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THIRD JUDICIAL DISTRICT COURT
SALT LAKE COUNTY, UTAH

STATE OF UTAH, Plaintiff, v. **WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; WALGREEN ARIZONA DRUG CO.; THE KROGER CO.; SMITH'S FOOD & DRUG CENTERS, INC.; RITE AID HDQTRS. CORP.; THRIFTY PAYLESS, INC.** Defendants.	**COMPLAINT** Case No. _____ Discovery Tier 3 Jury trial demanded. Judge:_____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. The Attorney General brings this action pursuant to his *parens patriae*, constitutional, statutory, and common law authority to prevent future harm and to redress past wrongs by Defendants Walgreens Boots Alliance, Inc., Walgreen Co., Walgreen Arizona Drug Co. (collectively "Walgreens"), the Kroger Co., Smith's Food & Drug Centers, Inc. (collectively "Kroger"), and Rite Aid Corporation, Rite Aid Hdqtrs. Corp., and Thrifty Payless, Inc. (collectively, "Rite Aid").

2. This case is part of the State's ongoing effort to combat the worst human-made epidemic in modern medical history—the overuse, misuse, and diversion of opioids. As a direct and foreseeable result of Defendants' conduct, communities across the nation, including the State, 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.[1] 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. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, but drug overdoses also rose to become the leading cause of death for Americans under 50 years old. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak.

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

[1] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

strategy, but from distributors' and pharmacies' equally deliberate efforts to evade restrictions on opioid distribution and dispensing.

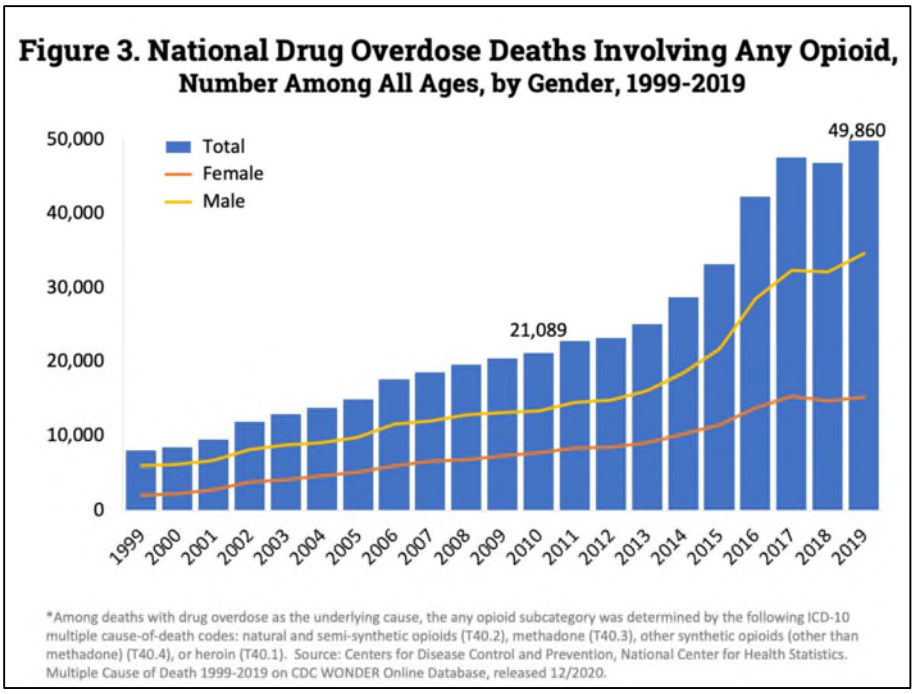
4. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month. In 2014 alone, the volume of opioids sold in Utah (114,047,848 pills) would provide every state resident roughly 34 pills. Defendants Kroger and Walgreens were the largest purchasers (and ultimately, sellers) of opioids in the State and Rite Aid was also among the largest buyers. Oxycodone and hydrocodone are two of the most frequently diverted opioids. Collectively, Defendants purchased, and by extension, sold, more than **300.6 million** dosage units (generally, pills) of these opioids between 2006 and 2014.[2]

5. The increased volume of opioid sales correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse and misuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

6. 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 twelve 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

[2] The opioid purchases disclosed in the data serve as an effective proxy for the opioids dispensed by the retail pharmacies, which have no incentive to purchase drugs they do not plan to sell. The data derives from the information for the years 2006 to 2014 made public from the federal Drug Enforcement Administration ("DEA") system of records, known as the "Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)," to which all manufacturers and distributors of controlled substances are required to report each transaction in these drugs.

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. Utah has been hit hard by the opioid epidemic, with lives lost in the state to drug overdoses at a rate that is higher than the national average.[3] In 2018, Utah Naloxone Executive Director, explained: "Every single day in the state of Utah at least one person on average

[3] Ctr. for Disease Control & Prevention, Morbidity and Mortality Report, December 28, 2018, *Drug and Opioid-Involved Overdose Deaths - United States*, 2013-2017, https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w#T1_down.

we're losing to an opiate overdose with where our numbers are."[4] The Utah Department of Health estimated, based on CDC data, that "[o]n average in Utah a year, 323 people die from a prescription opioid drug overdose, 156 die from a heroin overdose, and 88 people die from synthetic opioid overdose."[5]

9. 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. As the Attorney General put it, in describing the Utah Opioid Task Force initiative, the people "we are losing" are not a number; "those we are losing are many people we love."[6] And, "[t]he reality of the opioid epidemic affects every family, community, and city in the nation."[7] Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Further, overdose deaths, while tragic, are not the only consequence. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Opioid-related in-patient hospitalizations increased alongside the opioids distributed and sold in Utah. Emergency room visits have also increased, as have emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

10. 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. Many opioid users, having become addicted to but no longer able to obtain prescription opioids or trapped in a cycle of addiction that causes those

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[4] Lauren Handley, Study: Heroin Overdoses Skyrocketing in Utah, Fox13 Local News (Feb 26, 2018), https://fox13now.com/2018/02/26/study-heroin-overdoses-skyrocketing-in-utah/
[5] Utah Dept. of Health, Opioids, https://vipp.health.utah.gov/opioid-overdoses/#:~:text=On%20average%20in%20Utah%20a,die%20from%20synthetic%20opioid%20overdose.
[6] Office of the Attorney General, Utah Opioid Task Force, https://attorneygeneral.utah.gov/initiatives/utah-opioid-task-force/
[7] *Id.*

who suffer from the disease to need stronger and more potent drugs, have turned to heroin, fentanyl, and other illicit drugs. According to the American Society of Addiction Medicine, 80% 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.

11. The damage inflicted cuts across ages and generations. Children are displaced from their homes, families broken apart, and even infants are not immune from the epidemic. The State, like the nation, has seen a dramatic rise in babies born dependent on opioids due to prenatal exposure.

