THE STATE OF NEW HAMPSHIRE

MERRIMACK, SS. **SUPERIOR COURT**

STATE OF NEW HAMPSHIRE

V.

CVS HEALTH CORPORATION; CVS INDIANA L.L.C.; CVS PHARMACY, INC.; NEIGHBORCARE OF NEW HAMPSHIRE, LLC;
One CVS Drive
Woonsocket, Rhode Island 02895

RITE AID CORPORATION;
RITE AID HDQTRS. CORP.; RITE AID OF MARYLAND, INC., D/B/A RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.;
30 Hunter Lane
Camp Hill, Pennsylvania 17011

MAXI DRUG NORTH, INC.;
50 Service Road
Warwick, Rhode Island 02886

WALGREENS BOOTS ALLIANCE, INC.;
108 Wilmot Road
Deerfield, Illinois 60015

AND WALGREEN CO.
200 Wilmot Road
Deerfield, Illinois 60015

217-2022-CV-00690

DOCKET # _____

COMPLAINT

I. INTRODUCTION

1. The State of New Hampshire ("Plaintiff" or "the State") brings this action to prevent future harm and to redress past wrongs against Defendants CVS Health Corporation; CVS

Indiana L.L.C.; CVS Pharmacy, Inc.; NeighborCare of New Hampshire, LLC; Rite Aid Corporation; Rite Aid Hdqtrs. Corp.; Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.; Maxi Drug North, Inc.; Walgreens Boots Alliance, Inc.; and Walgreen Co. (collectively, "Defendants" or "Chain Pharmacies").

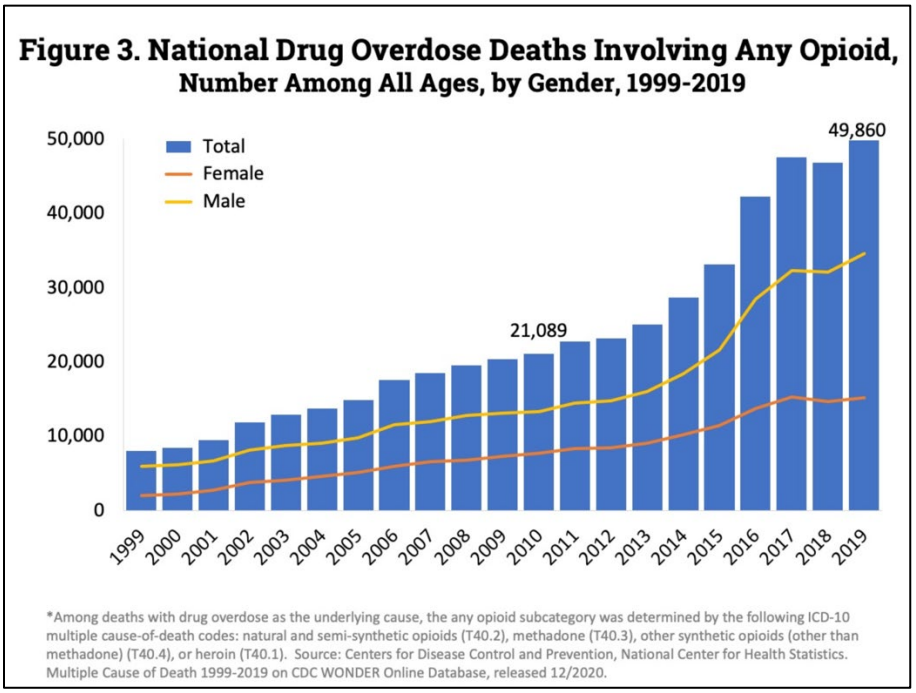
2. This case arises from the worst human-made epidemic in modern medical history—an epidemic of addiction, overdose, and death caused by Defendants' flooding the United States, including the State of New Hampshire, with prescription opioids, in violation of their common-law duties and obligations under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

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

4. According to *The Washington Post*'s review of a DEA database known as the Automation of Reports and Consolidated Orders System ("ARCOS"), from 2006 to 2014, 366,279,474 prescription opioids pills were supplied to New Hampshire. Defendants were well-aware that the overwhelming increase in opioids dispensed by their pharmacies, collectively and individually, was meeting more than an appropriate and legitimate market demand. Rather than continuing to sell, dispense, and profit from these highly dangerous drugs, they had a duty to investigate, report and stop some of their prescriptions and report them to the DEA and local law enforcement. Had they done so, the opioid epidemic in New Hampshire—and its enormous human and financial toll—would not have been as grave.

5. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United

States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the 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 estimated 75,673 opioid overdose deaths in the 12-month period ending in April 2021, up from 56,064 the year before.



6. 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.

7. 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

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.

8. The conduct of the manufacturers, distributors, and Chain Pharmacies caused the nation, and the State, to be awash in a flood of prescription opioids. This has had a profound impact on both morbidity and mortality, and those drugs have created an epidemic of addiction that has had severe and wide-ranging effects on public health and safety in New Hampshire 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.

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

10. In the words of Robert Anderson, who oversees death statistics at the CDC, "I don't think we've ever seen anything like this. Certainly not in modern times."

11. On October 27, 2017, the President declared the opioid epidemic a public health emergency.

12. New Hampshire has been hit particularly hard by the opioid epidemic. In 2018, the State's Office of Chief Medical Examiner ("OCME") reported 421 deaths caused by opiates/opioids. In 2008, by contrast, the OCME reported 117 deaths for all drugs. The number of reported deaths is almost certainly an underestimate.

13. On January 10, 2019, the Governor of New Hampshire, Christopher T. Sununu, issued Executive Order 2019-01, in which he stated that "New Hampshire continues to experience an opioid epidemic that has resulted in high levels of overdose deaths" and "has had a significant economic and societal impact upon the State." The Executive Order also stated that "a primary factor in the rise of opioid related deaths is excessive prescribing of prescription opioids, which increases the volume of non-naïve opioid users."

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

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

16. Children are being displaced from their homes and raised by relatives or placed in the State's care due to parents' addiction. Others lose the chance to go home. Unable to be

discharged from the hospital with their mothers, babies born with prenatal exposure are being placed in the care of the State or families or non-profits who do their best to care for them.

17. 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. Indeed, as discussed further below, the Chain Pharmacies have all paid millions of dollars to the Department of Justice ("DOJ") to resolve allegations of the same type of misconduct alleged herein, including misconduct in New Hampshire.

18. 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.

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

20. In particular, the Chain Pharmacies failed to design and operate systems to identify, halt, investigate and report suspicious orders of prescription opioids, maintain effective controls against diversion, and ensure that prescriptions were dispensed only for legitimate medical purposes, and instead actively contributed to the oversupply of such drugs and fueled an illegal secondary market.

21. Rather than complying with their obligations to do so, Defendants fraudulently concealed that they had failed to design and operate systems to identify, halt, investigate and report suspicious orders of prescription opioids, maintain effective controls against diversion, and ensure that prescriptions were dispensed only for legitimate medical purposes.

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

23. This explosion in opioid use and Defendants' profits has come at the expense of patients and residents and has caused ongoing harm to and a public nuisance in New Hampshire. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[1]

[1] Tr. for CDC Telebriefing: Guideline for Prescribing Opioids for Chronic Pain (Mar. 15, 2016), https://www.cdc.gov/media/releases/2016/t0315-prescribing-opioids-guidelines.html

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

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

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

II. JURISDICTION AND VENUE

27. The Court has subject matter jurisdiction over this action under RSA 491:7.

28. The Court has personal jurisdiction over Defendants because they regularly transact business in New Hampshire, and the claims asserted herein arise from their business conducted in New Hampshire.

29. Venue in this Court is proper because Defendants are non-residents. RSA 507:9.

30. The Complaint herein sets forth exclusively state law claims against the Defendants. The State does not plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law. The State expressly asserts that the only

causes of action asserted and the only remedies sought herein are founded upon the statutory, regulatory, common, and decisional laws of New Hampshire.

