinal has cited blind spots due to its lack of complete data on opioids supplied to pharmacies by other distributors, Cardinal also acknowledged that a distributor can ask a pharmacy for a report with information about all of the drugs it dispensed, not just those supplied by Cardinal. Specifically, in his May 2018 testimony, Cardinal Health's Chairman of the Board confirmed, for example, that a distributor could request a dispensing report from a pharmacy that would contain information about all of the prescriptions a pharmacy dispenses—not just those provided by that particular distributor.[24] The Committee's Report also observed that distributors can obtain dispensing data from pharmacies that includes the method of payment and physician associated with each prescription.[25]

119. During the 2018 hearing, Barrett testified that Cardinal had made significant improvements to its monitoring, explaining that Cardinal's current monitoring systems are now entirely "data driven." He testified: "We look at data, and if the data tells us there is an aberrant pattern, we simply stop." Yet, an "entirely data driven system" ignores many of the red flags identified by DEA—long patient lines, a heavily cash business, out-of-state patients—that are both known to Cardinal and also relevant to detect diversion of prescription opioids. Barrett also testified

[24] House of Representatives, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce; *Combating the opioid epidemic: examining concerns about distribution and diversion* (May 8, 2018).
[25] Energy and Commerce Committee, Majority Staff, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Dec. 19, 2018 ("Energy and Commerce Report), p. 112

that, beginning in 2012, Cardinal implemented stronger compliance systems that addressed many of the company's prior compliance failures. However, in March 2017, the California Board of Pharmacy filed a complaint against Cardinal's Valencia, California facility for shipping suspicious orders from 2012 to 2015. According to the complaint, Cardinal shipped orders for controlled substances "despite patterns of irregular ordering including significant increases in orders for commonly diverted controlled substances between 2012 and 2013 and 2013 and 2014."

120. In addition to continuing to ship sharp increases of controlled substances, Cardinal also shipped increasingly larger volumes of the highest available strength of certain drugs even though orders for higher dosage strengths of opioids are a red flag for diversion. However, as Barrett acknowledged during his testimony, if the threshold was not hit, Cardinal's system would not detect red flags such as this.

121. The flaws in Cardinal's suspicious order monitoring procedures are further underscored by its communications with third-party consultants. For example, a 2008 compliance audit conducted by Cegedim Dendrite ("Dendrite"), a company that routinely provided regulatory compliance services for the pharmaceutical industry, identified several reasons why Cardinal's "Phase I SOM system procedures" would not "meet the regulatory requirements without additional real-time monitoring capability." By that point, Cardinal had only implemented the first of two planned phases, and its system was "incomplete" and insufficient to comply with regulatory requirements.

122. For example, Dendrite expressed concern that Cardinal's system could not track deviations in individual ordering patterns even though "[t]his requirement is specifically addressed in the regulation." In response, Cardinal claimed that this type of information could be discerned from Cardinal's "Ingredient Limit Reports," ("ILRs") monthly retrospective reports that compared

a customer's monthly controlled substance purchases to predetermined averages for certain controlled substances. However, as Dendrite explained, "Cardinal's 'ingredient limit reports' are based upon historical information and are not sufficient to monitor deviations in ordering patterns on a real time basis." It further explained that ILRs "do not substitute for real time automated analysis of pattern and frequency." Instead, Dendrite emphasized that suspicious orders must be identified in real time, writing: "We believe a real time analysis is required."

123. As of 2012, Cardinal also still had not implemented many of the changes that Deloitte had suggested in 2007 when hired to assist Cardinal with its suspicious order monitoring program. In internal emails, Deloitte employees described the program at Cardinal as "chaotic" and noted that Cardinal "is losing focus already." The emails also stated that "more than half of the action items . . . were not completed and the sense of urgency, if not gone completely, at least was invisible," and that implementation plans continued to be pushed back from their initial deadlines. Despite its public affirmations of compliance, as described below, Cardinal had lacked the competence or commitment to ensure that its distribution of opioids met legal requirements to protect public safety.

124. In sum, Cardinal's compliance system was flawed in that it: (a) was limited to an evaluation of thresholds which, for the reasons described above, does not identify all and actual suspicious orders; and (b) failed to take into account other important measures of potential diversion, such as an area's population or a pharmacy's customers. Yet this was the system Cardinal employed in Montana.

c. Cardinal Failed to Report Suspicious Orders and Continued to Ship Orders it Identified or Should Have Identified as Suspicious

125. Cardinal's systemic failure to promptly report suspicious orders, including in Montana, occurred even though it has long been aware of and has acknowledged its obligation to

notify the DEA immediately upon discovery of a suspicious order. For example, Cardinal's "DEA Compliance Manual," dated November 20, 2000, explains "on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA."

126. Despite being aware of its responsibility to report suspicious orders upon their discovery, Cardinal ignored this obligation.

127. In its 2008 report, Dendrite noted that when Cardinal blocked an order as potentially suspicious for exceeding a threshold, it simply reduced the order to the threshold limit and filled it. It did not report the initial order to the DEA. This was despite the fact, as discussed above, that internal industry documents acknowledged that this practice was in contravention to DEA guidance.

128. Having failed to reform its conduct, on December 23, 2016, Cardinal once again agreed to a settlement with the U.S. Department of Justice—this time for $44 million—to resolve allegations that it violated the CSA by failing to report suspicious orders of controlled substances, including oxycodone, and admitted to systemic failures.

129. Additionally, Cardinal's Senior Vice President of Supply Chain Integrity testified that in 2018, Cardinal met with the DEA to discuss its failure to report approximately 14,000 suspicious orders from "across the country" from 2012 and 2015, the majority of which involved opioids.

130. This testimony reflects a corporate culture that had not changed, despite repeated admonitions. As a January 2008 internal email from Cardinal's then-CEO, Kerry Clark, observed, in the 18 months leading up to the CEO's email, Cardinal Health had accumulated nearly $1 billion in "fines, settlements, and lost business" as a result of multiple regulatory actions, including the suspension of Cardinal distribution centers' licenses for failure to maintain effective controls against the diversion of opioids. Clark noted that the company's "results-oriented culture" was perhaps "leading to ill-advised or short-sighted decisions."

d. Cardinal Failed to Conduct Meaningful Due Diligence and Gave Complete Deference to Chain Pharmacies

131. Cardinal also failed to maintain effective controls, across the nation and in Montana, by failing to conduct meaningful due diligence to ensure that opioids ordered by its customers were not diverted into other than legitimate channels.

132. Even if a salesperson identified signs of diversion, whether or not Cardinal continued to ship to a pharmacy was a purely subjective decision. During the May 2018 Congressional hearing, Barrett was questioned about an instance where Cardinal continued to ship to a pharmacy despite the concerns of a Cardinal employee that the pharmacy filled the prescriptions of a prescriber whose office "was essentially a pill mill." In response, Barrett admitted the failures of Cardinal's previous system, noting: "I think we had a system that allowed for too much subjectivity about the legitimacy of a pharmacy."[26]

133. In its pursuit of profits, Cardinal also gave inappropriate, unwarranted deference to chain pharmacies — its largest customers, who were responsible for dispensing the largest volume of opioids.

