IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT IN ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. McKesson Corporation, and Cardinal Health, Inc., and AmerisourceBergen Drug Company. Defendants.	)	Case No. _____

COMPLAINT

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I. INTRODUCTION

1. This case arises from the worst human-made epidemic in modern medical history—the over-use, misuse, and abuse of opioids. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control ("CDC"), "I don't think we've ever seen anything like this. Certainly not in modern times." On February 14, 2017, Governor Bill Walker issued a declaration of disaster emergency, explaining that "the severity and magnitude of [the opioid] epidemic make it a condition of public health importance that is beyond the timely and effective response and recovery capability of local resources…."

2. Opioid overdoses, whether from prescription opioids or heroin, have become far too common. In 2011, Alaska saw 66 fatal opioid overdoses; by 2016, that number reached 96, adding up to 475 deaths over those six years. The number continues to rise; in 2017, one hundred people died in Alaska from opioid overdoses.

3. Beyond overdoses, Alaska hospitals have struggled to deal with other effects of the opioid epidemic. Doctors and administrators report dealing with patients who threaten violence or suicide if they are not given prescription opioids. One doctor described opioids as a daily part of practice from patients seeking refills, to patients with complications from injecting opioids, to patients in active withdrawal from opioids. Depending on the day, 15 to 30 of the patients in one emergency department will be there on issues related to opioids.

4. Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal"), and AmerisourceBergen Drug Corporation ("AmerisourceBergen") (collectively "Distributors" or "Defendants") supply opioids to Alaska. They 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 can provide 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 make their money on the spread between their buy and sell prices, as well as a fee as a percentage of sales.[1] They take advantage of their central location in the health care marketplace to further leverage their profits, selling data and services upstream to manufacturers and downstream to pharmacies.

5. Distributors have an obligation to ensure that they safely hold and distribute all of the prescription drugs for which they are responsible. That duty is nowhere more important than with narcotic controlled substances, like opioids. Because of the addictive nature of these drugs and the existence of a black market for their use, distributors have a long-standing duty under Alaska and federal law to ensure that the controlled substances they buy and sell, including opioids, are managed and monitored to ensure they reach only a legitimate market and are not diverted for illicit use.

6. Over a critical decade, as orders for opioids skyrocketed, Defendants failed to comply with the law, oversupplying opioids into Alaska and neglecting obvious red flags of diversion. [redacted]

[1] 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 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.

[redacted]

7. In response to enforcement actions and public attention Defendants finally ramped up their compliance efforts, but it was too little too late. The opioid epidemic was well underway. Having shipped opioids at alarming volumes and doses into Alaska for years and failed to report suspicious orders to law enforcement, they had enabled and failed to prevent the rising tide of opioid overuse, abuse, addiction, overdose, and death. For those who became addicted to or lost their lives or loved ones to opioids, there was no going back.

8. Defendants have always had the resources to comply with the law and to prevent the wholesale diversion of the opioids they sold. McKesson, with $199 billion in revenue in 2017, ranks six on the Fortune 500 list, just behind Apple and ExxonMobil; AmerisourceBergen and Cardinal are close behind at numbers 12 and 14 with revenues of $153 billion and $130 billion last year, respectively.

9. Defendants were not the only causes of the opioid epidemic that has gripped Alaska. It is undoubtedly true that prescriptions would not have been written or dispensed without the deceptive marketing that prompted doctors to prescribe opioids long-term for a host of chronic conditions for which opioids are not, and have never been, accepted as appropriate. But if distributors had honored their legal duties to monitor, report, and reject orders of opioids that were excessive and clearly suspicious, these pills would have never reached the patients who became addicted to them and died from them.

10. The overwhelming increase of opioids ordered by Alaska pharmacies, collectively and individually, put Defendants on notice that they were meeting more than a predictable and legitimate market demand. Rather than continuing to sell, ship, and profit from these highly

dangerous drugs, they had a duty to report and stop some of their supply. Had they done so, the opioid epidemic in Alaska—and its enormous human and financial toll—would not have been as grave.

11. In Alaska, the oversupply and diversion of opioids have increased the need for addiction treatment; imposed a greater burden on first responders, hospitals and other health care providers dealing with opioid demand, overdoses, and other opioid-related injuries; created a generation of children with profound social service needs, either displaced by their parents' addiction or struggling with addiction themselves; and expanded the demands on law enforcement addressing diversion or other opioid-related crimes, among others. While many of those harms cannot be undone or ever adequately compensated, the State takes this action to hold Defendants responsible for their violations of law, to abate the ongoing opioid epidemic, and to reimburse the State for the damages these companies imposed.

II. JURISDICTION AND VENUE

12. Jurisdiction over the subject matter of this cause of action is proper based upon AS 22.10.020, 09.58.015, and 45.50.501. The State seeks damages in excess of $100,000.

13. This Court has personal jurisdiction over Defendants because they regularly conduct business in Alaska and/or have the requisite minimum contacts with Alaska necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Alaska's long-arm statute, as codified in AS 09.05/015.

14. Venue is appropriate in the Third Judicial District at Anchorage pursuant to Rule 3 of the Alaska Rules of Civil Procedure, in that many of the unlawful acts committed by Defendants were committed in Anchorage.

15. The Attorney General has determined that pursuit of this action is in the public interest, as required by AS 45.50.501(a).

III. PARTIES

A. PLAINTIFF

The State of Alaska brings this action, by and through its Attorney General, Jahna Lindemuth, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant to her constitutional, statutory, and common law authority, including the authority granted to her by AS 44.23.020, and the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 et seq.

B. DEFENDANTS

Cardinal Health, Inc.

16. 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 U.S., with annual revenue of $130 billion in 2017. Through its various DEA registrant subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country and in Alaska. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio.

17. Cardinal, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of dangerous drugs in Alaska since at least 2003. Based on Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

McKesson Corporation

18. McKesson Corporation ("McKesson") is sixth on the list of Fortune 500 companies, with annual revenue of $199 billion in 2017. McKesson, through its various DEA

registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country and in Alaska. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

19. McKesson has been licensed as a wholesale distributor of dangerous drugs in Alaska since 1997 and operates a distribution center in Anchorage.

AmerisourceBergen

20. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is twelfth on the list of Fortune 500 companies, with an annual revenue of $153 billion in 2017. AmerisourceBergen, through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country and in Alaska. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

21. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in Alaska since 1997.

22. Together, Cardinal Health, McKesson, and AmerisourceBergen, known as the "Big Three," dominate more than 85% of the market share for the distribution of prescription opioids.

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

IV. FACTUAL ALLEGATIONS

24. Nationally, from 1999 through 2016, more than 350,000 people died from an overdose involving any opioid. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription

medications like OxyContin, Opana, Vicodin, Subsys, and Duragesic, and generics like oxycodone, hydrocodone, and fentanyl.

25. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to prescription opioids, turned to heroin when they could no longer access or afford prescription pills. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers, which closely resemble heroin. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

26. The opioid epidemic was precipitated by the pharmaceutical companies that manufacture, sell, and market prescription opioid painkillers. Through a widespread, deceptive marketing campaign, these pharmaceutical companies engineered a dramatic shift in how and when opioids are prescribed by doctors and used by patients. They relentlessly, but untruthfully, asserted that the risk of addiction was low when opioids were prescribed for pain, and overstated the benefits and trivialized the risk of the long-term use of opioids. (The State of Alaska separately sued Purdue Pharma, L.P., Purdue Pharma Inc. and The Purdue Frederick Company for their deceptive marketing of these drugs in *State of AK v. Purdue Pharma L.P., et al,* Case No. 3AN-17-09966CI, (Alaska Super. Ct. July 12, 2018)).

27. As a result of the pharmaceutical companies' marketing and Defendants' distribution, since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

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

28. Although the pharmaceutical companies created a vastly and dangerously larger market for opioids, Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified. Their failure to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties and worsened and failed to prevent the opioid epidemic in Alaska.

29. Together, Defendants were the three largest distributors to Alaska pharmacies, delivering [redacted] total grams of opioids distributed from 2006 to 2014.[2] That amounted to an average of [redacted] for every resident of Alaska, including children, each year.[3] The number of pills per person increased by almost [redacted][4]

30. [redacted].[5]

[2] The data on the grams of opioids distributed in Alaska is based on an analysis of data produced by the United States Drug Enforcement Agency ("DEA") for the years 2006 to 2014 for the State of Alaska on opioids, opiates, opium derivatives, opiate intermediates, and narcotics (herein referred to as "opioids").