31. The claims asserted herein by the State consist of claims on behalf of the State, and the State does not assert any cause of action herein on behalf of any individual or any purported class of individuals.

III. PARTIES

The State

32. The State of New Hampshire brings this action through the Office of the Attorney General's Office.

33. The Attorney Generalate has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents and its municipalities. Opioid use and abuse has affected a substantial segment of the population of New Hampshire.

Defendants

34. 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.

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

CVS Defendants

36. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island. CVS Health, through its various DEA-registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and also operates retail stores, including in and around the State's geographical area, that sell prescription medicines, including opioids.

37. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. For much of the period the identification of and due diligence on suspicious orders for the entire country was to be performed at CVS Indiana L.L.C.

38. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy is a wholly owned subsidiary of CVS Health. CVS Pharmacy is both a DEA registered "distributor" and a DEA registered "dispenser" of prescription opioids and cocktail drugs and is registered to do business in New Hampshire.

39. Defendant NeighborCare of New Hampshire, LLC ("NeighborCare") operates pharmacies in New Hampshire. It is a subsidiary of Omnicare, Inc., which is in turn a subsidiary of CVS Health. NeighborCare purchased the most opioid dosage units and morphine milligram equivalents ("MMEs") of all retail and chain pharmacies in New Hampshire, and was also the largest pharmacy purchaser of higher dose opioid formulations. Opioid purchasing by this pharmacy increased dramatically between 2007 and 2009, with dosage units and MMEs increasing over 2.5-fold in just two years. Between 2006 and 2014, the pharmacy purchased over 307 million MMEs—enough to dispense approximately 35 opioid dosage units or 110 10mg pills of morphine to every man, woman, and child in Rockingham County.

40. Defendants CVS Health Corporation; CVS Indiana L.L.C.; CVS Pharmacy, Inc.; and NeighborCare of New Hampshire, LLC are collectively referred to as "CVS."

41. Between 2006 and 2014, CVS distributed 808,980,815 MMEs and bought 2,166,238,960 MMEs. CVS Store 640, located in Keene, New Hampshire, purchased 4,711,000 pills of oxycodone and hydrocodone—6.4 times the state average. CVS Store 639, located in Nashua, New Hampshire, purchased 4,328,400 pills of oxycodone and hydrocodone—5.9 times the state average.

Rite Aid Defendants

42. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

43. 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.

44. While Rite Aid Corporation may contend that it has no employees, upon information and belief it requested increases in its permitted amounts of prescription opioids (known as "thresholds") from McKesson Corp. on behalf of Rite Aid pharmacies. By requesting and submitting such increases, Rite Aid Corporation effectively engaged in the business enterprise of prescription opioid distribution. By doing so on behalf of its subsidiaries, Rite Aid Corporation exerted control over their operations. Rite Aid Corporation also directs and implements policies and procedures for dispensing controlled substances in its pharmacies and has direct involvement in directing, managing, or supervising the operations or the employees of at least some of its subsidiary companies. Rite Aid Corporation engages in the same business enterprise as Rite Aid

Hdqtrs. Corp. and other of its subsidiaries and/or exerts control over their operations such that they are alter egos of one another. RAC and Rite Aid Hdqtrs. Corp. disregard corporate formalities such that they are alter egos of one another.

45. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., is a subsidiary of Rite Aid Corporation and is itself a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At least until September 2014, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., distributed prescription opioids throughout the United States, including in New Hampshire.

46. During the relevant time period, Rite Aid entities also owned and operated pharmacies in the State through Defendant Maxi Drug North, Inc. ("Maxi Drug North").

47. Maxi Drug North purchased approximately 16 percent of the opioid dosage units in New Hampshire between 2006 and 2014.

48. Defendants Rite Aid Corporation; Rite Aid Hdqtrs. Corp.; Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.; and Maxi Drug North, Inc. are collectively referred to as "Rite Aid."