12. The conduct of alleged herein 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 Utah 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.

13. This devastation in the State was created by opioid manufacturers, distributors, and Chain Pharmacies, who worked together to dismantle the narcotic 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 protections designed to protect the public so more opioid drugs could be sold and the manufacturers, distributors, and Chain Pharmacies could reap the profits therefrom.

14. The success in extending the market for opioids to new patients and conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, misuse, and injury. Pharmacy chains fueled this epidemic by supplying a black market for diverted opioids that predictably developed.

15. 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.

16. This suit takes aim at a substantial contributing cause of the opioid crisis: the Chain Pharmacies, which act as both self-distributors and the last link in the opioid supply chain—are critical gatekeeping roles between dangerous opioid narcotics and the public. Straddling two links of the supply chain, Defendants, as vertically integrated distributors and dispensers of opioids, have both detailed information and key position in the opioid supply chain making them uniquely positioned to halt the flow of opioids before they reached the streets. Yet instead of using the information they had to maintain effective controls against diversion, Defendants abdicated their responsibilities, utterly failing in their gatekeeper role and flouting their duties to protect public health and safety.

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

effective controls against diversion and instead actively contributed to the oversupply of such drugs and fueled an illegal secondary market. At the same time, corporate policies focused on speed and corporate profits, undermining even the evolving, but still deficient controls at their pharmacy stores. The result is both deeply troubling and entirely predictable: opioids flowed out of Defendants' warehouses and stores, and into communities throughout Utah.

18. Many of those harms cannot be undone or ever adequately compensated, but the financial cost to address this crisis has been, and will be, staggering. The costs are borne by the State and other governmental entities. 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. The State brings this action to hold Defendants accountable for their conduct and to abate the epidemic, which can be done. The State seeks injunctive relief, abatement, and any other relief within this Court's powers to redress and halt these unlawful practices.

II. PARTIES

A. PLAINTIFF

19. The State of Utah brings this action on its own and on behalf of its state agencies. The Attorney General is statutorily authorized to initiate and maintain this action and does so pursuant to Utah Code § 67-5-1.

B. DEFENDANTS

Walgreens Defendants

20. 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.

21. 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.

22. Walgreen Arizona Drug Co. is an Arizona corporation with its principal place of business in Deerfield, Illinois.

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

24. At least between 2006 and 2014, Walgreens self-distributed opioids to Walgreens's retail pharmacies located in Utah.

25. At all times relevant to this Complaint, Walgreens sold (dispensed) prescription opioids throughout the United States, including in Utah. 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 47 stores in Utah.

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

Kroger Defendants

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

28. [redacted]

[redacted]

29. Defendant Smith's Food & Drug Centers, Inc. ("Smith's") is an Ohio corporation with its principal place of business in Salt Lake City, Utah. Smith's, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and as a dispenser, including through 52 Utah stores. At all times relevant to this Complaint, Smith's distributed and dispensed prescription opioids throughout the State. Smith's currently is a subsidiary of Kroger Co.

Rite Aid Defendants

30. Defendant Rite Aid Corporation ("RAC") is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

31. Defendant Rite Aid Hdqtrs. Corp. is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid Hdqtrs. Corp. and Defendant Rite Aid Corporation, by and through their various DEA registered subsidiaries and affiliated entities, conduct business as licensed wholesale distributors and pharmacy operators.

32. Rite Aid Corp. acquired Thrifty Payless, Inc. in 1996 and the Thrifty Payless pharmacies do business as Rite Aid.

33. Thrifty Payless, Inc. is a California corporation with its principal place of business in Camp Hill, Pennsylvania. During the relevant time, Thrifty Payless, Inc. distributed and sold (dispensed) opioids in Utah, including through more than 26 Utah stores.

34. Defendants Rite Aid Corporation, Rite Aid Hdqtrs. Corp., and Thrifty Payless, Inc. are collectively referred to as "Rite Aid."

Agency and Authority

35. 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.

III. JURISDICTION AND VENUE

36. This Court has subject matter jurisdiction over this matter pursuant to Utah Code § 78A-5-102(1).

37. The Attorney General has authority to bring this action pursuant to Utah Code §§ 67-5-1(2), 76-10-806, and 13-11-17(1).

38. Personal jurisdiction over Defendants is proper under the Utah Long Arm Statute as codified in Utah Code §§ 78B-3-201, 78B-3-205. This Court has personal jurisdiction over Defendants because each Defendant entity is, or was during the relevant time period, licensed to do business in Utah; is transacting or has transacted business in Utah; or has other significant contacts with Utah. Each Defendant has sufficient contacts with Utah to give rise to the current action, has continuous and systematic contacts with Utah, or has consented either explicitly or implicitly to the jurisdiction of this Court. Because of each Defendants' contacts with the State of Utah, exercise of personal jurisdiction in this forum would not offend traditional notions of fair play and substantial justice. Additionally, Smith's has its principal place of business in Salt Lake.

39. Venue is proper in Salt Lake County because Smith's has its principal place of business, and therefore resides, in Salt Lake City. Utah Code § 78B-3-307(3). In addition, some part of the cause of action arose in Salt Lake County. Utah Code § 78B-3-307(1).

40. There is no federal subject matter jurisdiction over this action. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. Section 1332(a) because the State of Utah is not a citizen of any state, so that there is no complete diversity.

41. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the State does not bring this case as a class action or as a mass action, and expressly and permanently disavows the existence of any alleged class or mass. The State expressly and permanently does not, and disavows, any proposal to try its claims with 99 other persons. The statements in this paragraph are controlling notwithstanding anything allegedly to the contrary in this complaint.

42. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because no claim in this petition arises under the Constitution, laws, or treaties of the United States. To the extent any federal law or proceeding is referenced, these allegations do not state any federal claim or raise any federal question but rather are factual allegations. The statements in this paragraph are controlling notwithstanding anything allegedly to the contrary in this complaint.

43. In addition, and for the sake of clarity, under no circumstance is the State bringing this action against, or bringing an action or claim of any kind directed to, any federal officer or person acting under any officer of the United States for or relating to any act under color of such office; nothing in this Complaint raises such an action or claim, and all such claims, actions, or liability, in law or in equity, are denied and disavowed in their entirety. Specifically, and without limitation, nothing in the State's Complaint seeks to bind any Defendant, in law or in equity, or to otherwise impose any liability or injunction, related to any United States government contract.

44. Finally, also for the sake of clarity, this is not a suit for personal injuries. The State is not asserting any medical malpractice claim, nor is any cause of action asserted in this Complaint based upon alleged personal injuries relating to or arising out of health care.