[26] House of Representatives, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce; *Combating the opioid epidemic: examining concerns about distribution and diversion* (May 8, 2018).

134. In a 2006 letter to the New York Attorney General, in the context of negotiating a settlement agreement, Cardinal acknowledged that it did not perform due diligence investigations as to certain chain pharmacy customers, indicating: "certain chain pharmacies refuse to allow any sort of intrusive inspection by Cardinal or to make certifications. And these large legitimate customers can of course take their billions upon billions of dollars in business to any wholesaler in the country." In other words, Cardinal did not want to agree to monitor chain pharmacies as it might lose their very substantial business if it did.

135. In 2009, the DEA reminded Cardinal's QRA Vice President, Anti-Diversion & Supply Chain Services, that "due diligence investigations must be performed on all customers, chain pharmacies included, when it appears that suspicious high volume orders of controlled substances are requested."[27] In response, Cardinal indicated "that QRA is unable to look at chain pharmacy systems in order to identify problem areas when there is not an order of interest or their threshold is not exceeded."[28] This, of course, was unacceptable, and the DEA "repeated that chain store due diligence reviews must not be treated any differently than independent retail pharmacy customers."[29]

136. Accordingly, Cardinal set artificially high thresholds for its chain pharmacy customers to avoid conducting deeper due diligence into these customers.

137. Further, a 2010 internal email between two Cardinal employees shows that Cardinal still shipped suspicious orders to CVS without performing any due diligence. One Cardinal employee wrote to the other employee, "I spoke with Brian Whalen at CVS a couple of times this morning… They will not provide the doctor or patient information you requested unless it is

[27] Declaration of Michael Arpaio, *In the Matter of Cardinal Health*, DEA Docket No. 12-32 ¶ 5 (Apr. 9, 2012)
[28] *Id.*
[29] *Id.*

requested by the DEA. He was quite adamant about this." This type of refusal to provide information should have been a red flag. Yet, Cardinal released the orders anyway. CVS was quick to remind Cardinal that its contract with CVS required it to do so. This is consistent with testimony from another former Cardinal employee that Cardinal failed to make any effort to evaluate chain pharmacies' anti-diversion programs, and instead relied on those pharmacies to police themselves.

138. In fact, Cardinal's distribution contract with CVS granted CVS the discretion to set its threshold quantities for controlled substances at any level CVS deems appropriate:

> CVS requires the ability to adjust (up or down) the quantity of product our stores receive, this adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. **Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.**

139. Based on this agreement, CVS did "not expect Cardinal to interrupt service to CVS stores." As described above, however, Cardinal had, and knew it had, a non-delegable to duty to perform due diligence and halt suspicious orders, even if one of its large accounts would be displeased with the "interrupt[ion]." Id. As described above and further below, ignoring violations by its chain pharmacy customers and failing to conduct meaningful due diligence investigations of these customers was Cardinal's policy at least up until another settlement with the DEA in 2012. As a result, Cardinal turned a blind eye to what were often obvious violations. Cardinal should have identified numerous red flags at both chain and independent pharmacies in Montana, but instead continued to ship large volumes of opioids to these stores, including the Broadway Pharmacy in Missoula and the Kmart Pharmacy in Butte (described above).

140. In May 2012, Cardinal entered into a Memorandum of Agreement with the DEA wherein it admitted that "its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." The agreement expressly applied to all

28 of Cardinal's DEA-registered distribution centers, including those that supplied opioids to Montana. Although it arose out of an investigation into one facility, the failures at issue reflected systemic failures in Cardinal's practices. Further, in the MDL, the DEA testified, through Thomas Prevoznik, that it was "in fact frustrated that registrants were blatantly violating the MOUs[/MOAs] from prior administrative actions" including "Cardinal Health's 2008 MO[A] and settlement which resulted in a second DEA fine."

141. Cardinal's ability to adequately conduct due diligence investigations was further limited by the fact that its compliance department was woefully understaffed. In a January 2005 Cardinal presentation regarding Cardinal's QRA department, it was noted that "[q]uality is not a mindset at Cardinal health – we are not proactive" and "[t]his is not high enough priority today[.]" It goes on to describe its QRA department as "under resourced today," and states that they "don't have enough bench strength" and there were "not enough people." Still, Cardinal ignored the problems highlighted in the 2005 presentation. In a year-end review of Cardinal's compliance budget for the 2006-2007 fiscal year, it was noted that QRA staff workloads were at "full capacity," that "[e]ffective management of current projects and initiatives is difficult," and that the company purportedly lacked resources "to improve and enhance existing programs." Subsequently, in a January 7, 2008 email to members of Cardinal's Anti-Diversion Steering Committee, Vice President of Retail Marketing, Steve Lawrence, voiced his concern that QRA did not have sufficient resources. Then, on January 26, 2008, Lawrence provided an update regarding Cardinal's efforts to staff its QRA department and stressed that the staff was working "day, night, and weekends" but that the group remained understaffed. Cardinal's Vice President of QRA, Steve Reardon, admitted that although Cardinal was a company with 30,000 employees, it tasked **only three people** with responsibility for conducting due diligence reviews for more than "**20-some-odd distribution**

centers," acknowledging that it was impossible for Cardinal to conduct proper investigations with such poor staffing.

142. Reardon also acknowledged that Cardinal's due diligence investigations were ineffective because they required a retrospective review, testifying:

> Q. [You were shown] earlier the amount, that the tens, if not hundreds of thousands, of pills that were being ordered by some of these pharmacies every month. But by the time we're reviewing the report, those pills are already gone and out on the street, aren't they?
>
> A. Correct.
>
> Q. It's not an effective system to prevent diversion if we've already sent out the pills, and then we're reviewing the report, is it?
>
> A. It could be suspect; we could prevent it.

D. Defendants are Uniquely Positioned to Detect Suspicious Orders

143. Defendants' role in the supply chain provides them with detailed data on the shipment of opioids to pharmacies and other dispensaries (such as hospitals) both over time and in real time. As described below, Defendants are enmeshed at virtually every level of the opioid supply chain, and they mine detailed information that they leverage into increased profits. Possession of this extensive information equips distributors to readily and efficiently identify potentially suspicious orders of opioids. Given Defendants' market share nationally, they have particularly extensive information. Indeed, based on Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

144. With access to detailed data and their analytical capabilities, these Defendants are able to determine, down to the pharmacy and the type, number, and dose of each pill, the volume of opioid sales across Montana and the country. Defendants have the ability to see total orders by

their customer pharmacies, including non-controlled substances and combinations of drugs that signal diversion — information even the DEA does not have. Indeed, distributors have even acknowledged in internal documents that their "analytical capabilities provide us with greater insight into our own customer base," leaving industry "frankly . . . in a better position to provide information to DEA than they could provide to us." For example, while they may not know the precise details of another distributor's market share, distributors can obtain dispensing data from their pharmacy customers that show the total volume of controlled substances the pharmacy dispenses, the physician associated with each prescription, and the method of payment used to pay for the prescription.