[3] Alaska's population is approximately 740,000 residents. The number of pills per person takes into account Morphine Milligram Equivalents ("MMEs"). MMEs reflect the overall strength of opioids. MMEs make possible comparative analyses of drugs with different molecular bases such as oxycodone, hydrocodone, fentanyl, and hydromorphone.

[4] The summary of suspicious order reporting is based on the suspicious order reports provided by DEA to the Attorney General's Office.

[5] *Id.*

1. Defendants Have a Duty to Prevent Diversion and to Detect, Report, and Reject Suspicious Orders

31. Defendants are obligated to prevent diversion, to report suspicious orders and not to fill those orders unless due diligence disproves those suspicions.

32. 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 them is appropriately high.

33. Second, Defendants are prohibited under Alaska law from engaging in unfair and deceptive acts and practices in trade and commerce. AS 45.50.471 *et seq.* Defendants must not engage in conduct that injures consumers, offends established public policy, and is unethical, oppressive, or unscrupulous. In addition, Defendants may not engage in conduct having a tendency to mislead consumers. Alaska Statute 45.50.471(b)(11) and (12). *See State v. O'Neill Investigations, Inc.,* 609 P.2d 520 (Alaska 1980); *Kenai Chrysler Ctr., Inc. v. Denison*, 167 P.3d 1240 (Alaska 2007). By publicly promoting their compliance efforts and their efforts to prevent diversion, Defendants deceived the public by creating the false impression that they were carrying out their legal obligations and actively working to combat the opioid epidemic.

34. Third, Defendants are required under the Alaska Controlled Substances Act, AS §17.30 *et seq.*, ("ACSA") to monitor, detect, report, investigate, and refuse to fill suspicious orders. Distributors must be licensed by the Alaska Board of Pharmacy to distribute controlled substances in Alaska. The ACSA incorporates the requirement of the federal Controlled Substances Act, ("CSA"), 21 U.S.C. § 811 - 830, and implementing regulations. AS §17.30.020 (a).

35. Requirements under federal law, incorporated, as noted above, under Alaska law, are clear and exacting. The CSA, enacted in 1970, and its implementing regulations created a "closed system" of distribution; every entity that handles controlled substances is required to meet

specific record-keeping and distribution standards. As the Congressional Record reflects, "Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." 970 U.S.C.C.A.N. 4566. In enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

36. Under federal (and thus state) law, Distributors' operations must be "consistent with the public interest," 21 U.S.C. § 824(a)(4), and "public health and safety." 21 U.S.C. § 823(b). Specifically, as registrants, 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.[6] 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." *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").

[6] *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").

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. To comply with the 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)).

39. As the DEA explains, "[i]t is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature."[7] A customer's order data, and the data of other similar customers, provides detailed insight into the volume, frequency, dose, and type of

[7] "Know Your Customer" Policy, U.S. Dept. of Justice, Drug Enforcement Administration, Diversion Control Division; https://www.deadiversion.usdoj.gov/chem_prog/susp.htm.

controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances (such as benzodiazepines), which are not reported to DEA, but whose use with opioids can be a red flag of diversion.

40. Through presentations at industry conferences and on its website, DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. For example, DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,[8] which suggests that distributors examine:

- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of goods to its customers (e.g., over-the-counter drugs, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?

[8] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/; *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).

- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?

- What ratio will you be supplying compared to other suppliers?

- Does the pharmacy serve out of state customers?

- Does it serve pain clinics?

- Are there particular practitioners who constitute most of the prescriptions it fills and who are these practitioners

- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.

41. Thus, under both common law and state law, incorporating federal law, Defendants had both significant obligations to avoid diversion of opioids, and detailed guidance in assessing both their customers and their orders to meet these obligations.

2. Defendants Have at Hand the Information that Enables Them to Detect the Excessive Supply and Suspicious Orders of Opioids

42. Distributors' 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. This allows distributors, especially the Big Three, to know, down to the pharmacy and the type, number, and dose of each pill, the volume of opioid sales across Alaska and the country. Possession of this extensive information both equips and obligates distributors to identify potential diversion and suspicious orders of opioids.

43. In addition to their own data from shipping prescription drugs to customers, Defendants also have national, regional, state, and local prescriber-level data that allowed them to track the prescribing of opioids. They obtained prescription data from various companies that collect and sell such data, such as IQVIA (formerly IMS), Wolters Kluwer, and Verispan. 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).[9] This extensive information would have allowed Defendants to track and identify instances of overprescribing. 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.[10] The breadth and depth of the data available to Cardinal Health, in particular, was made clear in a 2001 news article describing Cardinal's joint venture with major pharmacy chain 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."[11] The venture, called ArcLight Systems LLC, would have had data from nearly 1 billion prescriptions.

44. Defendants' sales representatives are 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 regularly visit existing customers to maintain and expand the products and services they sell to them. They know which pharmacies are in less populated areas, have parking lots filled with out-of-state license plates and young and seemingly healthy patients filling prescriptions for opioids, or a high proportion of cash transactions, or do not offer non-prescription products—all reds flag of diversion.

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[9] 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).

[10] 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).

[11] *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.

45. 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, and AmerisourceBergen's Good Neighbor Pharmacy). For example, Defendants provide pharmacies sophisticated ordering systems and other database management support, as well as marketing programs and patient services.[12] 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."[13] Cardinal's subsidiary, Kinray, assists independent pharmacies in managing business operations, increasing market share, and improving their reimbursements.[14] Through its Good Neighbor Pharmacy program, AmerisourceBergen offers "expert business coaches" to provide "guidance on every aspect of independent pharmacy operations," pharmacy analytics through its InSite program, and contract and third-party reimbursement negotiation through Elevate Provider Network, its pharmacy services administration organization ("PSAO").[15]

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[12] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

[13] RelayHealth, *Corporate Overview*, *available through Internet Archive at* https://web.archive.org/web/20180106063929/http://www.relayhealth.com/about-us/corporate-overview.

[14] *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").

[15] AmerisourceBergen, *Business Growth and Expert Guidance: Pharmacy Solutions*, https://www.amerisourcebergen.com/abcnew/solutions-pharmacies/business-growth-and-expert-guidance

46. Defendants also have significant information on a pharmacy's total orders of opioids, beyond what each of them supply. Upon information and belief, based on interviews conducted by the Attorney General's Office, Defendants enter into exclusivity agreements and/or offer pricing incentives to pharmacies in return for committing to purchase a certain percentage or volume of drugs from the companies, which, along with the data sources above, would allow them to extrapolate total volume of opioids received by a pharmacy. Distributors can request, and are expected to review, a new pharmacy customer's dispensing data, which allows them to determine the amount and proportion of opioids provided by another distributor.[16] The DEA, as described in ¶¶38-40 clearly laid out know-your-customer expectations that would require distributors to obtain information regarding other suppliers, total orders of controlled substances, and market share.

47. The information available to Defendants is not limited to pharmacy orders. Defendants also have detailed information on prescribing, which they sell to manufacturers. Cardinal's manufacturer business services include pharmacy marketing communications, regulatory consulting and healthcare analytics, which offer provider insights through Cardinal's "unique relationships with specialty practices across the country."[17] Cardinal website states that it will "recruit physicians to participate in studies related to [a manufacturer's] drug" and "capture and analyze prescribing, dosing and other patient management patterns … from a particular

[16] In a hearing concerning before the House of Representatives' Energy and Commerce Subcommittee on Oversight and Investigations concerning the distribution of opioids, 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 sends out—not just those provided by that particular distributor. House of Representatives, Subcommittee of Oversight and Investigations, Committee on Energy and Commerce; *Combating the opioid epidemic: examining concerns about distribution and diversion* (May 8, 2018).

[17] Cardinal Health, *Provider Insights, available at* https://www.cardinalhealth.com/en/services/manufacturer/biopharmaceutical/real-world-evidence-and-insights/market-insights/provider-insights.html (last accessed Aug. 10, 2018).

practice." Defendants also contract with various manufacturers to advertise their opioids to pharmacies and to conduct their copayment assistance and "adherence" programs (reminders to patients to refill their opioid prescriptions), which gives them access to information on manufacturers' marketing strategies and messages and patients' use of opioids.

48. As a result of these multiple services, subsidiaries, and data sources, Defendants have a role in, and data providing insight into, virtually every juncture in the supply chain, from manufacturer to patient. They have information on ordering, prescribing, dispensing, and use of controlled and non-controlled substances. They also have insight into their market share and whether their pharmacy customers are purchasing prescription drugs from other distributors. These sources of information both enable, and obligate, them to do far more in detecting, reporting, and preventing diversion.

3. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

49. Defendants were well aware they had an important role to play in the closed system of opioid distribution, and also knew or should have known that their failure to comply with their obligations would have serious consequences. As registrants, they were responsible for understanding and complying with their legal obligations.

50. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are

uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[18]

51. 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, 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.

52. 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 [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."[19] 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, an "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail

[18] 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).
[19] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013).

level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions."[20]

53. Since 2007, the DEA has hosted at least five conferences that provided registrants, including, upon information and belief, Defendants, with updated information about diversion trends and their regulatory obligations.

54. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including Cardinal, McKesson, and AmerisourceBergen. 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." The letter warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[21]

55. In numerous enforcement actions, DEA also made clear a distributor's obligations in complying with the CSA and the consequences (both to the distributor and the public interest) in failing to carry out those obligations. On June 22, 2007, DEA Deputy Administrator Michele M. Leonhart revoked Southwood Pharmaceuticals, Inc.'s ("Southwood") Certificate of Registration with the DEA stating that "continued registration constituted an imminent danger to

[20] U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, https://www.deadiversion.usdoj.gov/arcos/index.html.

[21] 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.

public health."[22] Between November 2005 and August 2006, Southwood's sales to pharmacies of hydrocodone products "increased from approximately 7,000 dosage units per month to approximately 3,000,000 dosage units per month."[23] In defining suspicious orders, the Administrator applied the standards in the federal regulations—"orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency."[24]

56. The Administrator further concluded that Southwood failed to create an effective system for detecting and reporting suspicious orders. Among other things, Southwood neglected to contact its customers to determine if they had increased their purchases for a legitimate reason; did not require that its due diligence questionnaire was answered completely or even submitted at all; and did not conduct further investigation when a pharmacy's answers on the questionnaire were inconsistent with a site visit or indicated suspicious activity. The Administrator also held that Southwood's filing of ARCOS reports did not excuse its failure to report suspicious orders, noting that ARCOS provides DEA with information regarding trends in the diversion of controlled substances and does not need to be submitted until 15 days after the reporting period—after a suspicious order already has been filled. In contrast, the purpose of the suspicious orders reporting requirement "exists to provide investigators in the field with information regarding potential illegal activity in an expeditious manner."[25]

57. DEA sent a second letter to distributors, including Cardinal, McKesson, and AmerisourceBergen on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they share, and must each abide by, statutory and regulatory

[22] *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007).
[23] *Id.*
[24] 21 C.F.R. § 1301.74(b).
[25] *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007).

duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[26] 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). Finally, the letter referenced the Revocation of Registration issued in *Southwood* for its discussion of criteria to use when determining whether an order is suspicious.

58. In October 2008, the DEA issued an Order to Show Cause which alleged that Masters Pharmaceuticals had "failed to maintain effective controls against diversion" and shipped suspicious orders of hydrocodone without performing adequate due diligence. Masters subsequently settled the charges, agreeing to create a compliance system, the "Suspicious Order Monitoring System" ("SOMS"). The system consisted of an employee protocol and a computer program that was designed to identify orders of an unusual size, frequency, or pattern. For each of the controlled substances sold, the computer program determined a customer's "Controlled Substance Limit" which was the highest monthly total out of the preceding six months. If a customer exceeded its limit in a 30-day period, the computer program would hold the customer's most recent order so that it could be reviewed by Masters' staff. Among other thing, the staff were required to call the customer to request an explanation and verify that the information the customer provided was correct. If Masters' staff deemed the order non-suspicious, it would be shipped, otherwise it would be reported to the DEA. On August 9, 2013, the DEA issued a second order to

[26] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office 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-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

show cause alleging that Masters consistently ignored and/or failed to implement its controlled substance policies and failed to comply with the reporting requirement.

59. The DEA Administrator found that not only had Masters' staff violated the company's reporting protocol, but that Masters' reporting policy itself was flawed. Staff deleted held orders or reduced their size so that they would no longer trigger a hold and then proceeded to fill them. They also failed to verify a pharmacy's explanation for exceeding its order limit or sometimes did not contact them at all. The enforcement action was appealed to the Court of Appeals to the D.C. Circuit, which upheld the DEA's findings and affirmed that, before shipping an order identified as suspicious, a distributor must dispel any suspicions based on "actually undertak[ing] [an] investigation" of the order that "must dispel all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances." *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 at 222-23 (D.C. Cir. 2017).

60. Between 2008 and 2012, DEA issued final decisions against distributors in 178 registrant actions and the Office of Administrative Law Judges recommended decisions in 117 actions, all for failures to report suspicious orders. Each of these published actions reiterated to Defendants their legal obligations to prevent diversion.

4. <u>Defendants Failed to Meet Their Legal Duties in Shipping Opioids in Alaska</u>

61. Despite the law and frequent reminders of their compliance obligations, Defendants funneled far more opioids into Alaska than could have been expected to serve legitimate use, ignored other red flags of diversion, failed to investigate their customers and to detect suspicious orders, and chose not report or reject even those suspicious orders that were, or should have been, evident.

a. Opioid Prescription Trends in Alaska

62. Given the volume and pattern of opioids distributed in Alaska, 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.

63. According to data from ARCOS database, between 2006 and 2014, approximately [redacted] opioids were distributed in Alaska. As noted above, that is the equivalent, at [redacted]. Given Alaska's population of just over 700,000 residents, that is an average of [redacted] for every resident of Alaska, including children.[27] The number of pills per person increased by almost [redacted].

[redacted]

64. This volume of opioids [redacted] indicate that distributors were dramatically oversupplying opioids into the state and raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

65. [redacted]

[27] The pill data was calculated taking into account Morphine Milligram Equivalents ("MMEs").

66. [redacted]

67. [redacted]

b. Defendants Failed to Report Orders They Should Have Flagged as Suspicious.

68. The information on the supply of opioids distributed in Alaska, along with the information known only to Defendants, including their analysis of individual order data and other data sources described above, would have alerted them to potentially suspicious orders of opioids in Alaska.

69. For example, [redacted]

70. Cardinal ignored similar red flags in its own orders in Alaska. [redacted]

71. [redacted]

[redacted]

72. Not only did McKesson, Cardinal and AmerisourceBergen ignore the red flags discussed above—large increases in the distribution of opioids year-to-year to a single pharmacy and opioid distribution that was excessive for the size of the community—they also disregarded a third red flag by distributing disproportionately large amounts of opioids to certain pharmacies as compared to other pharmacies in the same geographical area. For example, [redacted]

73. Further, multiple prescribers in Alaska were subject to disciplinary action for conduct relating to drug diversion. Upon information and belief, these prescribers, and the pharmacies at which their patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in a particular area, but specific instances of diversion.

74. In 2016, the Alaska State Medical Board suspended the license of Dr. Ahmad, an Arkansas anesthesiologist, who would travel to Anchorage a few days a month and prescribe vast quantities of painkillers at his one-man clinic.[28] The doctor prescribed more than 700 prescriptions

[28] Michelle Theriault Boots, Alaska News, *Medical board suspends license of doctor accused of running painkiller 'pill mill' clinic in Anchorage*, May 24, 2016, https://www.adn.com/alaska-

for controlled substances in five months—all issued during the few days he was in Alaska each month. According to the State's accusations against Dr. Ahmad: "Not only did every patient receive a prescription for controlled substances, they received high doses of opioids and frequently in combination with benzodiazepines, which increase the risk of overdose death and abuse."[29]

75. [redacted]

76. As laid out above, Defendants would have had access, [redacted], to data that would have revealed this suspicious prescribing. Moreover, the patients of these doctors would have filled prescriptions at pharmacies served by Cardinal, McKesson and AmerisourceBergen whose order and dispensing data and foot traffic should have

news/2016/05/23/medical-board-suspends-license-of-doctor-accused-of-running-painkiller-pill-mill-clinic-in-anchorage/.

[29] *Id.*

alerted them to potential diversion. Yet Defendants did not report their suspicious prescriptions to federal or state authorities.

77. From 2007 to 2014, [redacted] suspicious opioid orders in Alaska were reported to the DEA.[30] [redacted][31] These dramatic up-turns seem unrelated to any change in Defendants' volume or composition of opioid distribution—they reflect a change in diligence, not in suspicious orders, and provide some measure for the number of orders that should have been reported in earlier years.