IV. FACTUAL ALLEGATIONS

A. Defendants' Conduct Created an Abatable Public Nuisance

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

46. The public nuisance—i.e., the opioid oversupply and 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.

47. 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. These responsibilities exist independent of any Food and Drug Administration ("FDA") or Drug Enforcement Administration ("DEA") regulation to ensure that their products and practices meet both federal and state laws and regulations. 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.

48. 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" resulting 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.

49. Multiple sources impose duties on Defendants to report suspicious orders and not to ship those orders unless due diligence disproves those suspicions.

50. First, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Utah 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.

51. Second, Defendants are prohibited under Utah law from engaging in unconscionable acts and practices. *See* Utah Code Ann. §§ 13-11-2, 13-11-5. To that end, Defendants' conduct in flooding the market with opioids, failing to maintain effective controls against diversion, and fueling an illicit black market injures consumers and is an unconscionable practice under the CSPA. This is particularly true given that, at the same time, Defendants voluntarily undertook duties,

through their statements to the media, regulators, and the public at large, professing their commitment to taking precautions to prevent drug diversion and to solving the opioid epidemic. 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.

52. Third, through the Utah CSA and the Utah Pharmacy Practice Act, Defendants are subject to statutory obligations enacted to prevent oversupply and diversion into the illicit market — legal duties specifically designed to protect the public health and safety. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and retail pharmacies should not fall. Together, these laws set standards of care that make clear that wholesalers of controlled substances and retail pharmacies alike possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

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

54. As wholesalers, Defendants must obtain a registration from the Division of Occupational and Professional Licensing ("DOPL") to distribute or dispense controlled substances in the State. The Utah CSA requires that registration of distributors be consistent with the public interest, which in turn, requires the registrant to have "established effective controls against

diversion" and "maintained effective controls against diversion of controlled substances and any Schedule I or II substance compounded from any controlled substance into other than legitimate medical, scientific, or industrial channels." Utah Code Ann. § 58-37-6 (3)(a)(iii).

55. The Utah CSA and the Utah Pharmacy Practice Act, Utah Code Ann. § 58-17b-101, et seq., which also regulates distribution and sale of controlled substances, also incorporate and reference federal law regarding the marketing, distribution, and sale of prescription opioids. See, e.g., Utah Code Ann. § 58-17b-601(1)(b) (Division rules are consistent with regulations of the Drug Enforcement Administration); Utah Code Ann. § 58-17b-618 ("The entities licensed under Sections 58-17b-301 and 58-17b-302 shall comply with all state and federal laws and regulations relating to the practice of pharmacy."); Utah Code Ann. § 58-37-6(3)(d) (entitling distributors compliant with federal registration requirements to obtain state licensure). Thus, in order to operate in compliance with Utah laws and regulations, Defendants must meet these requirements and also comply with the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801, et seq., which was enacted in 1970. The federal CSA requires distributors' operations must be "consistent with the public interest," 21 U.S.C. § 824(a)(4), and "public health and safety." 21 U.S.C. § 823(b). Under the CSA, distributors and pharmacies are required to register with the DEA to distribute and/or dispense controlled substances under the CSA. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100; 28 C.F.R. § 1301.71.

56. Recognizing a need for greater scrutiny over controlled substances due to their potential for misuse and danger to public health and safety, the United States Congress enacted the CSA in 1970. Requirements under federal law, both independently paralleled and incorporated in Utah law, are clear and exacting. Enacted in 1970, the CSA and its implementing regulations created a "closed system" of distribution; every entity that handles controlled substances is required

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

57. 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 misuse 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.

58. As federal registrants, Defendants are required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. This includes a duty to

monitor, detect, report, investigate, and refuse to fill suspicious orders unless and until due diligence had eliminated the suspicion. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74.[8]

59. As such, 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."

60. 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.

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

61. 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).

62. 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.

63. In addition to their duties as distributors, Defendants also had a duty to monitor and report suspicious activity in their retail pharmacy operations.

64. 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 cannot absolve themselves of their own obligations by attempting to place unilateral responsibility on their agents.

65. Under the CSA, "[t]here is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances." *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020), *clarified on denial of reconsideration*, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020), *and cert. denied*, 18-OP-45032, 2022 WL 278954 (N.D. Ohio Jan. 31, 2022). DEA's agency "decisions interpreting its regulations, routinely" involve "a 'red flag analysis," and DEA "has even articulated the specific elements of a *prima facie* violation of a pharmacy-registrant's responsibility under 21 C.F.R. § 1306.04(a) using the term 'red flag.'" *Id.*

66. "A 'red flag of diversion' is "'a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription.'" *In re Nat'l Prescription Opiate Litig.*, 2022 WL 671219, at *2 n.2 (N.D. Ohio Mar. 7, 2022) (quoting *Holiday CVS, L.L.C.*, d/b/a CVS/Pharmacy Nos. 219 & 5195 Decision and Order, 11 Fed. Reg. 62,316 at 62,341 (DEA Oct. 12, 2012).

67. 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) patient obtaining multiple opioid prescriptions from different prescribers; (c) patient 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) a patient 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. Some prescriptions are so suspicious that they "present[ ] a collection of red flags that no reasonable and prudent pharmacist could resolve so as to lawfully fill the prescriptions." *In re Nat'l Prescription Opiate Litig.*, 2022 WL 671219, at *2 (quoting *Holiday CVS, L.L.C.*, d/b/a CVS/Pharmacy Nos. 219 & 5195 Decision and Order, 11 Fed. Reg. 62,316 at 62,320).

69. Chain pharmacies also exert control over their agents, including the responsibility to ensure they comply with applicable laws and regulations in all dispensing of controlled substances. Under 21 C.F.R. § 1306.04(a), "[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." "A violation of the corresponding responsibility occurs when a person knowingly fills or allows to be filled an illegitimate prescription." *In re Nat'l Prescription Opiate Litig.*, 18-OP-45032, 2022 WL 671219, at *3 (N.D. Ohio Mar. 7, 2022).

70. "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") stated in a recent lawsuit against, 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 filing 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).

71. DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."

72. At the same time, "[m]any of the red flags that [DEA] examines (which a registrant should have at least identified and, if possible, resolved) include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist about the prescription." *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d at 630.

> In other words, some prescriptions are not suspicious on their face but raise bright red flags when compared with other prescriptions in a database. One example of such a red flag is " 'pattern prescribing,' defined as 'prescriptions for the same drugs, the same quantities[,] coming in from the same doctor." *Holiday CVS*, 77 FR at 62344. Identifying prescriptions presented over time for the same drugs or combinations of drugs, in the same quantities, issued by the same doctor (and possibly presented to different pharmacists in different stores owned by the same pharmacy), would test the limits of human memory; this red flag would be nearly impossible for any individual pharmacist to discern absent some global mechanism for reference to other prescriptions. However, given that a ***pharmacy-registrant*** is required to collect the specific data needed to identify exactly such a pattern, the pharmacy—not the pharmacist—is in the best position to identify such a red flag (or at least provide the pharmacist with data reports to do so). Indeed, the fact that the DEA has revoked registrations of ***pharmacies*** for failure to identify such red flags necessarily means pharmacies are required to look for them, which can only be done by putting into place systems to identify them.