145. The Federal Trade Commission has recognized the unique role of distributors. Since their inception, the "Big Three" distributors, which also includes AmerisourceBergen, have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, these companies also offer their pharmacy or dispensing customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. They 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.[30] As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the range of additional services they offer, distributors have a unique insight into the ordering patterns and activities of their dispensing customers.

146. In addition to their own data from shipping prescription drugs to customers, Defendants also obtain national, regional, state, and local prescriber-level data from various companies, known as "data vendors," that collect and sell data, such as IQVIA (formerly IMS Health, Inc.), Wolters Kluwer, and Verispan. CVS Caremark's Director of Managed Care Operations, Scott Tierney, previously testified in other litigation that CVS would provide the data vendors with "prescriber level data, drug level data, plane level data, [and] de-identified patient data,"[31] illustrating the remarkable level of detail available to Defendants through data vendors.

147. The breadth and depth of the data available to and collected by Cardinal, for example, was made clear in a 2001 news article describing Cardinal's joint venture with CVS and retailers Wal-Mart, K-Mart, and Albertsons, all of which have pharmacy operations, to "collect and market real-time prescription-drug sales data."[32] The venture, called ArcLight Systems LLC, had access to data from nearly 1 billion prescriptions.

148. This information would have allowed distributors to analyze and track their competitors' sales and to determine their relative market shares (and thus the total supply of opioids in an area).[33] This extensive information likewise would have allowed Defendants to track and identify instances of overprescribing and orders that raised red flags. In fact, an expert for a data vendor testified in an unrelated proceeding that this information could be used to track and report suspicious orders of controlled substances.[34]

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[31] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-246 (Feb. 22, 2011).
[32] *Cardinal Health, Others Form Prescription-Data Analysis Firm*, BizJournals.com (July 30, 2001), available at: https://www.bizjournals.com/columbus/stories/2001/07/30/daily2.html.
[33] A Verispan representative testified that the Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).
[34] In *Sorrell*, expert Eugene "Mick" Kolassa testified that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health Inc.*, 2011 WL 687134, at *204 (Feb. 22, 2011).

149. Sales representatives from Defendants are also in frequent, direct contact with their pharmacy customers. Sales and compliance personnel are tasked with investigating new potential pharmacy customers to determine whether they can be trusted to handle controlled substances. Defendants' sales personnel also are responsible for regularly visiting existing customers to maintain and expand the products and services they sell. They know, for example, which pharmacies are in less populated areas, have a high proportion of cash transactions, or do not offer non-prescription products—all reds flag of diversion.

150. Defendants also offer their pharmacy customers a broad range of added services as stand-alone services or through their franchise programs (McKesson's Health Mart, Cardinal's The Medicine Shoppe and Medicap Pharmacy), giving them still more insight into their customers' practices. For example, Defendants provide pharmacies sophisticated ordering systems and other database management support, as well as marketing programs and patient services.[35] McKesson's AccessHealth provides integrated back-office services with assistance with pharmacy benefit manager (PBM) audits, and its RelayHealth offers information technology solutions to "streamline communications between patients, providers, payors, pharmacies, pharmaceutical manufacturers, and financial institutions."[36] Cardinal's subsidiary, Kinray, assists independent pharmacies in managing business operations, increasing market share, and improving their reimbursements.[37]

151. [redacted]

[35] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).
[36] RelayHealth, *Corporate Overview*, *available through Internet Archive at* https://web.archive.org/web/20180106063929/http://www.relayhealth.com/about-us/corporate-overview.
[37] *See* Cardinal Health, Press Release, *Cardinal Health To Acquire Kinray for $1.3 Billion*, Nov. 18, 2010 (noting that the addition of Kinray will "significantly expand" Cardinal's ability to serve retail independent pharmacies and will give Kinray customers the benefit of Cardinal's "value-added services").

[redacted]

152. [redacted]

153. Each of the Defendants offered manufacturers services that promised to enhance the launch and distribution of their opioid products.

154. McKesson, for example, had various programs to coach and "reinforce" patients' use of opioids, as well as a TrialScript voucher and "LoyaltyScript" Co-Pay Program, presumably to help patients start and stay on opioids. McKesson's "HealthHonors" adherence module allows patients to engage with manufacturers' branded patient resources. In addition, McKesson offered "awareness" services, such as "RxBulletin," an HTML e-mail message reaching approximately 7,000 pharmacy and "HealthMart" recipients, and "RxMail," which sent printed materials to the same targets. It also made customized telemarketing campaigns available.

155. For a time, Cardinal's predecessor offered screensavers. Cardinal also offered "Cardinal Choice and Rx Advantage Programs," programs driven by market share contracts which the vendor enters into with Cardinal, and pursuant to which the vendor would agree to grant Cardinal a rebate on incremental sales.

156. [redacted]

157. As a result of these multiple services, subsidiaries, and data sources, Defendants have a role in and have knowledge of virtually every link in the supply chain, from manufacturer to patient. They have information on ordering, prescribing, dispensing, and use of controlled and non-controlled substances. These sources of information both enable and obligate them to do far more in detecting, reporting, and preventing diversion.

E. Defendants Understood and Acknowledged Their Obligations to Maintain Effective Controls Against Diversion, and the Consequences of Failing to Meet Them Were Foreseeable

158. Defendants have long been aware they had an important role to play in the closed system of opioid distribution, and they knew, or should have known, that their failure to comply with their obligations would have serious consequences. Indeed, the DEA has repeatedly informed Defendants about their legal obligations, including obligations that were so obvious that they simply should not have required additional clarification. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

159. As early as 1984, correspondence between the DEA and the NWDA[38] illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting: "DEA has interpreted 'orders' to mean prior to shipment."

160. In April 1987, the DEA sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers." According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained: "any system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program." Another area of issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment."

161. In 2007 and 2008, the Healthcare Distribution Management Association ("HDMA,") now known as the Healthcare Distribution Alliance ("HDA"), a trade association of pharmaceutical distributors in which Defendants have long been members, began developing

[38] In 2000, the NWDA was renamed the "Healthcare Distribution Management Association" ("HMDA"). The HDMA's membership included CVS. In 2016, HDMA was once again renamed and is now known as the Healthcare Distribution Alliance ("HDA").

"Industry Compliance Guidelines" ("ICG") that aimed to outline certain "best practices" for the distributors. As part of its development of the ICG, the HDMA met with the DEA on at least three occasions. The HDMA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum. Internal discussions concerning the ICG further demonstrate the industry's knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDMA noted that one potential downside of this approach was that "DEA correspondence/interpretation do not support this practice."

162. The HDMA released the ICG in 2008 and, in doing so, it emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[39]

163. Internal HDMA documents from 2012 reveal that distributors considered petitioning the DEA for regulations clarifying their suspicious orders and/or suspicious order monitoring expectations. This option was "favored" on the logic that the DEA would be unlikely to actually create such a regulation, and thus there would be "low risk of resulting in something overly restrictive or difficult to follow." At the same time, it would be a "good ask" since "the optics would be positive." According to its own documents, the HDMA's request for guidance was not a genuine need or request for clarity.