78. In sum, all three Defendants disregarded their obligations under Alaska law to report suspicious orders and prevent diversion. Instead, they grossly over-supplied opioids into the State and consistently failed to report or suspend illicit orders, deepening the toll of opioid abuse, addiction, and death in Alaska.

[30] The DEA did not include records for suspicious orders for 2006 in the produced data.

[31] Prior to 2012 and 2013, Cardinal, McKesson and AmerisourceBergen reported excessive orders, which McKesson labeled "suspicious," to the DEA. These often voluminous reports did not indicate whether and what made these orders suspicious, and contained orders, for example, that were larger than usual because of distributors' own marketing promotions. DEA warned distributors that these reports were insufficient to comply with their suspicious order reporting obligations.

5. Defendants' Repeated Failures to Prevent Diversion Across the Country Confirm their Failures in Alaska

79. Over and over again, Defendants have been sanctioned for their failures to comply with the CSA, and have failed, even then, to bring their conduct in line with their legal obligations. Compliance failures that were demonstrated and sanctioned across the country also hobbled McKesson's compliance in Alaska and caused the improper supply of opioids in the state.

a. McKesson

80. [redacted]

81. In September 2005, one month after starting its Distributor Initiative, DEA officials met with McKesson to alert the company to its excessive sales to pharmacies filling illegal online prescriptions.

82. Nonetheless, on August 4, 2006, and November 1, 2007, the DEA issued orders to show cause for failure to maintain effective controls to prevent diversion against McKesson's distribution centers in Lakeland, Florida and Landover, Maryland.

83. In response to the 2007 order, McKesson developed a Lifestyle Drug Monitoring Program ("LDMP"). As part of the LDMP, McKesson monitored pharmacy orders of certain controlled substances, including oxycodone, hydrocodone and alprazolam, using technology that would enable each McKesson Distribution Center to generate automated reports to identify customers that met or exceeded a monthly threshold for their orders.

84. On April 30, 2008, McKesson entered into an agreement to settle allegations made by six U.S. Attorneys that the company failed to report suspicious orders of two Lifestyle drugs—hydrocodone and alprazolam (the "2008 DOJ Agreement"). The 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."[32]

85. In connection with the DOJ Agreement, McKesson also entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

86. McKesson's Controlled Substance Monitoring Program ("CSMP") was a modest improvement to the LDMP and applied to nine opioids described as "Highly Diverted Controlled Substances," including oxycodone, hydrocodone, hydromorphone, methadone, morphine, tramadol, and oxymorphone. The CSMP was established as a floor, but not a ceiling, for McKesson's compliance efforts; in the Compliance Addendum, McKesson acknowledged that the

[32] 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.

CSMP "must be and remain effective in identifying and reporting suspicious orders, as required by the CSA and the implementing regulations."

87. On January 5, 2017, despite having notice and nearly nine years to improve its compliance since the 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. The AMA noted that McKesson, *inter alia*, continued to fail to identify and report suspicious orders McKesson admitted that, from January 1, 2009 through January 17, 2017, at 12 of its distribution facilities, 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."[33] In Colorado, McKesson processed more than 1.6 million orders of controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious, all connected to one instance related to a recently terminated customer.[34]

88. 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 . . ." 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."[35]

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[33] *Id.* at 5.

[34] U.S. DOJ Office of Public Affairs, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (emphasis added).

[35] 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-

89. McKesson was "neither rehabilitated nor deterred" by the 2008 settlement, as a DEA official working on the case noted.[36] 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. 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."[37]

90. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued breach of its duties—as much as a billion dollars—and delicensing of certain facilities. 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."[38]

91. On *60 Minutes*, former DEA Assistant Special Agent David Schiller described how McKesson blatantly ignored the CSA requirement to report suspicious orders:

> DAVID SCHILLER: If they woulda stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day

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fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.bb606509a764

[36] *Id.*

[37] *Id.*

[38] *Id.*

> that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.
>
> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[39]

92. Schiller concluded: "They're killing people. … This is all for financial gain."

b. Cardinal

93. As with McKesson, the DEA repeatedly took action against Cardinal for failing to report suspicious orders and prevent diversion, demonstrating both Cardinal's awareness of its obligations and its failure to meet them. These actions include:

a. 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;

b. 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;

c. 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;

d. 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;

e. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The Agreement also referenced allegations by DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at

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

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.

f. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.

94. In response to the DEA's Order to Show Cause and Immediate Suspension Order of Cardinal's Lakeland facility, Cardinal filed a complaint and motion for a temporary restraining order in the United States District Court for the District of Columbia. Although the Court initially granted Cardinal's motion for a temporary restraining order, it ultimately upheld the DEA's Immediate Suspension Order ("ISO"). In denying Cardinal's motion for a preliminary injunction of the ISO, the Court reasoned:

> the factors considered by [the DEA]—including (1) the rampant pharmaceutical drug problem in Florida, (2) Cardinal Lakeland's history of inadequate anti-diversion controls, (3) the large and increasing amounts of oxycodone distributed by Cardinal Lakeland to the four pharmacies from 2009 to 2011, (4) the sizeable amounts of oxycodone distributed to 25 other pharmacies in 2011 that exceeded state and national averages, and (5) the evidence of Cardinal Lakeland's failure to monitor its chain pharmacy customers, despite clear warning signs of inadequate anti-diversion controls at those pharmacies—provided a reasonable basis for [the DEA's] conclusion that Cardinal Lakeland's continued registration posed an "imminent danger to the public health or safety" under § 824(d).

Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 225 (D.D.C. 2012).

95. On December 23, 2016, Cardinal Health 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, to DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between 2009 and 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

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

96. In January 2017, Cardinal agreed to pay $20 million to the state of West Virginia to settle allegations from a 2012 lawsuit that Cardinal was reckless and negligent in its distribution of an excessive number of opioids into the state.

97. In a hearing before the House of Representatives' Energy and Commerce Subcommittee on Oversight and Investigations on May 8, 2018, the Chairman of Miami-Luken, Inc., another distributor, was the only one who acknowledged that his company failed to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite frequent prior enforcement actions and penalties against each of their companies, neither McKesson, Cardinal nor AmerisourceBergen admitted any deficiencies in their compliance. Yet all three executives' testimony confirmed gaps and breakdowns in past and current practices that would affect their conduct in Alaska.

98. For example, Cardinal's former Executive Chairman, George Barrett, denied that **"**volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Cardinal thus took the position that it can ship disproportionate, facially unreasonable volumes of opioids into jurisdictions without triggering any red flag or any obligation to monitor, report, or stop sales that could not be tied to a legitimate market. And despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused

on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Even when a Cardinal employee flagged an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds. While Cardinal has cited blind spots due to its lack of complete data on opioids supplied to pharmacies by other distributors, Cardinal 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.

99. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of a single two-page document. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company shipped more than 36 times the monthly threshold to one pharmacy—9,500 pills *per day*.

c. AmerisourceBergen

100. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, one of its Florida distribution centers, alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its distribution center's DEA registration.

101. In 2012, the State of West Virginia sued AmerisourceBergen, along with other distributors, for numerous causes of action, including violations of the state CSA, consumer protection, and antitrust laws and for the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health,

together shipped 423 million opioids to West Virginia between 2007 and 2012 (with a population of approximately 1.8 million residents). AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills into the state during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million.

6. Defendants' Current Standard Operating Procedures are Inadequate to Track and Report Suspicious Orders in Alaska

102. Since 1970, and even now, Defendants have failed to put in place adequate mechanisms to prevent diversion, relying on customer thresholds as the principal tool for identifying problematic conduct. While Defendants have updated their compliance programs and adopted new technology to detect and report suspicious orders, their current policies remain inadequate to track and report suspicious orders of opioids and prevent diversion.

103. That is particularly true as each Defendants' anti-diversion efforts turn upon setting and monitoring thresholds for customers' orders of specific controlled substances, including opioids. The concept of a threshold appears nowhere in the CSA, its implementing regulations, or Alaska law.