Id. (emphasis in original).

73. The CSA also imposes important record-keeping 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).

74. 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. Indeed, the "CSA ***explicitly*** requires pharmacies to collect prescription data and use it to monitor for questionable prescriptions that might lead to diversion." *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 625 (N.D. Ohio 2020), *clarified on denial of reconsideration*, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020), and *cert. denied*, 18-OP-45032, 2022 WL 278954 (N.D. Ohio Jan. 31, 2022) (emphasis in original).

75. Simply put, chain pharmacies "cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled." *Id.* at 631. "Possessing, yet doing nothing with, information about possible diversion would actually ***facilitate*** diversion, and thus violate the CSA's fundamental mandate that "***All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.***'" *Id.* (quoting 21 C.F.R. § 1301.71(a)).

76. Rather, 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.

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

77. 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.

78. Under the Utah Pharmacy Practice Act, DOPL "shall make rules relating to the operations and conduct of facilities, individuals, and entities which are regulated" thereunder, the purpose of which is "to protect the public health, safety, and welfare" and which are to be consistent with the DEA's regulations, as well as other "laws relating to activities and persons regulated under" the statute. Utah Code Ann. § 58-17b-601(1)(a). Retail pharmacies must obtain a license from DOPL to operate in Utah, pursuant to which they must abide by operating standards designed to protect the public health, safety, and welfare. *See* Utah Code Ann. § 58-17b-302 & -306. Utah regulations provide that a pharmacy must "be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility." Utah Admin. Code R156-17b-614a(1)(d).

79. Utah regulations provide that a pharmacy may be sanctioned for misconduct, including, but not limited to violating the Utah CSA, the federal CSA, or their respective implementing regulations, or violating any other federal or state law relating to controlled substances. Utah Admin. Code R156-17b-402(20) & (80). Further, under Utah regulations, "failing to maintain controls over controlled substances that would be considered by a prudent licensee to be effective against diversion, theft, or shortage of controlled substances" is "unprofessional

conduct," by a pharmacy, for which it may face penalties, Utah Admin. Code R156-17b-402(82); R156-37-502(4); *see also* Utah Admin. Code R156-3717b-502(6) (providing that "unprofessional conduct" includes, among other things, "failing to abide by all applicable federal and state law regarding the practice of pharmacy"). Ultimately, "[w]henever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization." Utah Code Ann. § 58-17b-302(6).

80. 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.

81. 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.

82. 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 obligations to prevent diversion and to report and take steps to halt suspicious orders.

83. As described above, the regulations in the CSA and Utah CSA 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. Opioids are recognized as having a "high potential for abuse," with use potentially leading to "severe psychological or physical dependence." *See* 21 U.S.C. § 812. Distributors' and pharmacies' 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.

84. 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.

85. In fact, trade organizations in which Defendants have actively participated have acknowledged that distributors have been responsible for reporting suspicious orders for more than 40 years. The National Association of Chain Drug Stores ("NACDS") is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Walgreens, Kroger, and Rite Aid each serve or have served on the Board of Directors of NACDS. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA"), and prior to 2000, known as the National Wholesale Druggists' Association

("NWDA")) is a national trade association representing distributors that has partnered with a trade organization the NACDS. The two groups viewed their relationship as a strategic "alliance."

86. In *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016), the HDA and NACDS submitted a joint amicus brief regarding the legal duty of wholesale distributors that acknowledged that "HDMA and NACDS members" had a duty to prevent diversion. Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." As described in Section VIII below, both the HDMA and NACDS have both long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society.".

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

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

of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances." 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.

89. In addition, 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.

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

91. 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).

92. In September 2007, the NACDS, among others, also attended a DEA conference at which DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens, specifically, registered for the conference.

93. 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 registrants for their compliance failures. For example, in 2007, 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 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.

94. Meanwhile, obligations of Distributors include common sense. 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 misused in the meantime.

95. DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[9] The DEA, among

[9] *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

others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion.

96. 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 a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

97. 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.

98. 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

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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); *East Main Street Pharmacy*, Affirmance of Suspension Order, 75 FR 66149-01 (October 27, 2010); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

such as "blues" (a term referencing Mallinckrodt opioids). Pharmacies' training materials and controls should assist pharmacists and technicians in the identification of such behaviors.

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

100. Additionally, DEA guidance includes, for example, the August 2014 Pharmacy Diversion Awareness Conference DEA hosted in Salt Lake City, Utah. The conference was "designed to address the growing problem of diversion of pharmaceutical controlled substances throughout the United States," on a second day, "for the convenience of the pharmacy community."[10] DEA's conference description notes that "[i]n addition to pharmacy robberies and thefts, pharmaceutical controlled substances are often diverted by way of forged prescriptions, doctor shoppers, or illegitimate prescriptions from rogue practitioners" and the "objective of this conference was to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity."

3. Defendants are uniquely positioned to guard against diversion.

101. 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 Utah law.

[10] https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2014/august_2014/utah/index.html

102. Chain Pharmacies not only make observations through their local front doors, but 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 DEA investigations and enforcement actions, they have specifically warned Chain Pharmacies to monitor their sales in relation to the size of the community serviced by its stores.[11] This is particularly important given that it is recognized that as to the supply of opioids increases, so does the incidence of overdose and death. They could also use this information to monitor potentially suspicious prescribers. Pharmacies must use the information available to them to guard against supplying 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.

103. 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.

104. 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 identified patterns of diversion. Each could and should have

[11] *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).

also developed tools and programs to alert their pharmacists to red flags and to guard against diversion.

105. The Chain Pharmacies also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. 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."

106. 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, complete access to information revealing the opioids prescriptions dispensed by 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.

107. 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.

108. 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 the public health and safety. Despite their legal obligations as registrants under the CSA and Utah law, the Chain Pharmacies allowed widespread diversion to occur—and they did so knowingly.

109. 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 and adequately 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.

110. 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.

111. 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.

112. Upon information and belief, the Chain Pharmacies also failed to respond effectively to concerns raised by their own employees regarding 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

113. Acting as both a distributor and a retail pharmacy chain, Walgreens self-distributed opioids to its own individual pharmacies. From 2006 to 2014 alone, Walgreens purchased more than 119.4 million dosage units of oxycodone and hydrocodone, accounting for 12.93 of the total volume sold to retail stores in the State. Of those opioids, self-distribution more than 99.3 million dosage unites, more than any other pharmacy chain, and comprising 10.76% of the total distribution volume in the State.

114. 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.

115. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas 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.

116. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas 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.

117. The first variation on this formula was in place until March 2007, even though 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.

118. DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though 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.

119. 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.

120. 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.

121. In September 2012, 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." DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that require it to report to 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, 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."

122. A Walgreen's Pharmacy Operations Distribution Center Manager, Kristine Lucas, testified that she warned Walgreen'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 . . . [12]

123. In the ISO, 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."

- Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[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."

- "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

[12] *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).

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). 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)(l and (e)(l). [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]."

124. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, 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." 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."

125. These failures reflect nationwide systemic failures of Walgreens's SOM system that impacted its distribution in Utah. 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 Utah. For example, in connection with Walgreens's Woodland, California distribution center—which was among those shipping opioids into to Utah, 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.

126. 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 all together.

127. 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.

128. 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.

129. 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.

130. 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.

131. 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."

132. 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.

133. 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, including IMS, for descriptive statistics around prescriber patterns,

Walgreens was not aware of any consistent reports written using that data. Walgreens did not make this information available to its pharmacists.

134. 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.

135. Meanwhile, 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 profit that the pharmacy generated. Controlled substances were included in Walgreen'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 Walgreen's drive for speed, pharmacists often did not have enough time to review a prescription sufficiently and conduct the appropriate due diligence.

136. 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 Utah than could have been expected to serve legitimate medical use, ignored other indicia of suspicious orders, and failed to maintain effective controls against diversion from its pharmacy stores. According to information from the ARCOS database, nineteen Walgreens pharmacies in Utah bought more than three million dosage units of oxycodone and hydrocodone from 2006 to 2014, while many of its stores purchasing was even higher: Utah Walgreens bought more than four million dosage units of these opioids, four bought more than five million dosage units, and two of

Walgreen's Utah stores bought more than six million dosage units, each, of oxycodone and hydrocodone. The information described above, along with the information known only to distributors such as Walgreens and sellers (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

Kroger

137. Kroger was the largest pharmacy buyer (and by extension, dispenser) in Utah from 2006 to 2014, purchasing more than 140.7 million dosage units of oxycodone and hydrocodone, two of the most frequently diverted opioids, during that time — 15.24% of the statewide volume. More than 81.6 million hydrocodone dosage units Kroger self-distributed, accounting for 8.84% of the wholesale volume in the State.

138. 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.

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

140. 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.

141. An internal Kroger document titled [redacted] as opposed to all instances of potential diversion, as the law requires.

142. 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.

143. It is unclear when Kroger developed a "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 still appeared to allow release of orders based simply on contacting the pharmacy coordinator and obtaining a reason such as "[n]ew customers" to clear an order. This occurred even though Kroger understood that its "SOM system will fail if individuals clear orders without adequate investigation." As of October 2013, an internal document described "rolling out the SOM program to all" distribution centers and acknowledged it currently lacked any system to prevent a pharmacy from going to Kroger's outside vendor, Cardinal Health, to order items "pended" by the SOM program.

144. 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 misuse 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.

145. 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 Utah.

146. 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.

147. 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.

148. Given Kroger's retail pharmacy operations, Kroger knew or reasonably should have known about the disproportionate flow of opioids into Utah 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.

149. Upon information and belief, Kroger did not make any suspicious order report of an order in the State between 2007 and 2014. Instead, Kroger funneled far more opioids into Utah, and out of its stores, than could have been expected to serve legitimate medical use and ignored other indicia of suspicious orders. In fact, three Smith's Drug pharmacies in Utah bought more than five million dosage units of oxycodone and hydrocodone each from 2006 to 2014. These including a store in Price, a city of 8,216 people, which purchased far more of these dangerous drugs than the average Utah pharmacy. All told, it bought enough oxycodone and hydrocodone during this time to supply 71 pills per person in the community. Over this same time period, nine Smith's Drug

pharmacies bought more than four million dosage units of these frequently diverted opioids, nineteen Smith's Drug pharmacies bought more than three million dosage units, and 36 Smith's Drug pharmacies bought more than two million. This information, along with the information known only to distributors and sellers such as Kroger (especially with its pharmacy dispensing data), would have alerted Kroger to potential diversion of opioids.

Rite Aid

150. Rite Aid, in Utah, bought more than 40.5 million dosage units of oxycodone and hydrocodone from 2006 to 2014, 4.39% of the total volume in the State during that time. It self-distributed Schedule III opioids until 2014, with the rescheduling of hydrocodone products in 2014. That volume included more than 18 million dosage units of opioids from 2006 to 2014 (1.96% of the statewide volume).

151. Rite Aid relied on a patchwork system, spread across multiple departments, rather than a centralized suspicious order monitoring system. Ultimately, that patchwork system made it nearly impossible for any order to be identified, much less reported, as suspicious. Rite Aid imposed a universal 5,000 dosage-unit (DU) threshold, the distribution employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only "review" of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (*i.e.*, that it was not a "fat-finger" error). If the pharmacy confirmed that the above-threshold order amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped.

152. As a result of the company's policies and procedures, Rite Aid did not—and indeed, could not—identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed,

was set at of 5,000 DUs, per national drug code (NDC), per order (although Rite Aid does not know why it was set at 5,000 DUs). Rite Aid stores typically ordered once per week, but some stores ordered twice per week and others ordered every two weeks. That means that at its lowest, the Rite Aid threshold was 10,000 DUs per month, per store, and at its highest it was 40,000 DUs per month, per store. Further, Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees whom the DEA coordinator at the Rite Aid's distribution center testified were not able to actually do so.

153. Rite Aid also had little to no records about past order history to determine if an order was suspicious. All Rite Aid distribution centers kept what was called a "Threshold Log," which contained in hard copy only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. But any use of the log to potentially identify suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

154. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions for those suspicious prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate "suspicious prescriber" information that it may have collected in determining whether an order from any location was suspicious.

155. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In documenting such efforts, Rite Aid stated as follows:

> *The purpose of this project is to develop effective controls against the diversion of controlled substances* and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must

> ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

156. In the end, however, Rite Aid never adopted the new SOM system because it stopped distributing controlled substances before this system could be implemented.

157. Upon information and belief, Rite Aid, 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 misuse 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, Rite Aid ignored these obvious red flags.

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

159. Rite Aid 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.

160. Given Rite Aid's retail pharmacy operations, Rite Aid knew or reasonably should have known about the disproportionate flow of opioids into Utah 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.

161. Not only did it fail to in its obligations concerning its own wholesale operations, Rite Aid conspired with McKesson to avoid suspicious order reporting. McKesson was Rite Aid's

exclusive wholesaler for Schedule II controlled substances, including opioids, during the relevant time period.

162. McKesson provided Rite Aid with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without conducting any due diligence. For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to—and did—increase the thresholds for *all* Rite Aid locations by 50%. McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could "let [McKesson] know" if McKesson "need[ed] to make any adjustments to current thresholds."