164. Nevertheless, distributors including Defendants did receive repeated and detailed guidance, including, for example, concerning their obligations to know their customers and

[39] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

communities they serve. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,"[40] which suggests that distributors examine, among other things, the ratio of controlled vs. non-controlled orders placed by the pharmacy; the methods of payment accepted; whether, why, and to what extent the pharmacy also orders from other distributors; and the ratio of controlled substances the distributor will be shipping relative to other suppliers.

165. The DEA also repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

166. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national

[40] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

trends involving the abuse of prescription controlled substances."[41] The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS system, described above, from which certain data was recently made public.

167. The DEA has hosted many different conferences throughout the years to provide registrants, including Defendants, with updated information about diversion trends and their regulatory obligations. Such conferences have included, for example, an "industry conference in which [it] brought manufacturers, distributors, importers together" and other conferences. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

168. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including Defendants. The 2006 letter emphasized that distributors 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.

169. The letter also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[42]

[41] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

[42] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter").

170. The DEA sent a second letter to distributors and manufacturers alike on December 27, 2007. Again, the letter instructed that, as registrants entrusted with responsibility to handle 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."[43] DEA's 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 ARCOS data to the DEA).

171. During a 30(b)(6) deposition in the MDL taken in April 2019, the DEA's Unit Chief of Liaison was asked whether the DEA made it "clear to industry that the failure to prevent diversion was a threat to public safety and the public interest." In response, he testified:

> Yes, I think it's established in 823 [the Controlled Substances Act] where it's part of our -- part of the registrant that is applying to be a registrant understands that they have to maintain effective controls . . . . they also know that these drugs themselves are scheduled controlled substances for a particular reason, because they're addictive, psychologically and physically they're addictive, so they know that these drugs have these properties within themselves. **So they would understand that these drugs are categorized or scheduled in that manner because they have the potential to hurt**.[44]

172. And Defendants did understand. As described above, Defendants have themselves acknowledged their understanding of the potential consequences of their failure to report and cease shipping suspicious orders. In addition, in the summer of 2013, former DEA agent Gary Boggs was retained as a consultant for McKesson and gave a presentation to McKesson's Regulatory Affairs program entitled "The Impact of Effective Compliance." A slide titled "What can happen

[129] *Id.*

when these checks and balances collapse?" depicted a collapsing building. During a recent deposition, Mr. Boggs was asked to explain what that slide was intended to convey. In response, Mr. Boggs testified that he was emphasizing the importance of "all of the members within the closed system of distribution" following their regulatory obligations.

173. A corporate representative testifying on behalf of McKesson in a MDL deposition acknowledged that violations of the CSA's requirements result in a substantial and detrimental effect on the health and general welfare of the American people. During the same deposition, he further testified that McKesson accepts partial responsibility for the societal costs of the opioid epidemic now facing the nation.

F. Defendants Received and Offered Financial Incentives to Distribute and Sell Ever Higher Volumes Of Opioids, Instead of Exercising Due Diligence to Prevent Diversion

174. Distributors 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 of opioid sales and distribution may decrease the cost paid per pill by 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, increased sales volumes result in increased profits.

175. Conversely, Defendants may fear losing sales if they do not fill their customers' orders. If customers did not receive controlled substances orders they sought, sales representatives had reason to be concerned that pharmacy customers might take all of their business, including for non-controlled substances, elsewhere.

176. [redacted]

[redacted]

177. [redacted]

178. Marketing Defendants structured incentives and bonuses for their sales representatives to increase sales of their branded opioids as well. Sales representatives are provided targets and bonus-driven compensation, and the companies may also offer contests, competitions, or other special perks to further incentivize sales. Further, for manufacturers' and wholesalers' sales representatives alike, if they do not make enough sales, they risk losing their jobs.

G. Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement

179. As described above, wholesale pharmaceutical distributors, including Defendants, and opioid manufacturers had close relationships with each other, as well as with customers, and both Defendants had financial incentives to increase their sales and the volume of opioids flooding into Montana.

180. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA. McKesson was a member of the PCF, and McKesson and Cardinal were both members of the HDA.

181. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including "Front Group" organizations created to disseminate information that appears to be unbiased, but actually supports industry marketing. The PCF became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

182. 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."[45] 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.[46] The PCF met monthly in Washington, DC and has spent nearly $900 million on lobbying. By 2006, the PCF's interest was to "get people who know the DEA, how they work, who they answer to, their vulnerabilities, etc in a room to help APF devise a plan to successfully change DEA policy/actions regarding prescription pain medicines."

183. The HDA formed relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that

[45] Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr. for Pub. Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last updated Dec. 15, 2016, 9:09 AM) (emphasis added).
[46] *Id*.

Defendants were both members of the HDA. Additionally, the HDA advocated the many benefits of membership, including "strengthen[ing] . . . alliances."[47]

184. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[48] Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Defendants.

185. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Defendants with the opportunity to work closely together, confidentially, to further their goals.

186. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and Defendants advertise these conferences to manufacturers as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[49] The conferences also gave all Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[50] The HDA and its conferences

[47] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Apr. 25, 2018).
[48] *Id*.
[49] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.
[50] *Id*.

were significant opportunities for the Defendants to interact at a high-level of leadership. It is clear that Defendants embraced this opportunity by attending and sponsoring these events.[51]

187. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

d. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

188. Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers . . . ."

[51] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://web.archive.org/web/20160119143358/https://www.healthcaredistribution.org/events/2015-distribution-manag8ement-conference.

189. The HDA aimed to "help ease DEA pressure on our members for SO [suspicious order] monitoring." Its goals included "comprehensive DEA strategy" to limit enforcement.

190. In addition, the HDA retained multiple public relations consultants to modify public perception. This work included research and market-testing messaging to "[i]nform development of research-based positioning, including messages and strategies, that protects and enhances the reputation of the industry." HDA members received "key findings" from this research and a "Crisis Playbook" all of which were designed to be used so that the industry could deliver a uniform message and deflect attention from distributors as wrongdoers or a source of harm. Importantly, the Crisis Protocol and Playbook both identified "High Risk" "Diversion Issues," including "Distributor Facility Shutdown," "Diversion Lawsuit," and "Congressional Inquiry." Each of these high risk diversion issues included questions that the members should consider and talking points to address them. Defendants' internal documents indicate that they were aware of the Crisis Playbook and used it to develop talking points approved and used by the Defendants.

191. Taken together, the interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry.

192. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrate that each of the Defendants were in communication and cooperation.

193. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion.

As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

194. Defendants also cooperated in lobbying against restrictions on opioid use and DEA enforcement. After the Cardinal ISO, HDMA began considering legislative strategy to "alter the present direction DEA is taking with respect to suspicious order monitoring." In April 2016, several members of Congress aligned with the major drug distributors, including Defendants, to pass a law that weakened DEA enforcement against distributors. The new law, the Ensuring Patient Access and Effective Drug Enforcement Act, "imposed a dramatic diminution of the agency's authority," wrote DEA Chief Administrative Law Judge Mulrooney. According to Judge Mulrooney, it is now "all but logically impossible" for the DEA to stop suspicious narcotic shipments from companies.[52] The HDA executive Committee directed staff to "exhaust all efforts to secure passage" of the law. The effort succeeded. "The drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before," said Rannazzisi. "I mean, to get Congress to pass a bill to protect their interests in the height of an opioid epidemic just shows me how much influence they have."