49. Between 2006 and 2014, Rite Aid distributed 980,648,714 MMEs and (excluding Maxi Drug North) bought 2,006,164,137 MMEs in New Hampshire. In addition, Maxi Drug North bought 2,272,999,653 MMEs, which was ranked number one in the State at 15.3 percent of all MMEs bought. Rite Aid Store 4138, located in Colebrook, New Hampshire, purchased 3,207,850 pills of oxycodone and hydrocodone—4.4 times the state average.

50. In 2018, Rite Aid sold a significant number (1,932) of its stores to Walgreens Boots Alliance, Inc.

51. In connection with Rite Aid's sale of certain of its stores to Walgreens Boots Alliance, Inc., Rite Aid retained the liabilities associated with those stores' (and Rite Aid's) conduct prior to the transfer, at least to the extent that conduct relates to the allegations in the Complaint.

52. Walgreens is responsible for purchased stores' conduct and their associated liabilities as they relate to the allegations in the Complaint from the date of the transfer from Rite Aid to Walgreens Boots Alliance, Inc. to the present.

53. Rite Aid retains the liability associated with the conduct of its stores that it did not sell to Walgreens Boots Alliance, Inc.

54. In the alternative, Walgreens is liable for the conduct of the Rite Aid stores purchased by Walgreens Boots Alliance, Inc. that pre- and post-date the transfer of the purchased stores from Rite Aid to Walgreens Boots Alliance, Inc.

Walgreens Defendants

55. 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.

56. 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.

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

58. At least between 2006 and 2014, Walgreens self-distributed opioids to Walgreens retail pharmacies located in New Hampshire.

59. At all times relevant to this Complaint, Walgreens sold (dispensed) prescription opioids throughout the United States, including in New Hampshire. 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 approximately 30 stores in New Hampshire.

60. Walgreen Co. was the DEA-registrant for each of Walgreens's distribution centers.

61. Between 2006 and 2014, Walgreens distributed 1,156,975,379 MMEs and bought 1,706,849,227 MMEs in New Hampshire. Walgreens Store 3520, located in Rochester, New Hampshire, purchased 7,676,100 pills of oxycodone and hydrocodone—10.5 times the state average.

IV. FACTUAL ALLEGATIONS

A. Defendants' Conduct Created an Abatable Public Nuisance

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

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

64. Defendants have the ability to help end the public nuisance, and the CSA 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 FDA or 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.

65. For example, Walgreens has admitted its role in the opioid epidemic and its ability to abate the public nuisance, stating it has the ability and responsibility to fight the opioid crisis in a time when addiction 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.[2] 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.

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

67. Under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding New Hampshire 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.

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[2] CDC, National Center for Health Statistics, *All Injuries*, https://www.cdc.gov/nchs/fastats/injury.htm (last visited June 21, 2022).

68. In addition, 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. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the CSA in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. Maintaining the closed system under the CSA and effective controls to guard against diversion is a vital public health concern. Controlled substances, and prescription opioids specifically, are recognized as posing a high degree of risk from abuse and diversion. When the supply chain participants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

69. Likewise, 21 C.F.R. § 1306.04(a) states that "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Thus, all Chain Pharmacies, because they are registrants and dispensers, must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner

acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."

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 DOJ's recent lawsuit against Walmart alleges, 21 C.F.R. § 1306.06 requires that a pharmacist's conduct, when filling controlled-substance prescriptions adhere to the usual course of a pharmacist's professional practice. The obligation to identify any red flags relating to a controlled-substances prescription, to resolve them before 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. Under the CSA, the duty to prevent diversion lies with the Chain Pharmacies, not the individual pharmacist. As such, although it acts through its agents, the pharmacy is ultimately responsible to prevent diversion. Further, as described above, the obligations under the controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration holder or not. It is unlawful for any person knowingly to distribute or dispense controlled substances other than in accordance with the requirements of the CSA and its implementing regulations, or in violation of state-controlled substances laws and regulations. The Chain Pharmacies are responsible "persons" under the CSA. They also exert control over their agents, including the responsibility to ensure they comply with applicable laws and regulations in all dispensing of controlled substances. Defendants cannot absolve themselves of their own obligations by attempting to place unilateral responsibility on their agents.