163. Rite Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite Aid's self-distribution SOM system, negating any constraints from Rite Aid's even limited internal controls.

164. Rite Aid pharmacies also dispensed opioids in violation of the Controlled Substances Act and accompanying regulations. Such conduct was a result of Rite Aid's lack of robust policies and procedures regarding dispensing controlled substances as well as Rite Aid's focus on profitability over its legal obligations and public safety.

165. Rite Aid's dispensing policies and procedures used at all its Rite Aid pharmacies nationally were deficient in many ways. A few examples are illustrative.

166. Despite acknowledging the opioid epidemic many years earlier, Rite Aid implemented a policy for dispensing "high-alert" controlled substances—including opioids—for the first time in 2013. The policy was little more than a piece of paper consisting of six steps: 1) Receive the prescription; 2) Validate the Prescription; 3) Validate the Prescriber: 4) Validate the Patient; 5) Decide to dispense or not to dispense; and 6) Report any suspicious activity. Yet Rite

Aid provided little to no guidance on how to perform the vague tasks and the policy was little more than words on a page.

167. It was not until 2015 that Rite Aid integrated its High Alert process into its dispensing software and started tracking "High Alert data" at the corporate level. The 2015 update was the first time Rite Aid was able to systematically document due diligence—to the extent any was actually done—performed before dispensing.

168. Rite Aid also did nothing to ensure that even its pro forma policies were being followed. Rite Aid did not meaningfully audit its pharmacies for compliance with its own controlled substances dispensing policies or compliance with the CSA's requirements regarding legal dispensing.

169. Even then, between 2015 and 2018, the corporate monitoring of prescriptions was limited only to certain drugs and according to limiting parameters that meant that Rite Aid's corporate monitoring only identified an extremely small subset of suspicious dispensing activity.

170. Rite Aid did not use the data to effectively comply with its legal obligations to prevent diversion and ensure only legal prescriptions were being filled at its pharmacies. For example, a review of the top pharmacies' percentage controlled to non-controlled was not something that was done before 2018.

171. Rite Aid provided its pharmacists no visibility into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

172. Rite Aid did not make it possible, much less easy, for pharmacists to share information about red flags, suspicious prescribers, and suspicious patients. For example, despite Rite Aid instructing pharmacists that it is a red flag for a prescriber not to take insurance, the only way a pharmacist would know the existence of such a red flag is "through word of mouth." In

addition, Rite Aid did not provide pharmacists any analytics from its system to identify cocktail prescription trends. As another example, Rite Aid pharmacists also did not have any way to identify pattern prescribing beyond the pharmacist's own personal knowledge.

173. 2015 was the first time Rite Aid started to track refusals to fill, though even then, pharmacists would refuse prescriptions without using the process and making record of them.

174. This lack of refusal information meant even if a prescription was routinely denied by numerous pharmacists because of the illegitimacy of the prescription, a Rite Aid pharmacist would not necessarily know that key fact or be able to take that information into account when performing due diligence.

175. Even when it did start to record refusals to fill through the red flag verification questions, Rite Aid pharmacies only refused to fill extremely small numbers of prescriptions. Rite Aid did not leverage the information about refusals to fill to help identify diversion.

176. Rite Aid also did little to identify suspicious prescribers such as those who operated pill mills. Before 2013, there was not a formal process for how pharmacists were to report prescribers whose prescribing was suspicious. Even after Rite Aid implemented such a process, it failed to communicate corporate analysis with its pharmacists, nor did it share with pharmacists the IQVIA/IMS data available at the corporate level. Thus, Rite Aid pharmacists were kept in the dark about information that would help them evaluate prescriptions. Ultimately, Rite Aid blocked an extremely low number of prescribers, meaning that despite allegedly empowering its pharmacists to make the ultimate decision whether to dispense a prescription, Rite Aid nearly simply ignored pharmacists' concerns about prescribers.

177. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies in Utah, but Rite Aid failed to utilize this information to effectively prevent diversion.

178. In contrast to its lack of robust policies to ensure only prescriptions issued for a legitimate medical purpose were dispensed, Rite Aid had numerous and detailed policies regarding metrics to ensure its profitability. These policies ensured that Rite Aid pharmacists did not have the time, resources, or support to adequately discharge not only their legal duties as pharmacists, but also their alleged duties under Rite Aid's own policies and procedures.

179. Illustrating Rite Aid's push to fill more prescriptions as its singular, driving focus, a 2011 internal document states: "[w]e must fill more prescriptions" and even describes Rite Aid's "future as a company" as "dependent on this fact…" Similarly, the same year, an internal Rite Aid PowerPoint presentation described the role of Rite Aid's Pharmacy District Managers, explaining, "Driving Top-line prescription sales through aggressive prescription growth – This is YOUR NUMBER 1 JOB!" (emphasis in original). Rite Aid also placed strict emphasis on its pharmacists filling prescriptions as quickly as possible.

180. The problem of illegal dispensing caused by Rite Aid's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Rite Aid's inadequate pharmacy staffing. Often, single pharmacists were left as the only pharmacist at a location for entire shifts. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.

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

181. Beginning as early as the 1990s, outside distributors, largely through the HDA, began to get together with the Chain Pharmacies through NACDS to discuss "concerns regarding statutory requirements to report to DEA what are commonly referred to as suspicious orders."

182. The DEA's suspensions of the registrations of three major distributors in 2007 lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communications between NACDS members and members of the HDA, described above, as well as the now-notorious Pain Care Forum ("PCF"), a forum run by opioid manufacturers. A goal of HDA, which it shared with NACDS, was to "develop a comprehensive DEA strategy" to avoid enforcement actions against distributors.

183. The NACDS and Defendants' other trade groups saw their role in influencing diversion policy as being one that was absolutely critical, considering all that was at stake. At times, these groups adopted militaristic strategies and used terminology ironically similar to the "War on Drugs," developing "task forces" and viewing the DEA's crackdown on distributors and chain pharmacies as an assault on the companies themselves. Only this time, the war was being waged against the very regulatory authorities and government entities fighting to deal with the ever-growing problem of misuse and diversion in this country.

184. Manufacturers' participation in Defendants' trade groups as a means to effectuate favorable policies is clear when evaluated in the context of how Defendants and other stakeholders viewed the DEA's attempts to curb the opioid epidemic.

185. Walgreens, like other chain pharmacies, recognized the importance of being able to control and influence trade groups such as the NACDS in the context of influencing policy related to opioid drug misuse and diversion. The efforts taken by the NACDS and other trade groups on

behalf of Defendants were so important to their bottom line that Defendants spared no expense in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

186. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill." NACDS and Defendants intended the Marino Bill to "tie the hands" of the DEA to actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in the opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, not the individual members." The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

187. The Marino Bill effectively removed DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. It also permitted a non-compliant registrant an opportunity to cure its noncompliance before DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

188. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."

189. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their

state drug monitoring program before filling controlled prescriptions. NACDS also fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications."

190. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring DEA to "work with the [Food and Drug Administration] FDA on all drug diversion issues," ostensibly on the grounds that the DEA's diversion enforcement activities – including "clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" were harmful in "leading to patients not being able to receive their medications." This purported concern, however, was industry code for impediments to sales.

191. NACDS and HDA agreed that the pharmacies should "be more aggressive" and "lead the charge" with respect to certain DEA issues. NACDS members coordinated regarding pharmacy diversion and "DEA red flags" through a "DEA Compliance Workgroup." Defendants further used a NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media set meetings with legislators seeking to "address the problems with DEA actions," and "collaborate with, and support others' efforts" including HDA.

192. NACDS members coordinated regarding pharmacy diversion and "DEA red flags" through a "DEA Compliance Workgroup." Defendants further used a NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to

controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media, set meetings with legislators seeking to "address the problems with DEA actions," and "collaborate with, and support others' efforts" including HDA.

193. The collaboration between Walgreens and other industry partners extended beyond their mutual interest in limiting regulations and enforcement that constrained their ability to sell opioids. Walgreens formed a joint venture with AmerisourceBergen, beginning in 2012, when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain from Walgreens's "purchasing synergies," through the companies' relationship. Given that Walgreens and its outside vendor considered themselves partners invested in one another's success, there existed even less incentive to turn away from the blind deference the Chain Pharmacies received when buying and selling controlled substances.

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

194. 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 misuse them or who sell them to others to misuse. 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.

195. In August of 2018, after journalists at the Washington *Post* disclosed information gleaned from the ARCOS data regarding the staggering number of opioids Walgreens distributed

and sold, Walgreens again publicly promoted itself as being and "ha[ving] been an industry leader in combatting this crisis in the communities where our pharmacists live and work." Walgreens further asserted that "Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients."[13]

196. In January 2020, Walgreens released a Board Report on Oversight of Risks Related to Opioids. There, it claimed that: "In recent years, the Company has implemented a number of operational changes that it believes have helped to reduce its risk with respect to its dispensing of prescription opioids. The Company is focused on the continuous improvement of its controlled substances compliance program, implementing enhancements to prevent, identify and mitigate the risk of non-compliance with federal and state legal requirements."[14] It went on to tout its "Good Faith Dispensing policy," as "provid[ing] the foundation for our pharmacists to understand their roles and responsibilities when dispensing prescriptions for controlled substances."[15]

197. 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,

[13] Aaron C. Davis & Jenn Abelson, *Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales*, Washington Post (Aug. 8, 2019), https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html.

[14] https://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf.

[15] *Id.*

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.

198. Rite Aid similarly claims to be committed to working with "both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States."[16]

199. Kroger, too, claims to be "committed to partnering with our associates, customers, communities and" other "companies, like" its outside supplier "Cardinal Health, to help solve the opioid epidemic."[17]

200. NACDS, in response to media coverage concerning pharmacy working conditions and safety concerns, said that "'pharmacies consider even one prescription error to be too many' and 'seek continuous improvement.'"[18] NACDS also claimed one should not "assume cause-effect relationships" between errors and the workload of pharmacists such as "distraught pharmacists" who conveyed concerns to state boards and associations "in at least two dozen states."[19]

201. The NACDS also filed an amicus brief supporting a motion to dismiss in the 2020 DOJ action referenced above.

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[16] Rite Aid, Pharmacy, Health Information, https://www.riteaid.com/pharmacy/health-information

[17] https://www.cardinalhealth.com/en/about-us/corporate-citizenship/combating-opioid-misuse/news/kroger-and-cardinal-health-to-co-host-drug-take-back-events.html

[18] Ellen Gabler of the New York Times, Pharmacists at CVS, Rite Aid and Walgreens Are Struggling With Understaffed and Chaotic Workplaces, Chicago Tribune (Feb. 3, 2020), https://www.chicagotribune.com/business/ct-biz-nyt-pharmacy-mistakes-20200201-wp2ftrt2sjhfvjwnmwbtnl3y3i-story.html

[19] *Id.*

202. Through the above statements made on their behalf by their trade association, and other similar statements assuring its continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but further affirmed that their conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic.

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

203. 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 Utah.

Walgreens

204. On September 30, 2009, 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.

205. Similarly, in 2011, DEA took Walgreens "to the woodshed" over its dispensing cocktail drugs and opioids to questionable out-of-state customers, customers with the 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.

206. In April 2011, Walgreens entered into an MOA with 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.

207. On September 14, 2012, however, 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 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]."

208. 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 misuse or 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 the conduct at issue included 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."

209. 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.

210. 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.

211. 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 ten times the average amount.

212. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, the long term Controlled Substance Compliance Officer at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the CSA or the health of communities.

213. 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.

214. More recently, on May 4, 2022, Walgreens entered into a settlement agreement with the Florida Attorney General in connection with allegations for 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.

215. 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.

Rite Aid

216. Confirming its systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions. As recently as January 2019, it paid $177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

217. In 2018, Rite Aid also agreed to pay a $300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

218. In 2017, Rite Aid paid $834,200 in civil penalties to resolve allegations by DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least 1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."[20] Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[21]

219. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

220. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

Kroger

[20] DEA, *Rite Aid Pays $834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act.

[21] *Id.*

221. On October 24, 2005, the DEA announced that King Soopers, City Market, and their parent company, Kroger, agreed to pay a record $7 million dollar 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.

222. 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."

223. 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.

224. 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.

C. The effects of the opioid epidemic in Utah

225. All Defendants fueled the opioid epidemic in Utah by failing to put in place appropriate anti-diversion procedures in their wholesale and retail pharmacy operations. This ongoing crisis of addiction, overdose, and death that has wracked Utah.

226. From 2000 to 2015, overall, Utah experienced a nearly 400% increase in deaths related to prescription drugs. The State was ranked in the top ten states for overdose deaths over the course of a decade. Between 2013 and 2015, Utah ranked seventh in the United States for drug

poisoning deaths, which have outpaced deaths due to firearms, falls, and motor vehicle crashes. Carbon and Emery counties have rates of fatal overdoses 2.5 times the national average.

227. In 2016, Utah was one of twenty-two states with an overdose rate higher than the national average. As the opioid crisis unfolded, Utah experienced 326 deaths in one year due to prescription opioids.

228. Further, in 2013, statistics showed that more people in Utah were killed by impaired driving due to prescription pills than from accidents involving drivers who were under the influence of alcohol.