195. Instead of fulfilling their legal and moral responsibilities to safeguard the Montana public and prevent diversion, Defendants protected each other in their misconduct while the opioid epidemic was raging.

[52] Scott Higham and Lenny Bernstein, The Washington Post, *The Drug Industry's Triumph Over the DEA*, (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.f12a0ab29856.

H. Defendants Mispresented to the Public and Policy Makers that They Were Working Diligently with Law enforcement to Address the Opioid Crisis.

196. Despite their conduct in flooding Montana and other states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

197. For example, Cardinal has claimed to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." In its Standards of Business Conduct, Cardinal claims to be "committed to maintaining the integrity of the supply chain by developing and maintaining processes to help guard against diversion. Cardinal touted maintaining 'know your customer' policies and procedures to validate that products . . . ship[ped]are sold in accordance with legal and contract requirements and are received by customers for their legitimate use."[53] Cardinal also boasted that it "maintain[ed]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."[54]

198. In a 2017 shareholder document, Cardinal published its Opioid Anti-diversion Program and Board Oversight, in which the company noted its role in "maintaining a vigorous program to prevent opioid pain medications from being diverted to improper use."[55] During an earnings call that year, Cardinal's Chairman and Chief Executive Officer, George Barrett, promised that Cardinal "operate[s] a very strong, robust, suspicious order monitoring system and process that not only meets our regulatory requirements, we believe it exceeds what is required of distributors."

[53] 2009 Cardinal Health, *Standards of Business Conduct*, at 30.
[54] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.
[55] Cardinal Health Proxy, Form 14A at 7, filed Oct. 23, 2017.

One year later, Barrett returned to the same themes, describing Cardinal's "anti-diversion systems and controls" as "substantial," "well-funded," and "best in class."[56]

199. Cardinal continues to hold itself out as an industry leader, claiming on its website that it implements "state-of-the-art controls to combat the diversion of pain medications from legitimate uses."[57] McKesson's website touts its CSMP, which "uses sophisticated algorithms designed to monitor for suspicious orders, block the shipment of controlled substances to pharmacies when certain thresholds are reached and ultimately report those suspicious orders to the DEA."[58]

200. This misleading self-promotion is not new. In an October 2, 2008 press release, Cardinal Chairman and CEO, R. Kerry Clark, stated:

> Since November 2007, Cardinal Health has invested more than $20 million to significantly enhance its controls across its network to prevent the diversion of controlled substances and has worked diligently with the DEA to resolve the suspensions. Specifically, the company has expanded its training, implemented new processes, introduced an electronic system that identifies and blocks potentially suspicious orders pending further investigation, and enhanced the expertise and overall staffing of its pharmaceutical distribution compliance team.[59]

201. In a 2012 press release, Cardinal again discussed its advanced anti-diversion system and stated:

> Cardinal Health has robust controls and performs careful due diligence. The company's controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the company's program raises a red flag, its teams immediately investigate. Cardinal Health's anti-diversion specialists use their professional judgment and expertise to determine the appropriate

[56] Cardinal Health Quarterly Earning Call Transcript at 4, dated Nov. 6, 2017.
[57] Cardinal's website, Addressing the Opioid Crisis: Board Engagement and Governance, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance/board-engagement-and-governance.html.
[58] McKesson's website, About McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program.
[59] *Id.*

> action. The anti-diversion specialists are authorized to stop shipments, investigate further and when appropriate, report matters to the DEA who licenses pharmacies to sell controlled substances.[60]

202. Along the same lines, in 2005, McKesson's "Corporate Citizenship Report" touted the company's "compliance and integrity," claiming:

> Rigorous, unwavering compliance with laws and regulations is the foundation for economic performance and customer and shareholder value creation. McKesson focuses intensely on systems and processes that enable full compliance with the laws and regulations that govern our operations . . . . We are especially aware of our responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety. We provide our customers the complete range of pharmaceuticals approved for use by the FDA, and apply all necessary controls governing the distribution of these substances.[61]

203. 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. Its website offers assurances that the company's CSMP "uses sophisticated algorithms designed to monitor for suspicious orders, and block the shipment of controlled substances." McKesson also publicly claims that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and that it is "deeply passionate about curbing the opioid epidemic in our country."

204. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade association, the HDMA (now HDA), filed an amicus brief in the *Masters Pharmaceuticals* litigation, which made the following statements:[62]

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[60] *Cardinal Health Inc. Seeks Restraining Order to Avoid Disruption in Controlled Medicine Shipments from Florida*, Feb. 3, 2012, *available at* https://ir.cardinalhealth.com/news/press-release-details/2012/Cardinal-Health-Inc-Seeks-Restraining-Order-to-Avoid-Disruption-in-Controlled-Medicine-Shipments-from-Florida/default.aspx

[61] McKesson Corporate, *Citizenship Report 2005*, *available at* https://www.slideshare.net/finance2/mckesson-corporate-citizenship-report-74m-2005

[62] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

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."

205. Through the above statements and others, Defendants not only acknowledged that they understood their obligations under the law, but created the false and misleading impression that their conduct complied with those obligations.

I. Statutes Of Limitations are Tolled and Defendants are Estopped from Asserting Statutes of Limitations as Defenses

1. Continuing Conduct

206. The State continues to suffer harm from Defendants' unlawful actions.

207. 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. Defendants' wrongdoing and unlawful activity has not ceased. The public nuisance remains unabated, while Defendants continue to tout their own systems and ignore and disregard their statutory and common law duties to maintain effective controls against diversion.

2. Equitable Estoppel and Fraudulent Concealment

208. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the State and to purposefully conceal their unlawful conduct and fraudulently assure the public, including State government, 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 Montana and

continuing to generate profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, and the State, that they are working to curb the opioid epidemic.

209. In addition, Defendants were deliberate in taking steps to conceal their active role in the oversupply of opioids and their failure to prevent the entry of prescription drugs into illicit markets, which fueled the opioid epidemic.

210. As set forth herein, Defendants concealed the facts underlying 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, and deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims.

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

212. Defendants thus successfully concealed from the public, and the State, facts sufficient to put the State on notice of the claims that the State now asserts.

J. Defendants Fueled and Profited from a Devastating Public Health Epidemic in Montana

213. Defendants fueled the opioid epidemic in Montana by failing to put in place appropriate procedures to ensure suspicious orders would be reported and halted. Instead, Defendants supplied opioids beyond even what an artificially-inflated market for opioids could

bear, funneling so many opioids into Montana that they could only have been delivering a significant portion of those opioids for diversion, misuse, and illicit use. The disproportionate volume of opioids that flooded into Montana as a result of Defendants' wrongful conduct has devastated the State. An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions and pharmacy orders.[63] Many of these orders were the type that Defendants could have—but did not—detect and report as suspicious.

214. In a 60 Minutes interview in the Fall of 2017, 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:

> [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.

215. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He explained, "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." Further, as explained above, Defendants well understood their duties to maintain effective controls against diversion, and the serious consequences if they failed to meet them.

