

Treg R. Taylor, Attorney General
Margaret Paton Walsh
Department of Law
1031 W. Fourth Avenue, #200
Anchorage, AK 99501
Telephone: 907.269.5100

David Karl Gross
Mara E. Michaletz
Birch Horton Bittner & Cherot
510 L Street, #700
Anchorage, AK 99501
Telephone: 907.276.1550

Linda Singer (pro hac vice to be submitted)
Motley Rice LLC
401 Ninth Street, N.W., #1001
Washington, DC 20004
Telephone: 202.386.9626

Attorneys for Plaintiff

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT IN ANCHORAGE

THE STATE OF ALASKA,)
)
 Plaintiff,) Case No. 3AN-22-_____ CI
)
 vs.)
)
 WALGREEN CO.; WALGREENS BOOTS)
 ALLIANCE, INC.; WALMART INC., f/k/a)
 WAL-MART STORES, INC.;)
 ALBERTSONS COMPANIES, INC.;)
 ALBERTSONS COMPANIES LLC;)
 SAFEWAY, INC.; CARR-GOTTSTEIN)
 FOODS CO.; THE KROGER CO.; AND)
 FRED MEYER, INC.,)
)
 Defendants.)
 _____)

COMPLAINT

I. INTRODUCTION

1. The State of Alaska (“Plaintiff” or the “State”) brings this action to prevent future harm and to redress past wrongs against Defendants Walgreen Co. and Walgreens Boots Alliance, Inc. (together, “Walgreens”); Walmart Inc. (“Walmart”); Albertsons Companies, Inc., Albertsons Companies LLC, Safeway, Inc., and Carr Gottstein Foods Co. (together, “Safeway”); and The Kroger Co. and Fred Meyer, Inc. (together, “Kroger”) (collectively, “Defendants” or “Chain Pharmacies”).

2. This case arises from the worst man-made epidemic in modern medical history — an epidemic of addiction, overdose, and death caused by Defendants’ flooding the United States, including the State of Alaska, with prescription opioids, in violation of their common-law duties and obligations under the federal Controlled Substances Act (“CSA”) and Alaska Controlled Substances Act (“ACSA”).

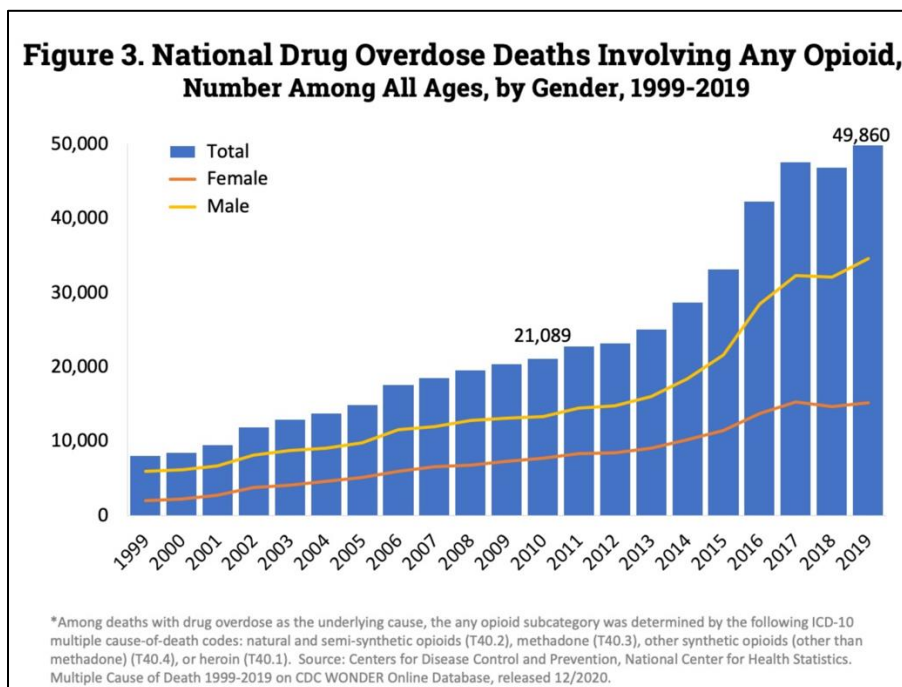
3. By now, most Americans have been affected, either directly or indirectly, by the opioid epidemic. This crisis arose not only from the opioid manufacturers’ deliberate marketing strategy, but from distributors’ and pharmacies’ equally deliberate efforts to evade restrictions on opioid distribution and dispensing.

4. All told, Alaska, with an average population from 2010 to 2017 of approximately 721,000, received a total of 303,646,336 retail doses of opioid analgesics during the same time frame.

5. The overwhelming increase in opioids dispensed by Alaska pharmacies, collectively and individually, put Defendants on notice that they were meeting more than an appropriate and legitimate market demand. Rather than continuing to sell, dispense, and profit from these highly dangerous drugs, they had a duty to investigate, report and stop some of their

prescriptions and report them to the DEA and local law enforcement. Had they done so, the opioid epidemic in Alaska — and its enormous human and financial toll — would not have been as grave.

6. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the 12 months that ended in September 2017, opioid overdoses claimed 45,000 lives. Another 46,000 opioid overdose deaths occurred in 2018, and in 2019 the number of opioid overdose deaths rose to over 49,000. There were an estimated 75,673 opioid overdose deaths in the 12-month period ending in April 2021, up from 56,064 the year before.



7. According to the Centers for Disease Control and Prevention (“CDC”), from 1999 to 2019, nearly 500,000 people died from an overdose involving any opioid. The prescription opioids include brand-name medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generic opioids like oxycodone, hydrocodone, and fentanyl.

8. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. As soon as prescription opioids took hold on a population, the biological and devastating progression to illicit drugs followed. Once addicted to, but no longer able to obtain, prescription opioids or trapped in a cycle of addiction that causes those who suffer from the disease to need stronger and more potent drugs, many opioid users have turned to heroin, fentanyl, and other illicit drugs. According to the American Society of Addiction Medicine, 80 percent of people who initiated heroin use in the past decade started with prescription painkillers — which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

9. The conduct of the manufacturers, distributors, and Chain Pharmacies caused the nation, and the State, to be awash in a flood of prescription opioids. This has had a profound impact on both morbidity and mortality, and those drugs have created an epidemic of addiction that has had severe and wide-ranging effects on public health and safety in Alaska and in communities across the country. Indeed, from those suffering with the disease of addiction themselves, to children whose parents suffer from addiction, to employers who employ an addicted population, to the first responders, law enforcement, court systems, and prison systems who cannot handle the burdens placed on them, there is almost no segment of society that has not been significantly impacted.

10. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses became the leading cause of death for Americans under 50.

11. In the words of Robert Anderson, who oversees death statistics at the CDC, “I don’t think we’ve ever seen anything like this. Certainly not in modern times.” On March 6, 2017, Governor Walker stated that “Alaska is in the grips of a tragic opioid epidemic.” On October 27, 2017, the President declared the opioid epidemic a public health emergency.

12. Alaska has been hit hard by the opioid epidemic. The State faces unique challenges in preventing drug addiction and related crime due to its geographic location and dispersed population. The City of Anchorage consists of 40 percent of Alaska’s population and is a central hub for narcotics distributed throughout Alaska, including to rural villages. Illegal opioids (illicit fentanyl and heroin) and prescription drugs are among the top regional drug threats in Alaska. According to the Department of Health and Social Services, from 2019 to 2020, fentanyl overdose deaths increased 193 percent statewide.

13. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Further, overdose deaths are not the only consequence. Hundreds of people in Alaska have been rushed to emergency rooms or revived by EMS or community members trained to administer Narcan — an antidote to overdose.

14. The damage inflicted cuts across ages and generations. Many who have succumbed to overdoses have overdosed more than once. Those who survive are often not alone at the time. Family members, including young children, have watched their loved ones lose consciousness or die. Young children, including toddlers, also have been the direct victims of overdoses themselves after coming into contact with opiates.