229. According to a study published in 2020, between 2005 and 2014, opioid misuse was the leading cause of death in new mothers and pregnant women in Utah. Most of these deaths occurred after the babies were born. The study has been described as highlighting new mothers as a vulnerable group that has often been overlooked.

230. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. Opioid-related in-patient hospitalizations increased alongside the opioids distributed and sold in Utah. Emergency room visits have also increased. Further, as described above, the CDC estimates that for every opioid-related death, there are 733 non-medical users.

231. The misuse of opioids has injured Utah residents in other respects, including through increases in the number of chronic Hepatitis C and diseases related to injection drug use. In 2017, half of the people reporting acute Hepatitis C infections had a history of injection drug use. Overall, the rate of such infections is increasing, and in Utah is more than three times the rate nationally.

232. Oversupply of opioids also had a significant detrimental impact on children in Utah. There has been a dramatic rise in the number of infants who are born dependent on opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from opioids once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In Utah, the incidence of NAS more than doubled from 2008 to 2014 alone, increasing from 2.2 to 5.4 cases per 1,000 hospital births.

233. Children are also injured by the dislocation caused by opioid diversion, misuse, and addiction. In 2016, 2,363 Utah children were placed in foster care in the State, and parental substance use was a factor in 56% of these placements.

234. Nationally, opioids now outpace other sources of addiction in demand for substance use treatment. Utah is struggling to meet that need. According to the American Academy of Pediatrics, nearly 85% of people suffering from drug dependence in the state go untreated. In 2020, 176 deaths in Utah were attributed to prescription opioids.

235. As described above, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. A more recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Utah

communities and is taking the lives of individuals previously addicted to prescription opioids who turned to heroin and now heroin laced with fentanyl. In Utah, 147 people died of heroin in 2017, a dramatic increase from 55 lives cut short by heroin-related overdoses in 2010.

D. Any Statutes of Limitations are Tolled and Defendants Are Estopped from Asserting Statutes of Limitations as Defenses.

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

237. The continued tortious and 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.

238. The public nuisance caused by Defendants' oversupply and the diversion of opioids remains unabated, as does Defendants' conduct causing the nuisance.

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

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

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

VII. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Nuisance)

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

243. "A nuisance is anything that is injurious to health, indecent, offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property." Utah Code § 78B-6-1101.

244. In addition:

> A public nuisance is a crime against the order and economy of the state and consists in unlawfully doing any act or omitting to perform any duty, which act or omission:
>
> (a) annoys, injures, or endangers the comfort, repose, health, or safety of three or more persons;
>
> (b) offends public decency;
>
> (c) unlawfully interferes with, obstructs, or tends to obstruct, or renders dangerous for passage, any lake, stream, canal, or basin, or any public park, square, street, or highway;
>
> (d) is a nuisance as described in Section 78B-6-1107; or
>
> (e) in any way renders three or more persons insecure in life or the use of property.

Utah Code Ann. § 76-10-803.

245. The Attorney General is authorized to bring suit on behalf of the State and its citizens to abate a public nuisance. Utah Code § 76-10-806.

246. 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 Utah.

247. This conduct includes Defendants' oversupplying opioids into the state and failing to maintain effective controls against opioid diversion, including by:

a. Distributing, selling, and dispensing opioids in ways that facilitated and encouraged their flow into an illegal, secondary market;

b. Failing to report suspicious orders of controlled substances;

c. Shipping suspicious orders for prescription opioids without having cleared such orders through diligent investigations;

d. Filling and failing to identify or report prescriptions of opioids in the face of red flags that such opioids would be diverted;

e. Choosing not to effectively monitor for suspicious orders and/or prescriptions;

f. Choosing not to use, and share with their pharmacy stores and employees, the data and other information available to them to ensure that their pharmacists were able to identify and reject prescriptions that were likely to be diverted;

g. Choosing not to monitor their pharmacy stores to ensure that they did not dispense opioids that were likely to be diverted;

h. Putting in place policies and procedures that encouraged pharmacists to fill, rather than reject, suspicious prescriptions and incentivized speed and sales over compliance;

i. Choosing not to implement policies to monitor distributing and dispensing activities to adjust their policies regarding the controlling and prevention diversion;

j. Choosing not to utilize the data available to assess and control distribution and dispensing of suspicious orders and prescriptions; and

k. Enacting corporate policy at retail pharmacy locations willfully ignoring signs of diversion and pharmacy obligations pursuant to Utah law.

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

249. Moreover, Defendants' conduct is injurious to health, indecent, offensive, and interferes with the comfortable enjoyment of life or property." See Utah Code § 78B-6-1101.

250. Defendants have also omitted to perform duties with respect to the sale and distribution of opioids.

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

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

b. to be free from the negative health and safety effects of widespread illegal drug sales on premises in and around Utah;

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

d. to live or work in a community in which community members are not subject to widespread use, addiction, diversion, and misuse of narcotics.

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

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

b. has harmed and will continue to harm Utah neighborhoods and communities by increasing crime, and thereby interfering with the rights of the community at large;

c. is proscribed by Utah statutes and regulations;

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

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

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

254. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid misuse, diversion, addiction, overdose, injuries, and deaths;

d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers having lost the value of productive and healthy employees; and

f. Increased costs and expenses for Plaintiffs relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

255. Here, Defendants' conduct is prescribed by statutes and regulations, including, without limitation, the CSPA, the Utah Controlled Substances Act, and the Utah Pharmacy Practice Act.

256. Defendants violated the standard of conduct set forth in the Utah CSA by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances, by failing to report and reject suspicious orders of opioids, and/or failing to maintain effective controls against diversion, and violated the CSPA through their unconscionable practices described in this Complaint.

257. 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 and to implement effective policies and procedures, and use the information available to them, to guard against diversion, would create or assist in the creation or maintenance of a public nuisance.

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

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

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

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

262. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in an illegal, secondary market, and in the public health crisis that followed. Defendants controlled these actions and, therefore, willingly participated to a

substantial extent in creating and maintaining the public nuisance. Defendants had access to enormous amounts of data and information regarding the patterns of opioid distribution and dispensing, and each of the Defendants occupied a special position within the closed system of opioid distribution and dispensing, Defendants were in a unique position to assess and prevent diversion. Without Defendants' actions, opioid use, misuse, diversion, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or much less severe.

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

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

265. Public resources have been, are being, and will be consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the Utah public at large.

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

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

VIII. PRAYER FOR RELIEF

Plaintiff, State of Utah, prays that this Court enter judgment in its favor against each Defendant and:

i. Order Defendants to pay the expenses required to abate fully the nuisance they have caused; and

ii. Order such further relief as justice and equity may require**.**

IX. REQUEST FOR JURY TRIAL

Utah respectfully requests that all issues presented by its above Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

DATED this 28th day of June 2022.

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