216. Had Defendants established and implemented programs to prevent diversion and identified, reported, and rejected suspicious orders, the supply of opioids would not have been as

[63] Simeone, Ronald, *Doctor Shopping Behavior and the Diversion of Prescription Opioids*, Substance Abuse, Research and Treatment, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5398712/, last visited July 25, 2019.

great, and substantially fewer opioids would have been available for diversion and improper use. The use and abuse of these opioids resulted in the epidemic of addiction, overdose, and death that have wracked Montana. Each Defendant's unconscionable failure to maintain effective controls against diversion was significant. Cardinal operated in Montana from 2006 until 2012 without reporting a single suspicious order. McKesson operated in Montana from 2006 until 2013 without reporting a suspicious order.

217. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend. In Montana, since 2000, there have been more than 700 deaths from opioid overdoses.

218. State agencies have had to, and will need to, develop programs and re-direct funding to address the opioid crisis. In 2010, Montana began "Operation Medicine Cabinet," a prescription drug drop-off program, which now has nearly 50 permanent drop off sites around the State. The State also began in 2012 to operate Montana's Prescription Drug Registry, allowing providers and pharmacies to improve patient safety and monitor for signs of abuse/misuse or diversion. In addition, several agencies—including the Office of the Attorney General—have published opioid education materials or created websites to help the public understand the risks of opioid medication and prevent diversion.

219. Montana is also incurring other costs related to overdose responses, naloxone spending for first responders, increased law enforcement spending, increased pretrial and post-trial incarceration costs, increased criminal defense costs, increased social services spending such as

representing parents and children in neglect proceedings, and other costs and response measures needed to address the epidemic.

220. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. Opioid-related in-patient hospitalizations increased alongside the opioids distributed and sold in Montana. Emergency room visits have also increased.

221. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with prescription painkiller use. Nearly half of surveyed men not in the labor force said they took painkillers daily, and two-thirds of them were on prescription medications—compared to just 20% of employed men who reported taking painkillers. Many of those taking painkillers still said they experienced pain daily.

225. Oversupply of opioids also had a significant detrimental impact on children in Montana. Montana's children have the third-highest rate of prescription drug abuse in the country. Almost 23% of Montana high school seniors and almost 10% of children ages 12-17 report that they have abused prescription drugs.[64]

226. There has been a dramatic rise in the number of infants who are born dependent on opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from opioids once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are

[64] "Know Your Dose Montana," Montana Medical Association, available at: https://knowyourdosemt.org/

still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. For every 1,000 babies born in Montana, nine of them require intensive care because of NAS. Hospitalization charges are much higher for newborns with NAS ($34,000 versus $6,800). Between 60-77% of infants with NAS had Montana Medicaid as the primary payer. The charges to Montana Medicaid for their care was $14.1 million for 2009-2015.

227. Children are also injured by the dislocation caused by opioid abuse and addiction. The Child and Family Services Division of the Montana Department of Health and Human Services ("DPHHS") reports that over the last seven years, an average of more than 11% of DPHHS's foster care placements have involved prescription drug abuse by the child's parents or guardians.

228. Nationally, opioids now outpace other sources of addiction in demand for substance abuse treatment. Montana is struggling to meet that need. DPHHS operates a chemical dependency treatment center in Butte and a state psychiatric hospital in Warm Springs. Both facilities treat patients with opioid use disorder.

229. According to the Montana Board of Crime Control, drug offenses have steadily risen since 2010, up 74%, to an all-time high. This rapid increase in drug offenses has put a substantial strain on law enforcement, corrections, and court resources. Sheriffs and jail administrators in Montana estimate that over 90% of the individuals held were charged with addiction-related offenses. This contributes to increases in outside medical expenditures for the Department of Corrections.

230. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Roughly 80% of heroin users previously used prescription opioids. Though still small in absolute numbers, according to the Montana State Crime Lab, heroin-related offenses increased 1,557% from 2010 to 2015. Prior to the explosion in prescription opioid use, there were virtually no heroin-related drug offenses in the State.

231. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into Montana communities and taking the lives of individuals previously addicted to prescription opioids who turned to heroin and now heroin laced with fentanyl.

232. The Montana Department of Justice's Narcotics Bureau investigates high-level drug cases. Pill diversion has now become one of the biggest drivers of Narcotics Bureau investigations.

233. The Montana Highway Patrol reports that since 2011, there have been 39 fatal automobile crashes involving opioid usage. Furthermore, drug arrests have increased dramatically over the past six years. The number of driving under the influence arrests involving drugs, rather than alcohol, prompted the Montana Highway Patrol to initiate a Drug Recognition Expert ("DRE") program in order to evaluate whether an impaired driver is under the influence of drugs.

234. In addition, the State has incurred law enforcement costs directly related to opioid and heroin-related crimes, including the larger populations within Montana jails and prisons and higher costs to treat opioid addiction among inmates.

235. The opioid epidemic also has hit Montana's Native American population especially hard. One former Blackfeet tribal leader stated: "The drug epidemic is our modern-day small pox."[65] Nationwide, drug overdose death rates from opioids are higher among Native Americans than the overall population. The Blackfeet Community Hospital reports that over 50% of the babies born there have been exposed to illicit substances. Likewise, hospitals on the Flathead Indian Reservation have reported that the percentage of newborns at risk for neonatal abstinence have increased from 15% in 2013 to 49% in 2016. In statewide comparisons of Native American and Non-Native American students in Montana, the percentages of students who used narcotic prescription drugs was higher in the Native American student population among every age group studied.

236. The State will need to incur significant additional expenses in the future to abate the public nuisance caused in part by Defendants' wrongdoing. This will include, but is by no means limited to, the costs of continuing to dispose of unused prescriptions; continuing education and re-education of doctors and patients about the appropriate use of opioids, the signs of addiction, and the availability of treatment; and treatment for opioid addiction and overdose, including naloxone and medication-assisted addiction treatments, like buprenorphine.

CAUSES OF ACTION

Count I: Violations of the Montana Consumer Protection Act

237. Montana realleges and incorporates by reference the foregoing allegations as if set forth herein.

[65] Rocky Mountain Tribal Epidemiology Center, Addressing Opioid Use in Pregnancy: Conversations and Next Steps in Blackfeet," www.rmtec.org/addressing-opioid-use-in-pregnancy/ (last visited Nov. 30, 2017).

238. At all times relevant to this Complaint, Defendants were engaged in the distribution and sale of prescription opioid pain medications in Montana. Each is a leading force in the prescription opioid market in Montana.

239. The Montana Consumer Protection Act ("MCPA") prohibits: "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]" Mont. Code Ann. § 30-14-103.

240. Defendants have violated its statutory duties to Montana and Montana citizens, and have preyed on Montana's most vulnerable residents, including the elderly, disabled and chronic-pain patients.

241. Defendants' unfair or deceptive acts or practices include, but are not limited to, failing to maintain effective controls against opioid diversion by:

a. Oversupplying opioids into Montana;

b. Failing to create, maintain, and/or use a compliance program that maintains effective controls against the diversion of opioids;

c. Failing to report suspicious orders of controlled substances;

d. Shipping suspicious orders of prescription opioids; and

e. Failing to exercise due diligence to ensure that customers could be trusted with opioids.