104. In its 2007 letter to Defendants (*see* ¶ 36), the DEA reiterated that suspicious orders included "orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency," and emphasized that "[r]egistrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."[40] The DEA also expressly explained that "a system that identifies orders as suspicious only if the total amount of a

[40] 2007 Rannazzisi Letter

controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient." [41]

105. Thus, monitoring thresholds is an adequate mechanism only to the extent that thresholds are effective in preventing diversion. For the reasons laid out below, they are not.

a. McKesson's use of order thresholds is not a sufficient compliance system

106. In its April 24, 2018 letter to the U.S. House of Representatives Committee on Energy and Commerce, 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 continues: "McKesson's model analyzes each 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 . . . "

107. 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, [redacted]

[41] *Id.*

[redacted]

108. 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. [redacted]

[redacted]

109. 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 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. It does not examine overdose or hospitalization rates to determine if those measures signal potential abuse or diversion, and does not focus its compliance attention on "hot spots" known to have greater levels of diversion of abuse; every jurisdiction subject to same level of compliance attention.

[42] Base code is a number the DEA assigns to a drug based on that drug's molecular structure.

110. 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.

111. Even the process for evaluating new customers to determine whether to supply them with controlled substances is flawed: questionnaires used to assess potential new pharmacy customers are filled out by the pharmacy or by sales representatives (who, have financial incentives based on new customers and, as explained below, opioid sales). [redacted]

b. Orders that exceeded thresholds merely prompted threshold increases

112. McKesson's threshold change request process creates additional incentives to inflate thresholds. Customers who have a legitimate reason to purchase additional controlled substances (e.g., the closure of an alternate pharmacy or the opening or a new nearby doctor's office) can seek to increase their threshold level.

113. [redacted]

[redacted]

114. [redacted]

115. [redacted]

[43] Independent and small to medium chain retail pharmacies.

[redacted]

116. [redacted]

117. By increasing the thresholds for opioids that were known to be a significant source of addiction and diversion throughout the county, even while decreasing supply ceilings for other drugs, McKesson added fuel to the fire.

118. [redacted]

c. McKesson has excluded chain pharmacies from its compliance efforts

119. In 2012, in *Cardinal Health v. Holder*, a federal district court upheld an enforcement action against Cardinal based, in part, on its failure to monitor, report, and reject suspicious orders to chain pharmacies. [redacted] In Alaska, [redacted], the loophole largely swallows the rule.

120. [redacted]

121. 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, [redacted]

d. Cardinal's exclusive reliance on thresholds to detect suspicious orders is similarly inadequate

122. Prior to 2007, when the DEA issued Immediate Suspension Orders against Cardinal, the company's anti-diversion measures focused mainly on price diversion, the practice of non-retail pharmacies purchasing pharmaceuticals from a wholesaler at contract or discount prices, and then reselling the pharmaceuticals at higher prices on the open market. Cardinal had no electronic system for analyzing orders.

123. In January 2008, Cardinal adopted its first standard operating procedures ("SOPs") for suspicious order monitoring. The Board of Directors of Cardinal Health described its 2008 system for setting thresholds in a 2013 investigative report:

> When the electronic system was created in 2008, Cardinal set thresholds by identifying a baseline drug quantity for one month, using the mean volume for each drug family for each class of trade. The customers were segmented into four main classes of trade: retail independents, chains, hospitals, and long-term care. The stores were segmented by size (small, medium, and large) and thresholds were set for each size category using multiples of 3, 5, or 8, depending on the drug family, based in part on multiples that the DEA had previously provided for certain combination products containing those controlled substances. …
>
> If a new retail independent pharmacy provided ordering and dispensing information, a pharmacist would create a customized threshold for the pharmacy, taking into account the size and location of the pharmacy, its history of dispensing, the normal wholesale package size of drugs ordered, the number of different strengths within a given family of controlled substances, the availability of generic drugs for the controlled substances, and whether the pharmacy used automated dispensing. …
> If a new retail independent pharmacy did not provide dispensing data, the pharmacy would receive the mid-level threshold limit. …
>
> Thresholds for new chain stores were based on a standard threshold for the entire chain, because chain stores usually have a known ordering pattern for the majority of stores. The Company also took into account the chain's anti-diversion measures in setting thresholds.

124. Although Cardinal's SOPs set thresholds based on the type or size of a pharmacy, as with McKesson, they wholly failed to account for other important facts, for example, the population of area that a particular pharmacy was serving, which would provide information about the expected legitimate prescription needs.

125. [redacted]

126. [redacted]

127. 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 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. After 2010, the Highlight Reports were replaced by a program called "Winwatcher," which allowed Cardinal salespeople to see what percentage of a customer's monthly threshold amount had been ordered at any given time and directed salespeople to investigate when a threshold was exceeded.

128. Yet, even if a salesperson investigated and identified further signs of diversion, whether or not Cardinal continued to ship to a pharmacy was a purely subjective decision. During the Congressional hearing, Cardinal's Chairman George 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, Mr. 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."[44]

129. According to Mr. Barrett, Cardinal's current monitoring systems are now are entirely "data driven," explaining: "I think the subjectivity of judgment of whether a pharmacy is legitimate or not legitimate today is really not the question. 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 cash-only business, out-of-state patients—that are both known to Cardinal and essential to detect diversion of prescription opioids.

130. Although Mr. Barrett also testified that, beginning in 2012, Cardinal implemented stronger compliance systems, a complaint was filed by the California Board of Pharmacy against Cardinal's Valencia, California facility for shipping suspicious orders from 2012 to 2015. In addition to sharp increases of controlled substances, the shipments involved orders of significant amounts of the highest available strength of drug versus lower strengths, which, the Congressional Committee noted, was a red flag for illegitimate dispensing. Mr. Barrett explained that if the threshold was not hit, Cardinal's system would not detect this red flag.

131. Thus, as with McKesson, Cardinal's compliance system was fundamentally flawed in that it: (a) was limited to an evaluation of thresholds which, for the reasons described above, does not identify actually 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.

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

132. Additionally, as a result of its flawed system, Cardinal routinely failed to properly identify and stop suspicious orders in Alaska, and, like McKesson, Cardinal shipped orders shortly after a transaction was reported to the DEA as suspicious. For example, [redacted]

e. AmerisourceBergen's "Order Monitoring Program" failed to properly identify suspicious orders and to prevent the shipment of such orders.

133. [redacted]

134. [redacted]

135. [redacted]

[redacted]

136. [redacted]

137. [redacted]

[45] Item families group opioids with the same molecules (e.g., all oxycodone or hydrocodone products).

[redacted]

138. [redacted]

139. Furthermore, [redacted]

140. [redacted]

[redacted]

141. Further, as discussed above with respect to both Cardinal and McKesson's monitoring systems, order thresholds alone are an inadequate means of monitoring for suspicious orders. By focusing largely on a customer's established threshold rather than other additional factors, AmerisourceBergen was disregarding possible suspicious orders that did not exceed a particular client's threshold. Moreover, the OMP guidelines did not require reviewing a customer's thresholds to ensure that such thresholds were appropriate.

142. In 2012, AmerisourceBergen introduced additional changes to its OMP. [redacted]

143. [redacted]

[46] National Drug Code is a unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States.

144. [redacted]

145. [redacted] Thus, even as AmerisourceBergen described its updated policies as "more systemic and less arbitrary," it nevertheless allowed its employees to continue making subjective judgment calls.

146. In practice, AmerisourceBergen's 2012 policies nevertheless failed to properly monitor for and prevent diversion. For example, according to a complaint filed with the California Board of Pharmacy, from 2012 to 2013, AmerisourceBergen failed to stop shipping controlled substance orders for a pharmacy that had appeared on AmerisourceBergen's Compliance Manager's "over threshold report" several times. Nor did AmerisourceBergen notify the DEA as to this suspicious order.[47]

147. Moreover, according to a recent Congressional investigation led by Sen. McCaskill, between 2012 and 2017, Distributors McKesson and AmerisourceBergen shipped nearly identical volumes of opioids to Missouri (roughly 650 million doses each), yet, whereas McKesson flagged 16,714 orders as suspicious during this time, AmerisourceBergen flagged only 224. As discussed above, the same trend is true in Alaska, where AmerisourceBergen reported only [redacted] transactions as suspicious from 2009 to 2012.

[47] *In the Matter of the Accusation Against AmerisourceBergen Drug Co., et* al¸ Case No. 4982, (October 4, 2014) *available at* https://www.pharmacy.ca.gov/enforcement/accusations/ac134982.pdf

148. [redacted] In sum, despite several updates since the OMP was instituted in 2005, AmerisourceBergen's compliance system also failed to take into account requisite measures of potential diversion and, when compared to the number of suspicious orders flagged during the same time periods by Cardinal and McKesson, AmerisourceBergen's monitoring program was markedly less effective.

7. Defendants Had Financial Incentives to Distribute Ever Higher Volumes of Opioids, and to Refrain from Reporting and Declining to Fill Suspicious Orders

149. 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 per pill to distributors. Decreased cost per pill, in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, increased sales volumes result in increased profits.