15. Children are being displaced from their homes and raised by relatives or placed in the State's care due to their parents' addiction. Others lose the chance to go home. Unable to be discharged from the hospital with their mothers, babies born with prenatal exposure are being placed in the care of the State, families or non-profits who do their best to care for them.

16. This devastation in the State was created by opioid manufacturers, distributors, and Chain Pharmacies, who worked together to dismantle the conservatism that had existed around prescription opioids for decades, opened the floodgates to an unreasonably large and unsafe supply of opioids, improperly normalized the widespread use of opioid drugs, violated laws and regulations designed to protect the public from the dangers of opioids, and worked to dismantle those regulations designed to protect the public so more opioid drugs could be sold and the manufacturers, distributors, and Chain Pharmacies could reap the profits therefrom.

17. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

18. This suit takes aim at a substantial contributing cause of the opioid crisis: the Chain Pharmacies, the last link in the opioid supply chain and the critical gatekeeper between dangerous opioid narcotics and the public, which utterly failed in their gatekeeper role and flouted their duties to protect public health and safety.

19. In particular, the Chain Pharmacies failed to design and operate systems to identify, halt, investigate and report suspicious orders of prescription opioids, maintain effective controls

against diversion, and ensure that prescriptions were dispensed only for legitimate medical purposes, and instead actively contributed to the oversupply of such drugs and fueled an illegal secondary market.

20. As a direct and foreseeable result of Defendants' conduct, communities across the nation, including in Alaska, are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis." The increased volume of opioid prescribing and dispensing, not all of which is for legitimate use, correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or could not afford prescription opioids.

21. This explosion in opioid use and Defendants' profits has come at the expense of patients and residents and has caused ongoing harm to and a public nuisance in Alaska. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

22. Defendants' conduct in fueling diversion has had severe and far-reaching consequences on public health, social services, and criminal justice, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by the State and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-withdrawing newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements.

23. The burdens imposed on the State are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Defendants' illegal actions. Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

24. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis and perpetuate the public nuisance.

II. JURISDICTION AND VENUE

25. Jurisdiction over the subject matter of this cause of action is proper based upon Alaska Statutes 22.10.2020, 09.58.015, and 45.50.501.

26. 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 permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Alaska's long-arm statute, as codified in Alaska Statute 09.05.015.

27. 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.

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

III. PARTIES

The State

29. The State of Alaska brings this action, by and through its Attorney General Treg Taylor, in its sovereign capacity to protect the interests of the State and its citizens. The Attorney

General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by the Alaska Consumer Protection Act, Alaska Statute 45.50.471, *et seq.*

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

31. The State alleges that the corporate parents named as defendants in this Complaint are liable as a result of their own actions and obligations in distributing and dispensing opioids, and not solely because of their vicarious responsibility for the actions of their subsidiaries and their pharmacy stores.

Walgreens Defendants

32. Defendant Walgreen Co. acted as a retail pharmacy in the United States until it completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company became Walgreens Boots Alliance, Inc.

33. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation that describes itself as the successor of Walgreen Co., an Illinois corporation. Both Walgreens Boots Alliance, Inc. and Walgreen Co. have their principal place of business in Illinois.

34. Defendants Walgreens Boots Alliance, Inc. and Walgreen Co. are collectively referred to as "Walgreens."

35. At least between 2006 and 2014, Walgreens self-distributed opioids to Walgreens retail pharmacies located in Alaska.

36. At all times relevant to this Complaint, Walgreens sold (dispensed) prescription opioids throughout the United States, including in Alaska. As of August 31, 2020, Walgreens operated approximately 9,021 drugstores in all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, including 11 stores in Alaska. Between 2006 and 2014, Walgreens stores in Alaska bought 329,682,492 morphine milligram equivalents (“MMEs”) of opioids.¹ In its role as a distributor, Walgreens distributed 187,031,656 MMEs in Alaska during this same time period. Between 2006 and 2014, a single Walgreens pharmacy in Wasilla dispensed 5,254,340 opioid pills.

37. The DEA distribution registrations for Walgreens’ controlled substances distribution centers that distributed opioids and cocktail drugs into the State were held by Walgreen Co.

Walmart Defendants

38. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

39. Walmart Inc., through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy. Walmart Inc. operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018. At the end of 2021, Walmart operated more than 5,100 pharmacies in the United States, including nine in Alaska. Between 2006 and 2014, Walmart stores in Alaska bought 344,726,274 MMEs of opioids. In its role as a distributor, Walmart distributed 306,159,550 MMEs in Alaska during this same time period.

¹ MMEs are the amount of milligrams of morphine an opioid dose is equal to when prescribed. Calculating MME accounts for differences in opioid drug type and strength.

Safeway Defendants

40. Albertsons Companies, Inc. is a Delaware corporation with its principal place of business in Boise, Idaho. Albertsons Companies, Inc. describes itself as one of the largest food and drug retailers in the United States. As of February 26, 2022, Albertsons Companies, Inc. stated that it operates 2,276 stores across 34 states and the District of Columbia under 24 banners, including Albertsons and Safeway. Additionally, as of February 26, 2022, Albertsons Companies, Inc. operated 1,722 pharmacies.

41. Albertsons Companies LLC is a Delaware business entity with its principal place of business in Boise, Idaho. Albertsons Companies LLC is authorized to conduct business in Alaska as a licensed wholesale distributor, through its various DEA-registered subsidiaries and affiliated entities. Albertsons Companies LLC is the parent company of Carrs-Safeway, which conducts business in Alaska.

42. Safeway, Inc. is a subsidiary of Albertsons Companies, Inc. Between 2006 and 2014, Albertsons/Safeway stores in Alaska bought 344,796,056 MMEs of opioids. Albertsons/Safeway pharmacies dispensed 1,549,990 opioid pills in Juneau between 2006 and 2012.

43. Carr-Gottstein Foods Co. operates approximately 49 stores throughout Alaska, including pharmacies that dispense prescription opioids. Safeway, Inc. acquired Carr-Gottstein Foods Co. in 1999 and it is now an indirect subsidiary of Albertsons Companies, Inc. Between 2006 and 2014, Carr-Gottstein Food Co. stores in Alaska bought 638,104,160 MMEs of opioids.

Kroger Defendants

44. The Kroger Co. is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

45. Fred Meyer, Inc. merged with The Kroger Co. in 1999 and is currently a subsidiary of The Kroger Co., with its principal place of business in Portland, Oregon. As of May 30, 2022, there are 141 Fred Meyer locations in the United States, with 13 locations in Alaska.

46. Between 2006 and 2014, Fred Meyer, Inc. stores in Alaska bought 856,568,928 MMEs of opioids — the highest of all purchasers in Alaska during this time period. Between 2006 and 2014, a Fred Meyer pharmacy in Wasilla dispensed 4,543,400 opioid pills and another in Anchorage dispensed 4,226,920 opioid pills. In Juneau, Fred Meyer’s retail locations dispensed a total of 1,909,330 opioid pills between 2006 and 2014.

47. The Kroger Co. is authorized to conduct business in Alaska as a licensed wholesale distributor through its various DEA-registered subsidiaries and affiliated entities, including Kroger Limited Partnership I and Kroger Limited Partnership II.

IV. FACTUAL ALLEGATIONS

A. Defendants’ Conduct Created an Abatable Public Nuisance

48. As alleged throughout this Complaint, Defendants’ conduct has created a public health crisis and a public nuisance.

49. The public nuisance — i.e., the opioid epidemic — created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be avoided by taking measures such as providing addiction treatment to patients who are already addicted to opioids, making naloxone widely available so that overdoses are less frequently fatal, and a number of other proven measures to address the epidemic.

50. Defendants have the ability to act to help end the public nuisance, and the law recognizes that they are uniquely well positioned to do so. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and

sold to appropriate patients and not diverted. As registered distributors and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as the key, last line of defense. Defendants, however, instead abused their position of special trust and responsibility within the closed system of opioid distribution and dispensing and fostered a black market for prescription opioids.