242. These acts and practices were particularly immoral, unethical, oppressive, or unscrupulous, and offensive to public policy in that they were undertaken while Defendants were publicly professing commitment to combating the opioid epidemic and claiming to use advanced analytics and technology to address suspicious orders and prevent illegitimate use of prescription opioids while they were actually failing to maintain effective controls against diversion.

243. These acts or practices offend established public policies including the policy reflected in both the Montana CSA and the Montana Wholesale Distributors Act, as well as their implementing regulations, which require the monitoring and reporting of suspicious orders of controlled substances as well compliance with state licensing requirements. By failing to monitor, detect, report, investigate, and refuse to fill suspicious orders as required by these laws, Defendants also failed to minimize the risk of diversion of controlled substances to unlawful use.

244. Defendants' conduct has caused substantial injury in the State—in lives lost to drug overdoses, addictions endured, emergency room visits, substance abuse treatment and associated physical and mental health treatments, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

245. Defendants' acts and practices as alleged herein substantially impacted the community of patients, health care providers, and the public, and caused significant actual harm.

246. Defendants' acts and practices as alleged herein were motivated by a desire to retain and increase their market share and profits. Their conduct in deliberately disregarding their obligation to maintain effective controls against diversion and to report and halt suspicious orders, as well as their conduct in misrepresenting and concealing the truth, reflects a cavalier corporate culture that persisted over many years.

247. Defendants' misconduct was substantial, and the acts and practices regarding Montana consumers as alleged in this Complaint were undertaken in bad faith. These acts or practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that Defendants deliberately disregarded obligations meant to protect the public health and safety.

248. At the time they engaged in the conduct described in this Complaint, Defendants knew, or should have known, that they were fueling an illicit market and demand for dangerous drugs.

Count II: Public Nuisance

249. Montana realleges and incorporates by reference the foregoing allegations as if set forth herein.

250. By statute, "[a] public nuisance is one which affects, at the same time, an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal." Mont. Code Ann. § 27-30-102. By common law, a public nuisance is a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience that unreasonably interferes with a public right.

251. The Attorney General is authorized to bring suit on behalf of the State and its citizens to abate a public nuisance.

252. Defendants' conduct, as described in the Complaint, affects, at the same time, the entire State of Montana, and a considerable number of persons therein, and therefore constitutes a public nuisance under Mont. Code Ann. § 27-30-10 and under common law. Furthermore, it involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right by creating a public health epidemic in Montana.

253. This conduct includes Defendants' oversupplying opioids into the State and failing to maintain effective controls against opioid diversion by:

a. Oversupplying opioids into Montana;

b. Failing to create, maintain, and/or use a compliance program that maintains effective controls against the diversion of opioids;

c. Failing to report suspicious orders of controlled substances;

d. Shipping suspicious orders for prescription opioids; and

e. Failing to exercise due diligence to ensure that customers could be trusted with opioids.

254. As the Restatement (Second) of Torts § 821B(2) (1979) explains, "[c]ircumstances that may sustain a holding that an interference with a public right is unreasonable include" conduct that "involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience," that "is proscribed by a statute, ordinance or administrative regulation," or that "is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right." Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of the State and its residents.

255. Defendants have caused, are causing, and will continue to cause a public nuisance, in that they have committed offenses against the order and economy of the State by unlawfully distributing an oversupply of addictive opioids.

256. Defendants have also omitted to perform duties with respect to the distribution of opioids.

257. Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the general public:

a. to be free from reasonable apprehension of danger to person and property to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread opioid abuse and addiction;

b. to a clean and healthful environment and to be free from the negative health and safety effects of widespread illegal drug sales on premises in and around Montana, Art. II, § 3, Mont. Const. ;

c. to be free from blights on the community created by areas of illegal drug use and opioid sales;

d. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

e. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

258. Defendants' interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

a. has harmed and will continue to harm the public health and public peace of Montana;

b. has harmed and will continue to harm Montana neighborhoods and communities by increasing crime, increasing rates of disability, decreasing worker productivity, and thereby interfering with the rights of the community at large;

c. is proscribed by Montana and Federal statutes;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is known to Defendants that its conduct has a significant effect upon the public rights of Montana citizens and the State.

259. The nuisance has undermined, is undermining, and will continue to undermine Montana citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within Montana. It has resulted in high rates of addiction, overdoses, and dysfunction within Montana families and entire communities.

260. Defendants' have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends the moral standards of communities throughout the State and significantly harmed any considerable number of the State's residents.

261. Here, Defendants' conduct is prescribed by statutes and regulations, including, without limitation, the MCPA, the Montana CSA, and the Montana Wholesale Distributors Act, including the federal CSA and regulations incorporated therein.

262. Defendants violated the standard of conduct required by the Montana CSA and Montana Wholesale Distributors Act by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids, and violated the Montana CPA through their unfair or deceptive practices described in this Complaint.

263. Defendants knew and should have known that their failure to comply with their statutory and common law duties to maintain effective controls against diversion, including by monitoring, reporting, and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.

264. Defendants' conduct is of a continuing nature and has produced a long-lasting effect on the public right that Defendants knew, or had reason to know, would occur.

265. Defendants' conduct created or increased an unreasonable risk of harm.

266. Defendants' conduct is unreasonable, intentional, reckless, and/or negligent, and unlawful.

267. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described in the Complaint.

268. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the State described herein.

269. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, and in the public health crisis that followed and has reached epidemic proportions. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions and unlawful omissions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or would have been substantially less severe.

270. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

271. The nuisance has undermined, is undermining, and will continue to undermine Montana citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage, lowered worker productivity, and increased rates of disability within Montana. It has resulted in high rates of addiction, overdoses, and dysfunction within Montana families and entire communities.

272. Public resources have been, are being, and will be consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Montana public at large.

273. As a direct and proximate result of the nuisance, Montana citizens have been injured in their ability to enjoy rights common to the public.

274. The State has been, and continues to be, injured by Defendants' actions and unlawful omissions in creating a public nuisance.

Count III: Negligence

275. Montana realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

276. Defendants owe a duty to Montana to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

277. Defendants' conduct has fallen below the reasonable standard of care. Their negligent acts have included:

a. Failing to adhere to all applicable law and regulations pertaining to the distribution of prescription opioids;

b. failing to train, investigate, or oversee their employees properly and/or to establish and implement policies and procedures to ensure their compliance with the law; and

c. failing to provide adequate safeguards against misleading marketing or unlawful distribution, even after being sanctioned for their failures in the past.

278. Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis-a-vis the State. Their duty cannot be delegated.

279. In addition, Defendants each had a duty under Montana law to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

280. Defendants were negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to

prevent or ameliorate such distinctive and significant dangers and to guard against the diversion of opioids into illicit channels.

281. Defendants breached their duties to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in marketing and introducing into commerce dangerous controlled substances.