150. Upon information and belief, Defendants also rewarded their sales representatives for increased sales, including the sales of opioids. [redacted]

[redacted]

8. To Protect their Profits, Defendants Lobbied Against Restrictions on Opioid Use and DEA Enforcement

151. Defendants worked behind the scenes, through the Pain Care Forum (as members and through their trade association, HDA), a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, to shape federal and state policies regarding the use of prescription opioids for more than a decade. 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.

152. For example, in June 2006, the Pain Care Forum organized a Capitol Hill briefing on "The Epidemic of Pain in America." Briefing materials included statements such as: "Appropriate use of opioid medications like oxycodone is safe and effective and unlikely to cause addiction in people who are under the care of a doctor and who have no history of substance abuse." Those who attended the briefing were asked to support a bill from then-Congressman Mike Rogers that called for the Institute of Medicine to develop a comprehensive report on pain in America. By focusing on the extent of untreated pain, PCF, on information and belief, intended—and succeeded—in pressing for the greater availability of opioids to treat that pain. Parts of the bill, rewritten by PCF, eventually passed with the 2010 Affordable Care Act.

153. In April 2016, several members of Congress aligned with the major drug distributors 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 John J. Mulrooney II. It is now "all but logically impossible" for the DEA to stop suspicious narcotic shipments from companies.[48] "The drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before," said former DEA agent Joseph T. 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."[49]

9. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

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

155. 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. We maintain 'know your customer' policies and procedures to validate that products we ship are sold in accordance with legal and contract requirements and are received by customers for their legitimate use."[50] Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block

[48] 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.
[49] *Id.*
[50] 2009 Cardinal Health, *Standards of Business Conduct*, at 30.

and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."

156. 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."[51] 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." 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."[52]

157. 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."[53] 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."[54]

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

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[51] Cardinal Health Proxy, Form 14A at 7, filed Oct. 23, 2017.
[52] Cardinal Health Quarterly Earning Call Transcript at 4, dated Nov. 6, 2017.
[53] 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.
[54] McKesson's website, About McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program.

> 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.[55]

159. 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 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.[56]

160. 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.[57]

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[55] *Id.*

[56] *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

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

161. McKesson also publicly claims that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

162. Similarly, AmerisourceBergen's website touts the company's order monitoring program as having "sophisticated technology that tests every controlled substance order against established governing criteria. Orders exceeding those criteria are redirected to experienced diversion control personnel for further analysis and possible cancellation."[58] AmerisourceBergen further contends that it performs "extensive due diligence on customers who intend to purchase controlled substances from us and vetting discovered information through a best-in-class diversion control team of internal and external experts before granting them permission to purchase." [59]

163. 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 was in compliance with those obligations.

B. The Devastating Effects of the Opioid Crisis in Alaska

164. While manufacturers overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use, Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into Alaska that they could only have been delivering a significant portion of those opioids for diversion and illicit use. The disproportionate

58

AmerisourceBergen's website, Fighting the Opioid Epidemic, Ensuring Sage and Secure Drug Distribution, https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.

59 *Id.* (AmerisourceBergen's website, Fighting the Opioid Epidemic)

volume of opioids that flooded into Alaska as a result of Defendants' wrongful conduct has devastated the state.

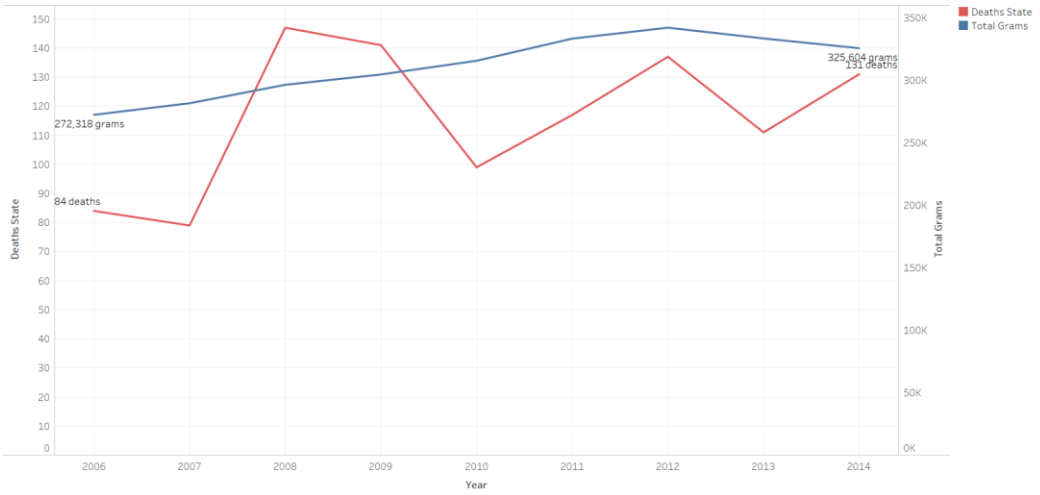
165. Alaska's Statewide Drug Enforcement Unit ("SDEU") has encountered a significant prescription medication diversion. Between 2015 and 2016 the number of opioid-based prescription drug dosage units seized by SDEU increased by 96% from 2,934 in 2015 to 5,750 in 2016 and OxyContin/oxycodone dosage units seized increased 1,685%, from 255 in 2015 to 4,552 in 2016.

166. 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 great, and 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 Alaska.

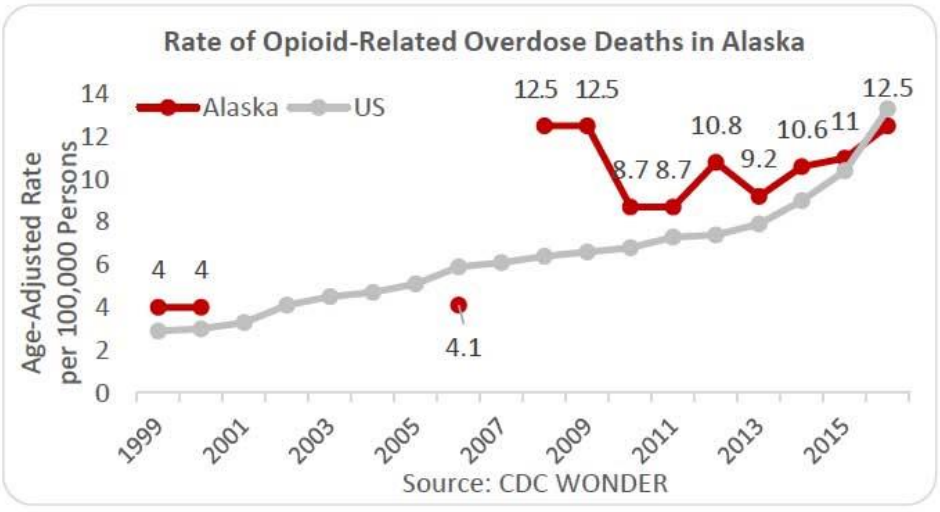
167. As the total grams of opioids shipped to Alaska increased from 2006 to 2014, so did the opioid-related deaths. Deaths related to opioids increased more than one-and-a-half times from 84 in 2006 to 131 in 2014. The chart below illustrates the correlation between the distribution of opioids and fatalities from opioids, recognizing that death is a lagging indicator of opioid use.

Opioid-Related Deaths Compared to Total Grams Over Time
(Alaska 2006 – 2014)[60]

[60] State-level data on deaths: the Centers for Disease Control and Prevention (CDC), CDC WONDER Online Database, http://wonder.cdc.gov/mcd-icd10.html. For the relevant ICD-10 codes on opioid-related deaths: CDC "Guide to ICD-9-CM and ICD-10 Codes Related to Poisoning and Pain" https://www.cdc.gov/drugoverdose/pdf/pdo_guide_to_icd-9-cm_and_icd-10_codes-a.pdf.



168. Alaska is on par with the national rate of opioid-related overdose deaths for 2016 and above the national rate for the preceding eight years. There were 94 opioid-related overdose deaths in Alaska in 2016, a rate of 12.5 deaths per 100,000 persons. From 2006 through 2016, the number of opioid-related deaths in Alaska tripled, though incomplete reporting likely understates the number of lives lost.