51. Walgreens has admitted its role in the opioid epidemic and its ability to abate the public nuisance, stating it has the “ability – and [] critical responsibility – to fight the opioid crisis” as the “nation’s largest pharmacy chain” in a time when “[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade” and “drug overdose deaths – the majority from prescription and illicit opioids” result in “more fatalities than from motor vehicle crashes and gun homicides combined.” Walgreens also admits the “opioid crisis” is caused by “misuse, abuse and addiction” that result from the “flow of opioids that fuel the epidemic.”

B. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion

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

52. There are multiple duties on Defendants to report suspicious orders and not to ship those orders unless due diligence disproves those suspicions.

53. First, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Alaska with more opioids than could be used for legitimate medical purposes, by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to maintain effective

controls against diversion from their retail stores, Defendants breached that duty. As a result, they created and failed to prevent a foreseeable risk of harm.

54. Second, Defendants are prohibited under Alaska law from engaging in unfair and deceptive acts and practices in trade and commerce. Under the Alaska Consumer Protection Act, 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. 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.

55. Third, Defendants are required under the ACSA to monitor, detect, investigate, report, and refuse to fill suspicious orders. Distributors must be licensed by the Alaska Board of Pharmacy to distribute controlled substances in Alaska.

56. Finally, distributors and pharmacies are required to register with the DEA to distribute and/or dispense controlled substances under the federal CSA. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100; 28 C.F.R. § 1301.71. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, Congress enacted the CSA in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation

by registrants within the drug delivery chain. All registrants must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. Maintaining the closed system under the CSA and effective controls to guard against diversion is a vital public health concern. Controlled substances, and prescription opioids specifically, are recognized as posing a high degree of risk from abuse and diversion. When the supply chain participants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

57. In addition, 21 C.F.R. § 1306.04(a) states that “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Thus, all Chain Pharmacies, because they are registrants and dispensers, must ensure that prescriptions of controlled substances are “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). The DEA has recognized that “as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion.”

58. “A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.” 21 C.F.R. § 1306.06. As the Department of Justice’s (“DOJ”) recent lawsuit against Walmart alleges, 21 C.F.R. § 1306.06 requires that a pharmacist’s conduct, when filling controlled-substance prescriptions, adhere to the usual course of a pharmacist’s professional practice. The obligation to identify any red flags relating to a controlled-substances prescription, to resolve them before filling the prescription, and to document any resolution of red flags is a well-recognized responsibility of a pharmacist in the professional practice of pharmacy. *United States of America v. Walmart Inc.*, No. 1:20-cv-01744 (D. Del.

Dec. 22, 2020). As the DOJ’s complaint alleges, when “‘Walmart pharmacists failed to comply with their own professional pharmacy standards’ in this respect, ‘Walmart . . . violated 21 C.F.R. § 1306.06.’”

59. Under the CSA, the duty to prevent diversion lies with the Chain Pharmacies, not the individual pharmacist. As such, although it acts through its agents, the pharmacy is ultimately responsible to prevent diversion. Further, as described above, the obligations under the controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration holder or not. It is unlawful for any person knowingly to distribute or dispense controlled substances other than in accordance with the requirements of the CSA and its implementing regulations, or in violation of state-controlled substances laws and regulations. The Chain Pharmacies are responsible “persons” under the CSA. They also exert control over their agents, including the responsibility to ensure they comply with applicable laws and regulations in all dispensing of controlled substances. Defendants cannot absolve themselves of their own obligations by attempting to place unilateral responsibility on their agents.

60. In addition to their duties as distributors, the Chain Pharmacies also have a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies have the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions suggestive of potential diversion. They also have a crucial role in creating chain-wide systems to identify and avoid filling “prescriptions” that are not issued for a legitimate medical purpose or by a prescriber with a valid, current license acting in the usual course of professional treatment.

61. Defendants’ obligations extend to monitoring and documenting the steps they take in accessing state prescription drug monitoring programs, often referred to as “PDMPs.” Yet, the

Chain Pharmacies generally relied on their pharmacists' discretion in this area rather than timely setting forth requirements concerning PDMP searches and implementing systems. Until just recently, Chain Pharmacies failed to monitor, track, and document PDMP searches and their results.

62. The CSA requires distributors, including Chain Pharmacy distributors, to: (a) register to distribute opioids; (b) maintain effective controls against diversion of the controlled substances; (c) design a system to identify suspicious orders such as orders of unusual size, unusual frequency, or unusual pattern; and (d) when suspicious orders are detected, to stop the order, investigate it, and report the suspicious order to the DEA. In connection with their distribution of prescription opioids in Alaska, the Chain Pharmacies failed to report suspicious orders to the DEA.

63. To ensure that controlled substances are not diverted, federal regulations issued under the CSA mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other indicia of potential diversion may include, for example, "[o]rdering the same controlled substance from multiple distributors."

64. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the

responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

65. To comply with the law, wholesale distributors, including Defendants, 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).

66. Pharmacy order data provides detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be indicative of diversion. Chain Pharmacies are in a unique position because they have access to their own dispensing data which should have been used to identify prescribers, patients, and pharmacies of potential concern and to investigate suspicious orders.

67. In addition to their duties as distributors, Defendants also had a duty to monitor and report suspicious activity in their retail pharmacy operations. Specifically, Defendants had a duty to analyze data and store-level information for known red flags such as (a) patients traveling long distances to a prescriber or a pharmacy; (b) patients obtaining multiple opioid prescriptions from different prescribers; (c) patients traveling to multiple pharmacies to fill opioid prescriptions; (d) prescriptions for an opioid and benzodiazepine, with or without an additional muscle relaxer,

which when combined intensifies the risk of overdose and death; (e) prescriptions for an excessive quantity of an opioid or multiple opioids on the same day or within an overlapping period of time; (f) prescribers prescribing the same medication, with the same directions, for the same quantity for a number of individuals; (g) an individual consistently requesting early refills or routinely attempting to obtain an early refill of an opioid; (h) patients paying cash or by using a cash discount card in a possible attempt to circumvent third-party billing restrictions; or (i) volumes, doses, or combinations that suggest that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose.

68. The CSA also imposes important recordkeeping obligations on pharmacies, including pharmacy chains. “[E]very registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him.” 21 USC § 827(a). “[A] registrant’s accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances.” Paul H. Volkman, 73 FR 30,630, 30,644 (2008). An important component of an anti-diversion system is the documentation Chain Pharmacies possess. They must utilize their information to identify patterns of diversion and for auditing, training, and investigation of suspicious activity.

69. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the Board of Pharmacy and DEA must be contacted.

70. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. Together, these laws and industry guidelines make clear that Defendants possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market

for scheduled prescription opioids and of the risks and dangers of the diversion of prescription opioids when the supply chain is not properly controlled.

71. Further, these laws and industry guidelines make clear that Defendants have a responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

72. Additionally, Chain Pharmacies have operating systems and methods to store and retain prescription dispensing data and records. The information they possess must be readily retrievable, and they have an obligation to use it to identify patterns of diversion, conduct internal audits and training programs, investigate suspicious prescribers, patients, and pharmacists, and prevent diversion of controlled substances. Their hiring, training, and management of pharmacy personnel, and their supporting policies, procedures, and systems should and must promote public health and safety and assist in the identification and prevention of the diversion of controlled substances.

2. Defendants were aware of and have acknowledged their obligation to prevent diversion and to report and take steps to halt suspicious orders

73. The regulations in the CSA and ACSA aim to create a “closed” system in order to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the gatekeepers in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors’ obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor

deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

74. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

75. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

76. The DEA 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, in August 2005, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations, including launching the “Distributor Initiative.”

77. 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.” 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, the “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 level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,” described above, from which certain data has now been made public.

78. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including retail pharmacies.

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.

79. The letter also warned that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

80. In September 2007, the DEA reminded registrants at a conference that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens registered for the conference.

81. The DEA sent a second letter to all registered distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The DEA’s 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).

82. The DEA’s regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against distributors for their compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health’s distribution centers, and on December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement (“AMA”) with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an AMA with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at several of its facilities.

83. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.² The DEA, among others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion. For example, the DEA has repeatedly emphasized that retail pharmacies, such as Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy’s “corresponding responsibility” under 21 C.F.R. § 1306.04(a) requires it either to take

² See, e.g., *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed.Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); *East Main Street Pharmacy*, 75 Fed.Reg. 66,149 (DEA Oct. 27, 2010) (affirmance of suspension order); *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145 (D.D.C. 2012); *Townwood Pharmacy*, 63 Fed.Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); *Grider Drug 1 & Grider Drug 2*, 77 Fed.Reg. 44,069 (DEA July 26, 2012) (decision and order); *The Medicine Dropper*, 76 Fed.Reg. 20,039 (DEA Apr. 11, 2011) (revocation of registration); *Medicine Shoppe-Jonesborough*, 73 Fed.Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.

84. The DEA has identified several types of “unresolvable red flags” which, when present in prescriptions presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address; prescribing the same controlled substances in each presented prescription; a high volume of patients presenting prescriptions and paying with cash; and a prescription presented by customers who have traveled significant and unreasonable distances from their home to see a doctor and/or to fill prescriptions at the pharmacy.

85. DEA guidance also instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area; and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by Defendants’ diversion control systems.

86. Red flags indicative of diversion include suspicious behavior of patients, such as stumbling while walking, slurred speech, appearance of intoxication, or of customers coming and appearing like they may not need the medication, or requesting drugs by brand name or street slang such as “blues” (a term referencing Mallinckrodt opioids). Pharmacies’ training materials and controls should assist pharmacists and technicians in the identification of such behaviors.

87. Pharmacies must resolve red flags before a prescription for addictive and dangerous drugs, such as opioids, are dispensed.

3. Defendants are uniquely positioned to guard against diversion

88. Not only do Chain Pharmacies often have firsthand knowledge of dispensing red flags — such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, cash transactions, and other significant information — but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. As with other distributors, these data points give the Chain Pharmacies insight into prescribing and dispensing conduct that enables them to prevent diversion and fulfill their obligations under the CSA and the ACSA.

89. Chain Pharmacies not only make observations through their individual retail outlets, but also have extensive data to which an individual pharmacist would not have access. They are uniquely positioned to monitor, for example, the volume of opioids being dispensed in their pharmacies relative to the size of the communities they serve. In fact, in investigations and enforcement actions, the DEA has specifically warned Chain Pharmacies to monitor their sales in relation to the size of the community serviced by their stores.³ This is particularly important given that it is recognized that as the supply of opioids increases, so does the incidence of overdose and death. The Chain Pharmacies could also use this information to monitor potentially suspicious prescribers. Pharmacies must use the information available to them to guard against supplying

³ See *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, Decision and Order, 77 FR 62316-01, 62325, 2012 WL 4832770 (DEA Oct. 12, 2012); Walgreens Immediate Suspension Order, WAGMDL00490963, at 7657 (Sept. 13, 2012).

controlled substances for non-medical use, identify red flags or potential diversion and share this information with their agents, as well as provide clear guidance and training on how to use it.

90. As explained above, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Specifically, the Chain Pharmacies had a duty to analyze data and the personal observations of their employees for known red flags such as those described above. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, store, and chain level, and to refuse to fill and to report prescriptions that suggested potential diversion.

91. They were particularly well-positioned to do so given the dispensing data available to them, which they could review at the corporate level to identify patterns of diversion and to create policies and practices to proactively identify patterns of diversion. Each could and should have also developed tools and programs to alert their pharmacists to red flags and to guard against diversion.

92. The Chain Pharmacies also possessed sufficiently detailed and valuable information for which other companies were willing to pay them. In 2010, for example, Walgreen's fiscal year 2010 Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at \$749,000,000. In addition, Walgreens's own advertising has acknowledged that Walgreens has centralized data such that customers' "complete prescription records" from Walgreens's "thousands of locations nationwide" are "instantly available."

93. Each of the Chain Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in the State, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the State, and

complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the State. Each of the Chain Pharmacies likewise had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the State, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the State. Further, each of the Chain Pharmacies had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the State and complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the State.

4. Defendants failed to maintain effective controls against diversion

94. Each participant in the supply chain of opioid distribution, including the Chain Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

95. Defendants systemically ignored red flags that they were fueling a black market, and failed to maintain effective controls against diversion at both the wholesale and retail pharmacy level. Instead, they put profits over public health and safety. Despite their legal obligations as registrants under the CSA and the ACSA, the Chain Pharmacies allowed widespread diversion to occur — and they did so knowingly.

96. Upon information and belief, this problem was compounded by the Chain Pharmacies' failure to train their pharmacists and pharmacy technicians adequately on how to properly handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate and what measures and/or actions to take when a prescription is identified as potentially illegitimate.

97. Upon information and belief, the Chain Pharmacies also failed to put in place effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market, and to conduct adequate internal or external reviews of their opioid sales to identify patterns regarding prescriptions that should not have been filled, or if they conducted such reviews, they failed to take any meaningful action as a result.

98. Upon information and belief, even where Chain Pharmacies enacted policies and procedures to prevent stores from facilitating diversion and selling into a black market, such policies were merely window-dressing and were not employed in any meaningful way.

99. Upon information and belief, the Chain Pharmacies also failed to respond effectively to concerns raised by their own employees concerning inadequate policies and procedures regarding the filling of opioid prescriptions. Instead, Chain Pharmacies put in place policies that required and rewarded speed and volume over safety and the care necessary to ensure that narcotics were distributed and sold lawfully. Defendants consistently put profits over safety in their distribution and sale of prescription opioids.

Walgreens

100. Acting as both a distributor and a retail pharmacy chain, Walgreens distributed opioids to its own individual pharmacies. Although Walgreens had visibility into indicia of diversion due to its vertically-integrated distribution and dispensing practices, it failed to take these factors into account in its suspicious order monitoring (“SOM”) program during the vast majority of the time it was distributing prescription opioids. Moreover, its SOM program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

101. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulae to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

102. Walgreens used two different formulae: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulae were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period.

103. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient" in a May 2006 Letter of Admonition. The letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio distribution center, but highlighted problems that went far beyond that particular facility.

104. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," although Walgreens failed to examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

105. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length. Walgreens did not perform any due diligence

on the thousands of orders identified as “suspicious” on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

106. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until after the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported when discovered. 21 C.F.R. § 1301.74(b). In some instances, months may have elapsed between an order’s shipment and its subsequent reporting to the DEA, given Walgreens’s requirement of two consecutive months of exceeding the three times multiplier to trigger reporting.

107. In September 2012, the DEA issued an immediate suspension order (“ISO”) regarding one of Walgreens’s three Schedule II distribution centers, finding Walgreens’s distribution practices constituted an “imminent danger to the public health and safety” and were “inconsistent with the public interest.” The DEA further found that Walgreens’s Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: “Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies.”

108. A Walgreen’s Pharmacy Operations Distribution Center Manager, Kristine Lucas, testified that she warned Walgreens’s headquarters of the extraordinary number of opioids being purchased and distributed:

- Q: Did Jupiter have enough space for the opioids that were coming in to satisfy these increased orders from the stores?
- A: No.
- Q: Did you have enough space in the vault to store all of the opioids that were coming in from the Manufacturers?
- A: No.
- Q: What would you do with all those extra opioids?
- A: Well, at one point, we would take, we took the racks out of the warehouse so that we could stack boxes floor to ceiling.
- Q: Was that sufficient to store them all?
- A: No. And then at night when we closed the vault, we would have to stack the pallets outside the vault, but within the cage. But there were times where that wasn't enough, so we would line them up outside the cage . . .⁴

109. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law regarding the reports and Walgreens's suspicious order monitoring system — applicable across Walgreens's operations:

- “[Walgreens’s] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled ‘Suspicious Control Drug Orders.’”
- “[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports.”
- “[Walgreens’s] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico.”
- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: “This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy’s location, the population it serves, or the number of other pharmacies in the area.”

⁴ *State of Florida, Office of the Att’y General, Dept. of Legal Affairs v. Purdue Pharma, L.P.*, No. 2018-CA-001438 (Fla. Cir. Ct.), Testimony of Kristine Lucas, 629:1-20 (Apr. 12, 2022).