72. 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 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.

73. 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, including, on information and belief, in New Hampshire.

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

75. To ensure that controlled substances are not diverted, federal regulations issued under the CSA mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled

to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other indicia of potential diversion may include, for example, ordering the same controlled substance from multiple distributors.

76. 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.

77. 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).

78. 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.

79. In addition to their duties as distributors, Defendants also had a duty to monitor and report suspicious activity in their retail pharmacy operations. Specifically, Defendants had a duty to analyze data and store-level information for known red flags such as (a) individuals traveling long distances to a prescriber or a pharmacy; (b) individuals obtaining multiple opioid prescriptions from different prescribers; (c) individuals 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) individuals consistently requesting early refills or routinely attempting to obtain an early refill of an opioid; (h) individuals 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.

80. 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 U.S.C. § 827(a). "[A] registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect

against the diversion of controlled substances." Paul H. Volkman, 73 FR 30,630, 30,644 (2008). An important component of an anti-diversion system is the documentation Chain Pharmacies possess. They must utilize their information to identify patterns of diversion and for auditing, training, and investigation of suspicious activity.

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

82. The CSA reflects a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. The CSA 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.

83. Further, the CSA 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.

84. 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.

85. The regulations in the 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. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

86. 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.

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

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

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

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

> one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

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

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

93. The DEA sent a second letter to all registered distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting ARCOS data to the DEA).

94. The public nature of the DEA's regulatory actions against the three largest wholesale distributors, including the DEA's public comments thereon, 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, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers and, on December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("AMA") with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an AMA with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at several of its facilities.

95. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[3] The DEA, among others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion. For example, the DEA has repeatedly emphasized that retail pharmacies, such as Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility" under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.

96. The DEA has identified several types of "unresolvable red flags" which, when present in prescriptions presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address; prescribing the same controlled substances in each presented prescription; a high volume of patients presenting prescriptions and paying with cash; and a prescription presented to 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.

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

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 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.

3. Defendants are uniquely positioned to guard against diversion.

100. 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 fulfil their obligations under the CSA.

101. 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.[4] This is particularly important given that it is recognized that as 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.

102. 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.

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

[4] *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).

104. On a number of occasions, pharmacists in New Hampshire reported suspicious prescribing activity to corporate headquarters, which failed to take any action concerning the prescriber.

105. For example, CVS pharmacists in New Hampshire warned of the high doses prescribed by a nurse practitioner, Kristen Khanna, from Salem, at least as early as 2014. Specific warnings about Ms. Khanna were also provided to CVS headquarters through CVS's store monitoring program. Various subpoenas served on CVS related to prescriptions written by Ms. Khanna also placed CVS headquarters on notice of her suspicious conduct. Upon information and belief, CVS never conveyed to its pharmacists the data it collected concerning this prescriber, never warned the DEA, and never blocked her controlled substance prescriptions from being filled at CVS until after she was indicted.

106. In September 2018, Ms. Khanna pled guilty to prescription fraud. She admitted that she would often leave a pad of pre-signed but blank prescriptions with an employee to fill out for patients as the patients engaged in "drive by" visits.

107. CVS was also made aware of suspicious prescribing practices of Christopher Clough as early as 2014 yet permitted his prescriptions to be filled until he was banned by the New Hampshire Board of Medicine in 2015.

108. The State offers these instances as examples of prescribers who were known to CVS, though there are other examples.

109. Had CVS and other Defendants appropriately analyzed their data and shared that information with their pharmacists, the volume of opioids dispensed and the risk of diversion in New Hampshire would have significantly decreased.

110. 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."

111. Each of the Chain Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in and around 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.

112. 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.

113. 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, the Chain Pharmacies allowed widespread diversion to occur—and they did so knowingly.

114. 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.

115. 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.

116. 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.

117. 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.