169. Research from the American Action Forum shows that as authorities went after pill mills and rogue doctors, sales of heroin and powerful synthetic opioids such as fentanyl filled the void. Because heroin is cheaper than prescription painkillers, many prescription opioid

addicts migrate to heroin. An individual who abuses opioid pain medication is 40 times more likely to develop a heroin addiction. According to one emergency department doctor, every one of her patients who abuses heroin began with prescription opioids—theirs or someone else's. From 2009 to 2015, the number of heroin-associated deaths in Alaska more than quadrupled.

170. A recent, even more sinister 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, has made its way into Alaska communities. Patients who traveled from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. Fentanyl-related overdoses now far exceed those involving heroin alone. In Alaska, the rise in fentanyl-related deaths has been steep with 5 deaths in 2016 and 28 fentanyl-specific deaths in 2017. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. And fentanyl abuse is often a game of Russian roulette, with users not knowing what mixture of fentanyl and heroin they are taking.

171. Overdose deaths are only one consequence of the proliferation of opioid use. 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. Between 2016 and 2017, hospital visits in Alaska due to opioid overdoses cost more than $23 million. There were 375 opioid overdose emergency department visits between July 1, 2017 and June 30, 2018. In a similar one-year period, from June 1, 2017 and May 31, 2018, Emergency Medical Services and law enforcement administered 550 doses of Narcan and Project Hope, a state-wide program to get Narcan into the hands of heroin users, distributed 7,082 kits in Alaska.

172. As communities have worked to save lives, the opioid epidemic has continued to outpace their efforts. According to the National Survey on Drug Use and Health, an estimated 60,128 Alaskan adults, 11.5% of the state's population, need substance use disorder treatment. In 2016, Alaska funded programs provided substance use disorder treatment to 7,808 people. Yet, 88.2% of people in Alaska suffering from drug dependence or abuse go untreated.

173. Diseases connected to injecting drugs, particularly hepatitis C, are another side effect of opioid and heroin addiction. According to Dr. Jay Butler, Alaska's Chief Medical Officer and Division of Public Health Director, "[w]e talk mostly about opioid overdose deaths, but there's a lot more that happens related to opioid use than just deaths . . . The most concerning trend that we see is an increasing number of diagnoses [of hepatitis C in people] age 18 to 29."[61] While there are new direct-acting antiviral drugs to treat hepatitis C, the cost of treatment, approximately $85,000 to $94,500 for two common medications, puts an enormous burden on the State's Medicaid program. In 2015, Alaska's Medicaid program spent $5.9 million on hepatitis C treatments, according to Erin Narus, the lead pharmacist for the state's Medicaid program. The next year, that more than doubled to $13.6 million. The McDowell Group, a research and consulting firm in Alaska, calculated that treating just the estimated 1,009 people in Alaska infected with hepatitis C from injecting drugs in 2015 would cost $90 million.

174. Perhaps the most profound effect of the opioid crisis has been on children and teenagers. Across the country there is a significant increase in children being abused, neglected, and eventually separated from their parents due to opioid addiction. Alaska is no exception. From 2012 to 2016, the number of children in foster care in Alaska increased from 1,860 to

[61] Zachariah Hughes, KTOO Public Media, *Wave of addiction costs is hitting Alaska's health care system*, June 29, 2017, https://www.ktoo.org/2017/06/29/wave-addiction-costs-hitting-alaskas-healthcare-system/.

2,802, more than 50%—five times the national rate. In 48% of Alaska's foster care placements, parental substance use was a factor. Grandparents have also been caring for children impacted by the opioid epidemic.

175. According to the Centers for Disease Control, from 2009 to 2015, while alcohol and marijuana use among Alaska youths declined, prescription drug use[62] remained stable. A survey taken by the Alaska Youth Risk Behavior Surveillance of high school students ages 14 to 18, determined that prescription drugs are the most frequently used drug category after alcohol and marijuana. More youth reported current prescription drug use than reported using cocaine, heroin, or methamphetamine. According to data from the National Survey on Drug Use and Health, one-third of all new prescription drug users in the past year were youth between the ages of 12 and 17.

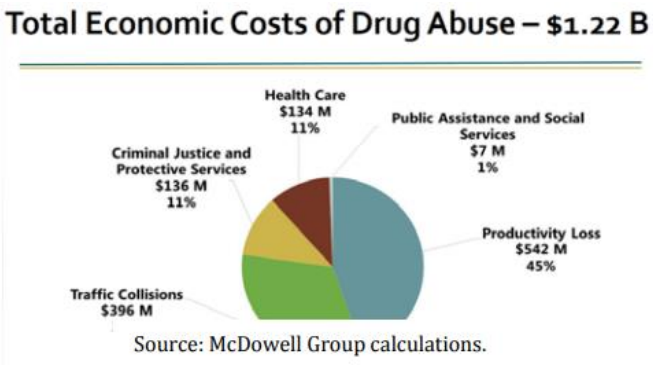
176. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug 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 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.

[62] Prescription drug use in this study is defined as the non-medical use of prescription drugs.

177. A State of Alaska Epidemiology study of births between 2004 through 2015, found that there was a 566% increase in babies diagnosed with NAS during that time period, from 15 in 2004 to 100 in 2015—541 infants in total over the twelve-year period. According to an Alaskan maternal and child health epidemiologist and study author Abigail Newby-Kew, the study only looks at Medicaid-eligible births because that's the most complete, long-term data set available, therefore these numbers do not represent the entire population. Moreover, because of difficulties in identifying symptoms, or delays in manifesting them, additional babies may not have been included in the statistics.

178. From 2014 to 2015, 97 babies admitted to Providence Alaska Medical Center's Neonatal Intensive Care Unit ("NICU") had NAS. Dr. Mary-Alice Johnson, the NICU medical director at Providence, stated: "Everybody is concerned about the fact that we're seeing more moms exposed and therefore more babies suffering from neonatal abstinence syndrome."

179. The costs of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. The McDowell Group, a research and consulting firm in Alaska, estimated that the economic cost of substance abuse and addiction in Alaska amounted to $1.22 billion in 2015 alone. This estimate includes costs related to loss of productivity, traffic collisions, criminal justice and protective services, healthcare, public assistance and social services.



C. Facts Pertaining to Punitive Damages

180. As set forth above, Cardinal, McKesson and AmerisourceBergen acted deliberately to increase sales of, and profits from, opioid drugs. Moreover, Defendants knew that large and suspicious quantities of opioids were being poured into communities throughout Alaska, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion.

181. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warning signs. Defendants paid their fines, made promises to do better, and carried on as before. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to the State.

182. Defendants' actions demonstrated both malice and aggravated and egregious fraud. Defendants engaged in the conduct described in this Complaint with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. In fact, Defendants' conduct has taken an unmatched toll in the state, as described above.

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

> [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.

184. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further 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."

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

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Public Nuisance

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

187. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

188. Defendants' acts and omissions, as described above, involve a significant interference with the public health, 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 Alaska.

189. 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."

190. 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. *See* Restatement (Second) of Torts § 821B.[63]

191. Here, Defendants' conduct is prescribed by statutes and regulations, including the ACSA, AS §17.30 *et seq.*, and the federal CSA and regulations incorporated therein.

192. Defendants violated the standard of conduct set forth in the Alaska Controlled Substances 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 Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 through their unfair and deceptive practices described in this Complaint.

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

[63] Alaska courts have cited to the Restatement (Second) of Tort's definition of nuisance with approval. *See, e.g., Friends of Willow Lake, Inc. v State, Dept. of Transp. & Pub. Fac.*, 280 P.3d 542, 548 (Alaska 2012).

194. Each Defendant is liable for creating the public nuisance because the unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to the State.

195. 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.

196. Defendants also knew and should have known that misleading the State and the public regarding their efforts to combat the opioid epidemic and compliance with their statutory and common law duties to maintain effective controls against diversion, would create or assist in the creation of a hazard to public health and safety and a public nuisance.

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

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

199. Prescription opioids are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are regulated as controlled substances under federal and state law as a result of their high potential for abuse and severe addiction.

200. The opioid epidemic has received widespread publicity and Defendants' own surveillance, as well as government data and academic and other research, demonstrated the widening toll of opioid addiction, overdose, hospitalizations, and fatalities, first in specific regions and then across the country.

201. The injury inflicted by Defendants was of a type that a reasonable controlled-substances distributor would see as a likely result of its conduct.

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

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

204. Each Defendant's actions were, at the very least, a material element and substantial factor in bringing about the injury. Each Defendant's actions were, at the very least, a material element and substantial factor in opioids becoming widely available and widely used in the state. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without each Defendant's actions, 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 much less severe.