- “As made clear in 21 CFR § 1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order’s legitimacy is concluded.”
- “DEA’s investigation of [Walgreens] . . . revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. § 1301.74(b).”
- “DEA investigation of [Walgreens’s] distribution practices and policies . . . demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. 823(b)(1) and (e)(1). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein.”
- “[DEA’s] concerns with [Walgreens’s] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens’s dispensing registration].”

110. Walgreens knew its procedures were inadequate well before the 2012 ISO issued.

In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that “[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders.” The DEA further advised Walgreens that, while “[a]n electronic data system may provide the means and mechanism for complying with the regulations . . . the system is not complete until the data is carefully reviewed and monitored by the registrant.”

111. These failures reflect nationwide systemic failures of Walgreens’s SOM system that impacted its distribution in Alaska. Walgreens admits that the SOM systems and procedures at all of its distribution centers were the same, including those at the facilities that continued shipping opioids into Alaska. For example, in connection with Walgreens’s Woodland, California distribution center, when Walgreens did submit suspicious order lists to the DEA, it included orders that had already been shipped. The Woodland distribution center also did not have a monitoring process in place to prevent the fulfillment of an order that was deemed suspicious.

112. Walgreens never equipped its distribution operations to monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution altogether.

113. With respect to dispensing, although Walgreens purported to have in place “Good Faith Dispensing” (“GFD”) policies for many years, it failed to apply policies and procedures meaningfully, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

114. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens’s dispensing policies explicitly instructed pharmacists who received a questionable prescription or otherwise were unable to dispense a prescription in good faith to contact the prescriber and, if confirmed as “valid” by the prescriber, to then process the prescription as normal.

115. In 2012, Walgreens finally removed this “process the prescription as normal” language from its formal GFD policies, admitting that under the law “it is not enough to get

confirmation that the prescriber wrote the prescription.” However, Walgreens still failed to ensure it complied with its duties.

116. Indeed, during the course of a 2009 DEA investigation into Walgreens’s dispensing noncompliance, Walgreens internally noted that it currently had “no training” for employees dispensing controlled substances. Meanwhile, Walgreens’s corporate officers turned a blind eye to these abuses.

117. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement (“MOA”) regarding all “Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances,” requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide “compliance program to detect and prevent diversion of controlled substances as required by the . . . (CSA) and applicable DEA regulations.” Pursuant to the MOA, the “program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills,” as well as “routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA.” Further, Walgreens was required to “implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations.”

118. Even where Walgreens’s policies recognized red flags, Walgreens failed to provide its pharmacists with effective tools for assessing them. For example, Walgreens’s policies and internal documents acknowledged that distance between the patient, pharmacists, and/or prescriber constituted a red flag, but Walgreens did not even begin piloting an automated process for flagging

such distances through common and long available technological solutions until the spring of 2021.

119. Upon information and belief, Walgreens did not make any suspicious order report of an order in the State between 2007 and 2014. Instead, Walgreens funneled far more opioids into Alaska than could have been expected to serve legitimate medical use, and ignored other indicia of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

120. Walgreens used metrics to evaluate pharmacists' compensation and staffing needs. Often these metrics interfered with patient safety and health. Incentive awards were tied to the number of prescriptions a pharmacy filled and profits that the pharmacy generated. Controlled substances were included in Walgreens's pharmacy incentive program until Walgreens entered into the MOA with the DEA. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walgreens's drive for speed, pharmacists often did not have enough time to review a prescription sufficiently to conduct the appropriate due diligence.

121. At the store level, Walgreens did not make any controlled substance metrics available to pharmacists for specific prescribers. Further, despite the fact that at the corporate level Walgreens utilized many tools for descriptive statistics around prescriber patterns, Walgreens did not make this information available to its pharmacists.

122. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to analyze and address its opioid sales to identify patterns

regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

Walmart

123. During most of the time period relevant to the State's claims, Walmart acted as both a distributor of controlled substances to its own pharmacies and a retailer dispensing controlled substances at Walmart pharmacies and Sam's Club pharmacies. While operating under different brand names, both Walmart and Sam's Club pharmacies were subject to the same flawed policies, lack of oversight, and inadequate implementation emanating from Walmart's home office in Arkansas. In both its capacity as a distributor and as a dispenser of controlled substances, Walmart failed to implement effective policies and practices to prevent diversion of opioids in Alaska. By the time Walmart implemented a system for monitoring suspicious orders or policies allowing corporate blocks of known pill mill doctors, the opioid epidemic had already claimed hundreds of thousands of lives.

124. Walmart is the largest private employer in the United States, employing over 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Despite Walmart's obligations as a distributor of controlled substances, it was not until 2014 that Walmart began to take any meaningful steps toward developing a system for monitoring suspicious orders.

125. Prior to 2011, Walmart did not have any written policy or procedure in place to monitor orders of controlled substances shipped by its pharmacy distribution centers.

126. In the absence of an established policy or procedure, Walmart relied on its hourly employees and associates filling orders at the distribution centers to monitor the orders they were

filling for anything they might consider unusual. Those associates were responsible for filling and reviewing several hundred orders a day.

127. Walmart did not provide any guidance or training to its associates as to what constitutes a suspicious order or how to evaluate an order for unusual size, frequency, or pattern. On information and belief, no Walmart employee ever flagged an order as suspicious prior to 2011.

128. Although Walmart did create a procedure for identifying suspicious orders of controlled substances beginning in 2011, this procedure was insufficient to identify suspicious orders of controlled substances. Walmart's program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders for more than 20 bottles (2,000 dosage units) that were 30 percent higher than a rolling four-week average for that item. Orders under 2,000 dosage units per week were never flagged, meaning that a pharmacy could order 8,000 dosage units per month without ever being flagged. Moreover, that meant that even if an order was more than 30 percent greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

129. Under this system, an alert did not mean Walmart would report the order to the DEA or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart never reported an order flagged by its monitoring program to the DEA as suspicious in Alaska. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50-bottle threshold and shipped it. Walmart never reported cut orders to the DEA. Although the distribution centers sent information regarding flagged orders daily to Walmart's corporate headquarters in Arkansas, no system existed for follow-up on flagged orders by employees at the home office.

130. In mid-2012, Walmart implemented a “hard limit” on orders of a single opioid product, 30 mg. oxycodone (“Oxy 30”). Under this approach, an order for over 20 bottles of Oxy 30 was automatically reduced to 20 bottles. Walmart would not report the excessive orders of Oxy 30 to the DEA.

131. At the same time, Walmart’s distribution center began generating a daily report of all the pharmacies placing orders for over 20 bottles of various oxycodone medications, although Walmart did not place a “hard limit” on any dosage strength or product other than Oxy 30. This report, called the “Over 20 Report,” later included other controlled substances as well. Although the report was generated and circulated on a daily basis, Walmart did not have an adequate system in place to review and follow up on the excessive orders beyond investigating for indicators of internal theft, and it did not have a system in place to address stores that repeatedly appeared on the Over 20 Report. Regardless of having been identified on the Over 20 Report, those stores’ orders were filled and shipped. Upon information and belief, there is no evidence of any order being held or halted pursuant to this practice.

132. Even if Walmart’s distribution center reduced an order to a smaller number of bottles, nothing prevented a Walmart or Sam’s Club pharmacy from making up the difference by ordering opioids from an outside distributor, such as McKesson and AmerisourceBergen. Not only could Walmart pharmacies place another order with these outside vendors to make up the difference, they could have orders fulfilled by both Walmart and a third-party distributor at the same time. Even though Walmart had the ability to monitor orders to outside vendors for suspicious orders, it did not, which allowed Walmart pharmacies to exceed the already high thresholds simply by ordering drugs from a third party.

133. Walmart knew that its policies and procedures were insufficient to fulfill its obligations to prevent diversion of controlled substances. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It also stated that it was “TBD” when Walmart would develop such a system. In 2014, Walmart acknowledged that it still lacked a compliant monitoring program and that it had “no process in place” to comply with government regulations and that this created the “severe” risk of “financial or reputational impact to the company.” At this point, Walmart still had no written policies and procedures that required orders of interest to be held and investigated.

134. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy’s order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

135. For almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). An order under this minimum threshold would not be flagged regardless of changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg. per month to 7,999 per month without any order being flagged or reviewed. Thus, even Walmart’s “enhanced” order monitoring program failed to provide effective controls against diversion.

136. According to data from the ARCOS database, between 2006 and 2014, Walmart pharmacies in Alaska bought 14,814,620 dosage units of oxycodone and hydrocodone. Two Walmart pharmacies, one in Anchorage and one in Wasilla, each bought over 3 million dosage

units of oxycodone and hydrocodone in this time period. The volume of opioids Walmart brought into the State was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

137. Walmart funneled far more opioids into Alaska than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walmart (especially with its pharmacy dispensing data), would have alerted Walmart to potential diversion of opioids.

138. In an email sent to Brad Nelson, former Walmart Senior Manager for Controlled Substances, from C. Scott Ortolani, a Walmart Market Director, Mr. Ortolani described a conversation that Mr. Ortolani had with an inspector who voiced concerns that Walmart's "more liberal policies on dispensing pain meds" were making Walmart a "funnel" for Schedule II controlled substances such as opioids.

139. Even though Walmart was required pursuant to a Memorandum of Understanding entered into with the U.S. Government to report all controlled substance prescriptions it refused to fill to the DEA, Walmart did not initially develop a system to share this information with its own pharmacists. During a recent trial in the federal MDL (in which a jury found Walmart liable for public nuisance), Mr. Nelson testified he was not aware of Walmart having any systems that would show pharmacists at one store if a customer's opioid prescription had previously been rejected as illegitimate at another Walmart store.

140. Even when Walmart pharmacists suspected that an individual prescriber was consistently writing prescriptions for other than a legitimate medical purpose, they could not use a "blanket" refusal to fill all prescriptions from that prescriber. Instead, Walmart pharmacists were required to evaluate every prescription on a case-by-case basis, even for those prescribers who

Walmart pharmacists identified as operating pill mills. A 2011 document from Walmart Regulatory Affairs regarding the “Proper Prescriber-Patient Relationship” stated, “Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill.” The prescription-by-prescription refusal to fill procedure was time-consuming and placed the burden on Walmart and Sam’s Club pharmacists, who were already under pressure to fill prescriptions quickly. Moreover, many red flags for diversion are based on prescribing patterns that are readily apparent from aggregate data — for example, the percentage of controlled substance prescriptions compared to non-controlled substances written by a prescriber — but not apparent based on an individual prescription.

141. Walmart’s pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Controlled substances were included in Walmart’s pharmacy incentive program until 2013. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart’s drive for speed, pharmacists often did not have enough time to review a prescription sufficiently and conduct the appropriate due diligence.

142. Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists’ focus misdirected. One internal email showed that in response to a question from a regional manager in 2015 about documenting pharmacists’ concerns about doctors believed to be

operating pill mills, Mr. Nelson wrote that: [REDACTED]

[REDACTED]

[REDACTED]⁵

Safeway

143. Upon information and belief, Safeway, by virtue of the dispensing data available to it, had actual knowledge of indicia of diversion, such as (1) individuals traveling long distances to see prescribers or fill prescriptions; (2) prescriptions for drug “cocktails” known for their abuse potential, such as oxycodone and benzodiazepine; (3) individuals arriving together with identical or nearly identical prescriptions; (4) pattern prescribing; and (5) purchasing their prescriptions with cash. However, Safeway ignored these obvious red flags.

144. Safeway refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Safeway failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Alaska.

145. Safeway was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

146. Given Safeway’s retail pharmacy operations, Safeway knew or reasonably should have known about the disproportionate flow of opioids into Alaska and the operation of “pill mills”

⁵ WMT_MDL_000232072 (e-mail from Brad Nelson to David Reitnauer (Feb. 13, 2015)).

that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, diversion.

147. The DOJ investigated Safeway regarding violations of the CSA at its Wasilla (and other) pharmacies. The investigation revealed a widespread practice of Safeway pharmacies failing to timely report missing or stolen controlled substances and resulted in a \$3 million settlement.

148. In addition, a Carr-Gottstein pharmacy located in Homer sold enough opioids from 2006 to 2014 for every one of its 52,049 residents to receive 46 10 mg. opioid pills. Another pharmacy in Juneau, population 30,777, received the equivalent of roughly 2.6 million 10 mg. opioid pills from McKesson between 2006 and 2014, enough for 83 10 mg. opioid pills for every resident.

Kroger

149. Although Kroger had access to significant information about red flags due to its vertical integration with its stores, it failed to use this information in order to more effectively prevent diversion.

150. First, Kroger did not develop and implement a formal SOM system until 2013. Kroger's internal documents noted that Kroger was [REDACTED]

151. Prior to developing a formal SOM system, Kroger's loss prevention team would monitor product movement and investigate suspicious activity, but this occurred only after the product had been shipped to its pharmacies and potentially dispensed to customers.

152. An internal Kroger document titled [REDACTED]

[REDACTED]

[REDACTED] as opposed to all instances of potential diversion, as the law requires.

153. Kroger appears to have assigned responsibility for reviewing “unusual orders” to the Pharmacy Manager, who had the ability to release the order. Kroger had computer-assisted ordering systems aiming to ensure it had enough supply of controlled substances and other drugs on hand. “Excessive purchase” information about individual pharmacies was forwarded to a “Pharmacy Coordinator,” who would either file a report internally or alert the Division Merchandiser to start an internal investigation.

154. It is unclear when Kroger developed “computerized statistical information” for purposes of “pending” orders for evaluation, but it contracted with an outside consultant in 2013. Even with that system in place, however, it apparently still allowed release of orders based simply on contacting one of its coordinators who would provide a reason such as “[n]ew customers” to clear an order. This occurred even though Kroger understood that its [REDACTED]

[REDACTED] As of October 2013, an internal document described [REDACTED]

[REDACTED]

[REDACTED]

155. Upon information and belief, Kroger, by virtue of the dispensing data available to it, had actual knowledge of indicia of diversion, such as (1) individuals traveling long distances to see prescribers or fill prescriptions; (2) prescriptions for drug “cocktails” known for their abuse potential, such as oxycodone and benzodiazepine; (3) individuals arriving together with identical

or nearly identical prescriptions; (4) pattern prescribing; and (5) purchasing their prescriptions with cash. However, Kroger ignored these obvious red flags.

156. Kroger refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Kroger failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Alaska.

157. Instead, on information and belief, Kroger implemented policies whereby pharmacists would be entitled to bonuses based on the number and speed of prescriptions filled, including prescriptions for controlled substances.

158. Kroger was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet it did not take meaningful action to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

159. Given Kroger's retail pharmacy operations, Kroger knew or reasonably should have known about the disproportionate flow of opioids into Alaska and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, diversion.

5. Defendants delayed a response to the opioid crisis by pretending to cooperate with law enforcement

160. When a distributor does not report or stop suspicious orders, or a pharmacy fails to maintain effective policies and procedures to guard against diversion, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses.

Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action — or may not know to take action at all.

161. Yet, at the end of January 2020, the *New York Times* revealed that Walgreens had not reformed its policies putting speed ahead of safety and pharmacists continued to feel pressed to do more with less. According to the article, pharmacists at Walgreens and Rite Aid stores “described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors.” The article explained that these pharmacists “struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies,” while “racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less.” Citing company documents, the article showed that Walgreens continues to tie bonuses to achieving performance metrics.

162. Walmart also claimed that it was eager to comply with the law. For example, a Walmart spokesperson claimed that: “We take record keeping seriously[,]” and “[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law.” Walmart also reportedly claimed to be cooperating with a federal investigation and “taking action to fix its opioid dispensing practices.” In fact, however, Walmart subsequently “acknowledged that it halted its cooperation in mid-2018.”