282. Defendants also were negligent or reckless in voluntarily undertaking duties to the State that they breached. Defendants, through their affirmative statements regarding protecting consumers, undertook duties to take all reasonable precautions to monitor and detected suspicious orders, to halt such orders, and to protect against diversion of highly addictive drugs into illicit channels.

283. Defendants had a duty to exercise reasonable care in distributing controlled substances. By distributing more opioids into Montana than could be used for legitimate medical purposes, and by failing to report orders that they knew or should have known were suspicious, the Defendants breached this duty. In addition to failing to prevent foreseeable harm, Defendants created foreseeable and preventable harm to Montana and its citizens.

284. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on Montana communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Montana law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty

to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

285. Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to the State, including but not limited to the following: increased costs for healthcare, criminal justice, social services, welfare, and education systems, babies born suffering from symptoms of NAS, as well as the cost of lost productivity, increased rates of disability, and lower tax revenues.

286. Montana is without fault, and its injuries would not have happened in the ordinary course of events if Defendants had used due care commensurate to the dangers involved in the distribution of controlled substances.

Count IV: Gross Negligence

287. Montana realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

288. By engaging in the above-described acts and omissions, Defendants failed to observe even slight care and acted with carelessness or recklessness to a degree that shows utter indifference to the consequences that may result.

289. Defendants' conduct as described in this Complaint constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the State.

290. Defendants have a duty to exercise reasonable care in distributing highly dangerous opioid drugs in and around the State.

291. Defendants are part of a limited class of registrants authorized to legally distribute controlled substances, which places them in a position of great trust and responsibility vis a vis the State. Their duty cannot be delegated.

292. In addition, Defendants each had a duty under Montana law to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and to not fill suspicious orders unless and until due diligence had eliminated the suspicion.

293. Upon information and belief, both Defendants repeatedly and intentionally breached its duties.

294. Defendants acted with wanton and reckless disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

295. The foreseeable harm from a breach of these duties is the diversion, abuse, and overdose of prescription opioids, causing morbidity and mortality in the state's communities.

296. Reasonably prudent distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Montana law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

297. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

298. Defendants' conduct as described herein constitutes actual malice and justifies an award of punitive damages pursuant to Mont. Code Ann § 27-1-221.

299. These Defendants' breach of the duties directly and proximately resulted in the injuries and damages alleged by the State.

300. The misconduct alleged in this case is ongoing and persistent.

Count V: Unjust Enrichment

301. Montana realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

302. Defendants have unjustly retained a benefit to the State's detriment, and Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

303. The State has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Defendants substantially helped create and foster.

304. Further, as an expected and intended result of its conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the State, including from opioids foreseeably and deliberately diverted within Montana. The State has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct. These expenditures include the provision of healthcare services and treatment services to people who use opioids. These expenditures have helped sustain Defendants' businesses.

305. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

306. The State has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' distribution practices. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

307. Accordingly, under principles of equity, Defendants should be disgorged of money retained by reason of their illegal acts that in equity and good conscience belong to the State.

Count VI: Civil Conspiracy

308. Montana alleges and incorporates by reference the foregoing allegations as if set forth at length herein.

309. Defendants engaged in a civil conspiracy in their unlawful distribution and of opioids into Montana.

310. Defendants, in coordinated and concerted action with each other, engaged in a joint scheme to materially expand opioid use by altering the medical community's prescribing practices of opioids.

311. Defendants deceptively created and maintained the market for their opioids and unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids. Through PCF, HDA, and other organizations, Defendants knowingly circulated misinformation that distorted the risks, benefits, and appropriate uses of opioids, concealed their misconduct, worked to permit the broadest distribution of opioids, and constrained enforcement actions against them.

312. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

313. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

314. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement, understanding, or course of conduct between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

315. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

316. 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 has a great probability of causing substantial harm.

PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against each Defendant, as permitted by Montana law, as follows:

317. For a declaration that each Defendant has willfully violated the Montana Unfair Trade Practices and Consumer Protection Act;

318. For injunctions pursuant to Mont. Code Ann. § 30-14-111 enjoining each Defendant from engaging in any acts that violate the Montana Unfair Trade Practices and Consumer Protection Act, including, but not limited to, the unfair and deceptive acts and practices alleged in this Complaint;

319. For civil penalties against each Defendant in the amount of $10,000 for each and every violation of the Montana Unfair Trade Practices and Consumer Protection Act under Mont. Code Ann. § 30-14-142(1);

320. For civil penalties against each Defendant in the amount of $10,000 for each and every violation of the Montana Unfair Trade Practices and Consumer Protection Act directed toward older persons or developmentally disabled persons under Mont. Code. Ann. §30-14-144 (1)(a);

321. For civil penalties against each Defendant in the amount of $10,000 for each and every willful violation of the Montana Unfair Trade Practices and Consumer Protection Act under Mont. Code. Ann. §30-14-142(2);

322. For an injunction permanently enjoining each Defendant from engaging in the acts and practices that caused the public nuisance;

323. For an order directing each Defendant to abate and pay the expenses required to abate fully the public nuisance it has caused and damages to the State under Mont. Code Ann. § 27-30-103;

324. For restoration of money Defendants obtained from the State, directly or indirectly, as well as other equitable relief, under Mont. Code Ann. § 30-14-131;

325. For restitution and/or disgorgement of each Defendants' unjust enrichment and ill-gotten gains, plus interest, acquired, either directly or indirectly, as a result of the unlawful or wrongful conduct alleged herein;

326. For an award of compensatory damages for the increased costs to Montana's healthcare, criminal justice, social services, welfare, and educational systems, as well as the cost of lost productivity and lower tax revenue due to Defendants' negligence;

327. For an award of punitive damages against each Defendant;

328. For expenses, costs, attorneys' fees, and interest thereon; and

329. For all other relief deemed just and proper by the Court.

Respectfully submitted this 3rd day of February, 2020.

THE STATE OF MONTANA

TIMOTHY C. FOX
Montana Attorney General
MATTHEW COCHENOUR
Acting Solicitor General
P.O. Box 201401
Helena, MT 59620-1401
mcochenour2@mt.gov
phone: (406) 444-2026

MARK W. MATTIOLI
Consumer Protection Chief
CHUCK R. MUNSON
Assistant Attorney General
Office of Consumer Protection
P.O. Box 200151
Helena, MT 59620-0151
mmattioli@mt.gov
phone: (406) 444-2026
fax: (406) 442-1894

WILLIAM A. ROSSBACH
Special Assistant Attorney General
Rossbach Law, PC
P.O. Box 8988
Missoula, MT 59807
bill@rossbachlaw.com
phone: (406) 543-5156
fax: (406) 728-8878

LINDA SINGER*
DAVID I. ACKERMAN*
Motley Rice LLC

401 9th Street NW, Suite 1001
Washington, DC 20004
lsinger@motleyrice.com
jnelson@motleyrice.com
phone: (202) 232-5504
fax: (202) 386-9622
* To be admitted *pro hac vice*

P. GRAHAM MAIDEN (MT Bar No. 45914760)
Motley Rice, LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
gmaiden@motleyrice.com
phone: (843) 216-9000
fax: (843) 216-9450

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in the above case on all issues so triable.

MARK W. MATTIOLI
Consumer Protection Chief