205. The nuisance created by Defendants' conduct is abatable.

206. Defendants have engaged in a pattern of ongoing and persistent wrongful conduct, which caused the State to incur costs.

207. The State alleges wrongful acts that are neither discrete nor of the sort a local government can reasonably expect.

208. As a result of the harm inflicted by Defendants, the State incurred extraordinary and unpredictable costs for services it was forced to provide, over and above its ordinary public services.

209. The opioid epidemic is unprecedented in terms of its impact on the State of Alaska.

210. The State seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, abatement of the public nuisance and all damages allowed by law to be paid by Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

SECOND CLAIM FOR RELIEF

Negligence/ Negligence per se

211. The State incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

212. Under Alaska law, to establish actionable negligence, the State must show, in addition to the existence of a duty, a breach of that duty, and the breach was a substantial factor in causing injury. All such elements exist here.

213. Defendants owed the State a duty not to expose the State to an unreasonable risk of harm.

214. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in distributing highly dangerous opioid drugs in the state. This includes a duty not to cause foreseeable harm to others.

215. Defendants had a duty not to breach the standard of care established under Alaska law, which incorporates the federal CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

216. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in distributing and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility vis a vis the State. Their duty cannot be delegated.

217. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in distributing dangerous controlled substances.

218. Defendants breached their duty to the State by, *inter alia*:

a. Supplying opioids in Alaska in quantities that were facially unreasonable;

b. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

c. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

d. Choosing not to effectively monitor for suspicious orders;

e. Choosing not to investigate suspicious orders;

f. Choosing not to report suspicious orders;

g. Choosing not to stop or suspend shipments of suspicious orders; and

h. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

219. Defendants have engaged in affirmative acts of oversupplying opioids and facilitating an illegal, secondary opioid market by failing to exercise adequate control over the distribution and sale of their prescription opioids.

220. The method by which Defendants created this market was by distributing and selling opioids without regard to the likelihood that the opioids would fuel addiction, abuse, misuse, overdose, and death and be placed in the hands of individuals not permitted to use or possess prescription opioids.

221. A reasonably prudent opioid distributor should have anticipated an injury to the State as a probable result of distributing and selling prescription opioids in this manner.

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

223. Defendants had control over their conduct in Alaska. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion,

including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

224. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

225. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders and prevent diversion.

226. Defendants are in the business of selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

227. Reasonably prudent distributors of prescription opioids would have anticipated that opioid addiction would wreak havoc in the state, and that significant costs would be imposed upon the governmental entities.

228. Indeed, it is a violation of the ACSA, the federal CSA, and related regulations for Defendants not to set up a system to prevent diversion, detect and report suspicious orders and 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, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

229. Defendants' negligence and negligence *per se* were substantial factors in causing the State's damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services to address the opioid epidemic.

230. Defendants have engaged in a pattern of ongoing and persistent wrongful conduct, which caused the State to incur costs.

231. The State alleges wrongful acts that are neither discrete nor of the sort a local government can reasonably expect.

232. As a result of the harm inflicted by Defendants, the State incurred extraordinary and unpredictable costs for services it was forced to provide, over and above its ordinary public services.

233. The opioid epidemic is unprecedented in terms of its impact on the State of Alaska.

234. The State has suffered an indivisible injury as a result of the tortious conduct of Defendants.

235. The tortious conduct of each Defendant was a substantial factor in producing harm to the State.

236. Defendants acted with a conscious disregard for the rights and safety of others, despite the great probability of causing substantial harm.

237. Alaska is without fault and the injuries to the State and its residents would not have occurred in the ordinary course of events had Defendants exercised the due care commensurate to the dangers involved in the distribution of opioids.

238. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, enhanced compensatory damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

THIRD CLAIM FOR RELIEF

Unfair Practices – Unfair Trae Practices and Consumer Protection Act AS 45.50.471, *et seq.*

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

240. The Alaska Unfair Trade Practices and Consumer Protection Act (the "UTPA") states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce are declared to be unlawful." AS 45.50.471(a).[64] The UTPA lists fifty-seven different trade practices or acts that are expressly considered "unfair" or "deceptive" in violation of the Act, but does not limit violations of the Act to these enumerated practices. AS 45.50.471(b). The Alaska Supreme Court determines if actions are unfair or deceptive by inquiring:

> (1) Whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen).[65]

241. At all times relevant to this Complaint, Defendants violated AS 45.50.471, et seq., by engaging in unfair acts or practices in distributing opioids in Alaska. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous;

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[64] In light of the exemption set forth in A.S. § 45.50.481(a)(1) and the statute's subsequent amendment in 2012, Plaintiff only asserts claims under the UTPA for Defendants' post-August 15, 2012 conduct.

[65] *State v. O'Niell Investigations, Inc.,* 609 P.2d 520, 528 (Alaska 1980).

and have resulted in substantial injury to Alaska consumers that is not outweighed by any countervailing benefits to consumers or competition.

242. In addition, Defendant's actions violated AS 45.50.471(b)(11) and (12), which makes it unlawful (1) to engage in conduct that creates a likelihood of confusion or misunderstanding and which misleads, deceives or damages a buyer in connection with the sale of or advertisement of goods; and (2) to use "deception, fraud, false pretense, false promise, misrepresentation, or knowingly conceal, suppress, or omit a material fact with intent that others rely" on that concealment or omission in connection with the sale of goods regardless of whether a person has been mislead.

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

a. Oversupplying opioids into Alaska;

b. Failing to create, maintain, and use a compliance program that effectively detects and prevents suspicious orders of controlled substances;

c. Failing to report suspicious reports of controlled substances;

d. Filling suspicious orders for prescription opioids;

e. Failing to exercise due diligence to ensure that pharmacies could be trusted with opioids; and

f. Publicly claiming to use advanced analytics and technology to address suspicious orders and prevent illegitimate use of prescription opioids while actually failing to maintain effective controls against diversion.

244. These acts or practice were unfair in that they offend public policy, reflected in ACSA and incorporated federal law, which requires the monitoring and reporting of suspicious orders of controlled substances. By failing to monitor, detect, report, investigate, and refuse to fill suspicious orders as required by the ACSA, Defendants also failed to minimize the risk of diversion of controlled substances to unlawful use.

245. Defendants' acts or practices were deceptive in that by claiming that they had developed and applied rigorous protocols to prevent diversion—despite Defendants' pattern and practice of failing to detect and report suspicious orders—impeded law enforcement's ability to find and stop potential illegal activity.

246. Defendants' conduct has caused substantial injury to the State—in lives lost to drug overdoses, addictions endured, emergency room visits, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

247. The profound injuries to the State are not outweighed by any countervailing benefits to consumers or competition. Particularly in light of Defendants' lack of transparency and public claims of commitment to exercising due diligence not to fuel abuse and diversion of prescription opioids, and given the addictive nature of opioids, consumers could not reasonably have avoided their injuries.

248. By reason of Defendants' unlawful acts, the State and its residents have been damaged and continue to be damaged, in a substantial amount to be determined at trial.

249. Pursuant to AS 45.50.551, the State requests the maximum amount of penalties against each Defendant.

250. In addition to penalties and restitution, the State requests an order awarding to the State all legal costs and expenses pursuant to AS 45.50.537(d).

FOURTH CLAIM FOR RELIEF

Unjust Enrichment

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

252. As an expected and intended result of their 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 Alaska.

253. 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.

254. The State has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

255. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

256. These expenditures have helped sustain Defendants' businesses.

257. The State has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

258. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

259. By distributing a large volume of opioids to the State, Defendants have unjustly enriched themselves at the State's expense. The State has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the State lacks a remedy provided by law.

260. Defendants have unjustly retained benefits to the State's detriment, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

261. The State seeks an order compelling disgorgement of all unjust enrichment by Defendants to the State, divestiture of proceeds and assets, and awarding attorney fees and costs, and pre- and post-judgment interest.

VI. PRAYER FOR RELIEF

262. The State respectfully requests that this Court enter an order of judgment granting all relief requested in this Complaint, and/or allowed at law or in equity, including:

a. abatement of the nuisance;

b. actual damages;

c. punitive damages;

d. treble damages;

e. civil penalties as allowed by statute;

f. enhanced compensatory damages;

g. injunctive relief;

h. forfeiture, disgorgement, and/or divestiture of proceeds and assets;

i. attorneys' fees;

j. costs and expenses of suit;

k. pre- and post-judgment interest; and

l. such other and further relief as this Court deems appropriate.

Dated October _____, 2018

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