6. Multiple enforcement actions against the Chain Pharmacies confirm their compliance failures

163. The Chain Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Chain Pharmacies have been penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations,

these enforcement actions are the product of, and confirm, the failures of national policies and practices of the Chain Pharmacies that were in effect in Alaska.

Walgreens

164. On September 30, 2009, the DEA issued an Order to Show Cause (“OTSC”) against a Walgreens retail facility in San Diego, California, based in part on allegations that it was dispensing controlled substances, including opioids, to individuals that it knew or should have known were diverting the controlled substances. Although the Order addressed this specific location, the response, including Walgreens’s internal assessment of its compliance, or lack thereof, revealed systemic failures from which its pharmacies in the State would not have been exempt.

165. Similarly, in 2011, the DEA took Walgreens “to the woodshed” over its dispensing cocktail drugs and opioids to questionable out-of-state customers, customers with duplicate diagnoses, young people, and customers only paying cash. Many of these same red flags were highlighted in the 2009 Walgreens OTSC and resulting 2011 MOA, discussed below.

166. In April 2011, Walgreens entered into an MOA with the DEA arising from the San Diego OTSC and expressly agreed that it would “maintain a compliance program to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations,” including regarding the dispensing practices at all of its nationwide pharmacies.”

167. On September 14, 2012, however, the DEA also issued an Order to Show Cause and Immediate Suspension Order (“ISO”), described above against Walgreens’s distribution center in Jupiter, Florida, as well as an OTSC related to certain Walgreens pharmacies. Evidencing the existence of systemic failures, the ISO stated that, “[DEA’s] concerns with [Walgreens’s] distribution practices are not limited to the six Walgreens pharmacies [discussed in the ISO].”

168. In 2013, Walgreens agreed to the largest settlement in DEA history at the time — \$80 million — to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. The DOJ, in describing the settlement, explained that Walgreens’s “alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens’s retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone.”

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

170. As part of the 2013 MOA described above, Walgreens “acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations.” The 2013 MOA required Walgreens to, among other things, “maintain a compliance program in an effort to detect and prevent diversion of controlled substances,” as required by law.

171. Walgreens’s Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens’s Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011 — more than 10 times the average amount.

172. They increased their orders over time, in some cases as much as 600 percent in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens’s corporate officers turned a blind eye to these abuses. In fact, the long-term Controlled Substance Compliance Officer at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that [REDACTED]

[REDACTED]

[REDACTED] underscoring Walgreens’s attitude that profit outweighed compliance with the CSA or the health of communities.

173. Walgreens has also settled with a number of state attorneys general, including West Virginia and Massachusetts. The Massachusetts Attorney General’s Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and failed to use sound professional judgment when dispensing opioids and other controlled substances — despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

174. More recently, on May 4, 2022, Walgreens entered into a settlement agreement with the Florida Attorney General in connection with allegations of public nuisance, negligence, conspiracy, fraud, and violations of the Florida Deceptive and Unfair Trade Practices Act and Racketeer Influenced and Corrupt Organization Act, based on allegations that Walgreens distributed and dispensed prescription opioid pain medication improperly in a fashion that has

caused harm to the health of Florida residents and to the State. Walgreens paid \$683,000,000 to resolve these claims.

175. The actions against Walgreens as both a distributor and a retail pharmacy demonstrate it routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations governing the distribution and dispensing of prescription opioids.

Walmart

176. A prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber, even though she failed to provide the prescriber's DEA number. Despite the absence of information required by DEA regulations, the Walmart pharmacy would fill the prescription. By mid-November 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office, and advised "that somebody was fraudulently using [his] DEA number." Although he asked that his DEA number be blocked, the same pharmacy still filled two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filled notwithstanding that they were facially invalid," and that "the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."

177. In 2009, the DEA issued an OTSC seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

(1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

178. In addition, a 2011 MOA arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

179. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a “compliance program,” states that it is applicable to “all current and future Walmart Pharmacy locations.”

180. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program. Instead, systemic failures continued, and Walmart’s national corporate office not only failed to insist that Walmart implement adequate controls against diversion, but ignored concerns raised by Walmart pharmacists.

181. In December 2020, the DOJ filed a lawsuit against Walmart over its opioid dispensing and distribution practices. *United States of America v. Walmart Inc.*, No. 1:20-cv-01744 (D. Del.). After a multi-year investigation, and based on a review of millions of pages of documents, the DOJ alleged that Walmart pharmacists filled prescriptions issued by “known pill-mill prescribers” and filled “numerous prescriptions that, on their face, showed such obvious red

flags . . . that Walmart pharmacists would have known that the prescriptions had a very high probability of being invalid,” in addition to Walmart having a “grossly inadequate suspicious-order monitoring program.” Pharmacists or pharmacy managers would contact Walmart’s central compliance personnel for guidance on handling suspected pill mill doctors but felt that their “concerns are falling upon deaf ears.” Pharmacists repeatedly sought help from Walmart’s corporate office, to no avail. Walmart compliance officials failed to take action in response to these alarms. Instead, they repeatedly sent the same boilerplate response, stating that pharmacists must use their professional judgment but that they must continue to evaluate and refuse to fill on an individual, prescription-by-prescription basis, even in situations where other retail pharmacies had stopped filling any prescriptions from particular prescribers. As a result, Walmart and Sam’s Club pharmacies often became channels for illegitimate controlled substance prescriptions from known pill mills. Even in circumstances where a prescriber was under investigation by the DEA, Walmart’s compliance department informed pharmacists that would not be a reason to refuse to fill that prescriber’s controlled substance prescriptions.

182. Federal prosecutors have also taken action against five Walmart and Sam’s Club pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, “accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA.” A U.S. Attorney further explained that “[b]ecause of the pharmacies’ lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted.”

Safeway

183. In April 2014, the DEA learned that Safeway pharmacies in North Bend, Washington and Wasilla, Alaska did not notify DEA of losses of tens of thousands of hydrocodone tablets until months after Safeway discovered the pills were stolen by employees. The DOJ conducted an investigation that was later widened to review practices at all Safeway pharmacies nationwide between 2009 and 2014. The investigation revealed a widespread practice of Safeway pharmacies failing to report missing or stolen controlled substances in a timely manner.

184. On July 18, 2017, the DOJ and Safeway reached a civil settlement of allegations the company failed to report controlled substances that were missing from pharmacies in a timely manner. In connection with the settlement, Safeway agreed to pay the United States \$3 million and implement a compliance agreement reached with the DEA.

Kroger

185. On October 24, 2005, the DEA announced that King Soopers, City Market, and their parent company, Kroger, agreed to pay a record \$7 million settlement for systemic violations of the CSA by the company's pharmacies. In addition to the penalty, Kroger agreed to implement a pharmacy compliance program in all 1,900 of its pharmacies nationwide.

186. In connection with the settlement, the DEA Special Agent in Charge, Jeffrey Sweetin, stated: "This record settlement is a clear message that DEA will hold companies accountable for not safeguarding these potentially dangerous substances, as well as an acknowledgement by Kroger that their internal monitoring systems need to be changed."

187. On December 4, 2019, the DOJ announced that Kroger Limited Partnership and Kroger Pharmacy had agreed to pay the United States \$225,000 to settle civil allegations that it

violated the CSA more than a dozen times at its Rio Hill Center location in Charlottesville, Virginia.

188. Among other things, the United States claimed that Kroger #334 violated the CSA by improperly filling “office use only” prescriptions for Schedule II controlled substances; failed to make and keep DEA 222 order forms; improperly distributed a Schedule II controlled substance absent the required DEA 222 form; and failed to provide effective controls and procedures to guard against diversion of controlled substances.

V. THE EFFECTS OF THE OPIOID EPIDEMIC IN ALASKA

189. In 2008, the rate of prescription drug overdose deaths in Alaska was more than twice that of the United States overall (14.2 versus 6.5 per 100,000 persons, respectively).

190. In 2011, Alaska saw 66 fatal opioid overdoses; by 2016, that number reached 96, and by 2017, 107 — 582 deaths over those seven years.

191. More recently, Alaska has experienced a 68 percent increase in the number of drug overdose deaths between 2020 and 2021 — from 146 drug overdose deaths in 2020 to 245 in 2021. There were 140 fentanyl overdose deaths in Alaska in 2021. Alaska’s Chief Medical Officer, Dr. Anne Zink, stated: “This increase continues to be driven primarily by fentanyl, a very powerful opioid often found in counterfeit pills and a variety of illicit drugs, with six out of every 10 drug overdose deaths in Alaska involving fentanyl.”

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

193. As a result of the rise in illicit sources of opioids, areas surrounding Anchorage, Fairbanks, and Juneau have been designated as High Intensity Drug Trafficking Areas by the Office of National Drug Control Policy.

194. According to the National Survey on Drug Use and Health, an estimated 60,128 Alaskan adults, 11.5 percent of the State's population, need substance use disorder treatment.

195. Beyond overdoses, Alaska hospitals have struggled to deal with other effects of the opioid epidemic. Dealing with these impacts has become a new normal for doctors and administrators, who 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 associated with 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, and one doctor described it as surprising to see patients not affected by opioids.

196. 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 to 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. Between 2012 and 2017, Naloxone administrations by EMS more than doubled, from 8.0 per 1,000 EMS calls in 2012 to 17.7 per 1,000 EMS calls in 2017. Anchorage Fire Department paramedics and emergency responders administered Narcan for suspected overdoses 65 times from the start of January through the end of March 2022 and responded to 43 calls where Narcan had already been administered in a suspected overdose during the same time period.

197. In a single-day count in March 2019, 848 people in Alaska were receiving methadone in opioid treatment programs as part of their substance use treatment (an increase from 331 people in 2015) and 120 people were receiving buprenorphine as part of their substance use treatment (an increase from 91 people in 2015).

198. Diseases connected to injecting drugs, particularly hepatitis C, are another side effect of opioid and heroin addiction. According to Dr. Jay Butler, Alaska’s former 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.” 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.

199. Alaska’s younger population has also been drawn into the devastating effects of the opioid epidemic. In 2011, the Alaska Youth Risk Behavior Survey began monitoring prescription drug abuse (OxyContin, Percocet, Vicodin, Codeine, Adderall, Ritalin, Xanax). In 2015, 13 percent of female adolescents and 16 percent of male adolescents reported using prescription drugs without a doctor’s prescription. Students in grade 12 exhibited the highest prevalence of using prescription drugs without a doctor’s prescription (19 percent) followed by students in grade

10 (18 percent). During 2015–2016, respondents aged 18-25 also had a higher prevalence of reported misuse of prescription pain relievers in the past year.

200. 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 2,802, more than 50 percent — five times the national rate. In 48 percent of Alaska’s foster care placements, parental substance use was a factor. Grandparents have also been caring for children impacted by the opioid epidemic.

201. 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 who suffer from neonatal abstinence syndrome (“NAS,” also known as neonatal opioid withdrawal syndrome, or “NOWS”). A State of Alaska epidemiology study of births between 2004 through 2015 found that there was a 566 percent increase in babies diagnosed with NAS during that time period, from 15 in 2004 to 100 in 2015 — 541 infants in total over the 12-year period. According to Alaska maternal and child health epidemiologist and study author Abigail Newby-Kew, the study only looks at Medicaid-eligible births because that represents the most complete, long-term data set available. Therefore, these numbers do not represent the entire population.

202. 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.”

203. The full cost of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. The McDowell Group 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.

VI. STATUTES OF LIMITATION

204. No statutes of limitation apply to the State's public nuisance and Consumer Protection Act claims.

205. The State continues to suffer harm from the unlawful actions by Defendants.

206. The continued unlawful conduct by the Chain Pharmacies causes a repeated or continuous injury. The harms have not occurred all at once but have continued to occur and have increased as time progresses. The wrongdoing and unlawful activity by the Chain Pharmacies has not ceased. The public nuisance remains unabated. The conduct causing the harm remains unabated.

207. The Chain Pharmacies are also equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the State about their role in the oversupply of opioids and to conceal their unlawful conduct, by claiming that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor and/or dispenser status and to continue generating profits.

208. The State did not discover the nature, scope, and magnitude of the Chain Pharmacies' misconduct, and its full impact on the State, until it completed its Civil Investigative

Demand, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

VII. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF (Violations of the Alaska Consumer Protection Act)

209. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

210. Defendants engaged in trade or commerce in the State of Alaska.

211. The Alaska Consumer Protection Act 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).

212. The Alaska Supreme Court has determined 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 — in other words, whether 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).

213. Further, the Alaska Consumer Protection Act lists 57 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).

214. Defendants’ acts and practices were unfair under AS 45.50.471(a). These unfair acts or practices include, but are not limited to, failing to maintain effective controls against opioid

diversion by oversupplying opioids into Alaska while failing to create, maintain, and use an adequate compliance program; failing to investigate, report, and halt suspicious orders; filling suspicious orders; and failing to exercise due diligence to ensure the prescriptions they dispensed were for legitimate medical purposes.

215. In addition, Defendants' acts or practices were immoral, unethical, oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and violated public policy aimed at preventing diversion of controlled substances and preventing and treating addiction.

216. As a direct result of the foregoing deceptive acts and practices, Defendants obtained income, profits, and other benefits that they would not otherwise have obtained.

217. Defendants' acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

218. 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 of its concomitant crime and costs, and broken lives, families, and homes.

219. Defendants' acts and practices as alleged herein were motivated by a desire to retain and increase their market share and profits.

220. The State expressly disclaims that it is bringing any claim to enforce — directly or indirectly — the CSA or the ACSA.

221. Defendants' use of acts or practices in violation of the Alaska Consumer Protection Act warrant the maximum civil penalties under AS 45.50.551.

222. As a result of Defendants' conduct as alleged herein, Alaska consumers, including the State and its agencies, suffered and continue to suffer injury.

223. In addition to penalties and restitution, Defendants are liable for attorneys' fees and costs, including costs of investigation, under AS 45.50.537(d).

**SECOND CLAIM FOR RELIEF
(Public Nuisance)**

224. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

225. 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.

226. Defendants' conduct, as described in the Complaint, involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right by creating a public health epidemic in Alaska.

227. 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.”

228. 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.

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

230. Defendants' conduct is prescribed by statutes and regulations, including the Alaska Consumer Protection Act, the ACSA, the CSA, and regulations incorporated therein.

231. Defendants violated the standard of conduct set forth in the CSA and ACSA 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 Consumer Protection Act through their unfair and deceptive practices described in this Complaint.

232. The State expressly disclaims that it is bringing any claim to enforce — directly or indirectly — the CSA or the ACSA.

233. 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.

234. 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.

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

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

237. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the complaint.

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

239. Defendants' actions were, at the very least, a substantial factor in the public health crisis that followed and has reached a state of emergency. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' 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 be much less severe.

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

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

PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against Defendants as permitted by Alaska law, as follows:

1. For a declaration that each Defendant has violated the Alaska Consumer Protection Act;

2. For an injunction pursuant to AS 45.50.501 enjoining Defendants from engaging in any acts that violate the Alaska Consumer Protection Act, including, but not limited to, the unfair and deceptive acts and practices alleged in this Complaint;

3. For restoration of money Defendants obtained from consumers under AS 45.50.501(b);

4. For civil penalties in the amount of \$25,000 for each and every violation of the Alaska Consumer Protection Act under AS 45.50.551;

5. For an injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

6. For an order directing Defendants to abate the public nuisance;

7. For costs, interest, and attorneys' fees; and

8. For all other relief deemed just by the Court.

DATED this 16th day of June, 2022.

Respectfully submitted,

BIRCH HORTON BITTNER & CHEROT
Attorneys for Plaintiff

By: 

David Karl Gross, ABA #9611065
Mara E. Michaletz, ABA #0803007
dgross@bhb.com
mmichaletz@bhb.com

STATE OF ALASKA
Treg R. Taylor, Attorney General
Margaret Paton Walsh, ABA #0411074
margaret.paton-walsh@alaska.gov

MOTLEY RICE LLC
Linda Singer (*pro hac vice* to be submitted)