CVS

118. CVS distribution centers, in tandem with outside wholesalers, such as Cardinal Health and McKesson Corp., supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products and cocktail drugs to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014.

119. Before 2009, CVS lacked any meaningful suspicious order monitoring ("SOM") system. Instead, CVS relied on the gut instincts of "pickers and packers" of the drugs in the distribution center—workers responsible for pulling items off distribution shelves for delivery to pharmacy stores—to identify "really big" orders that they believed were too large. This, of course, was not an effective SOM system.

120. Moreover, CVS lacked a training program to train its pickers and packers how to identify unusual orders of size, frequency, or pattern. CVS also did not have any written policies, procedures, or protocols with respect to the pickers and packers' obligations until August 2013. There were no formal job requirements to be employed as a picker and packer.

121. In 2009, CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. CVS called the output of the flagged orders an Item Review Report ("IRR"), which was the primary SOM process. CVS neglected to provide written instructions to its employees for how to perform that critical review until February 2012.

122. CVS's SOM algorithm also failed to consider outside vendor orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third-party

distributors such as Cardinal Health when evaluating whether to distribute opioids to one of its pharmacies.

123. At select times in 2013, CVS had only one full-time employee in the position of "SOM analyst" reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors and "pend" the order. Even though the orders had been identified as potentially suspicious, the CVS SOM analysts would conduct an "in depth" dive on only select orders. In fact, even though the SOM program could identify as many as 1,000 suspicious orders a day, the CVS employee would only do a "deep dive" on one to six orders per day.

124. On August 5, 2013 the DEA commenced an audit and investigation of the CVS distribution center in Indiana. In response to queries from the DEA, CVS wrote a letter to the DEA revealing that it had only stopped seven suspicious orders across the entire country. In May of 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system.

125. Unsurprisingly, the DEA concluded that CVS failed to design and maintain a system to detect and report suspicious orders for Schedule III-V Controlled Substances as required by 21 U.S.C. 821, 21 U.S.C. 823(e)(1), and 21 C.F.R. 1301.74(b), in violation of 21 U.S.C. 842(a)(5).

126. CVS did not fully implement a new SOM system until 2014. Even then, CVS encountered problems in evaluating suspicious orders for opioids and its SOMS was entirely lacking. The deployment was further delayed due to system data feed issues that created inaccuracies in the SOM historical data.

127. A risk analysis of the new system was conducted in June 2014. The risk level was determined to be high for the SOM system in the following categories covering seemingly every aspect of its operation: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; and lack of clarity in how the new SOM system is identifying suspicious orders.

128. CVS also lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. It was not until 2012 that CVS created guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

129. The effects of CVS's misconduct can be seen in New Hampshire. For example, while the CDC recommends reassessing opioid treatment before increasing dosage to 50 MME or more per day and avoiding or carefully justifying opioid titration to 90 MME or more per day, one CVS customer in New Hampshire received an average of over 1,700 MME per day over four years. This individual obtained multiple overlapping prescriptions for opioids based on the date the prescription was filled, the quantity of the prescription, and the recommended daily dosage, such that, as of December 3, 2011, CVS was filling 24 overlapping opioid prescriptions for this customer—a clear and dangerous red flag. This individual filled 272 prescriptions for oxycodone and fentanyl at CVS over a four-year period.

Rite Aid

130. Rite Aid distributed Schedule III controlled substances (e.g., hydrocodone combination products) to its own Rite Aid stores until late 2014.

131. Rite Aid's controlled substance distribution process was fairly simple. Rite Aid used a computerized "auto-replenishment system" ("ARS") through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center. This ARS relied directly on dispensing data and the dispensing patterns of individual Rite Aid stores. If the ARS generated an order that was above Rite Aid's universal 5,000 dosage-unit threshold, the distribution center employees filling the order were supposed to 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 distribution center simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were supposed to be maintained on a handwritten log containing only basic information about the order.

132. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. Rite Aid did not use the Navicase/Naviscript system to identify—much less report—suspicious orders.

133. Rite Aid also had little to no records about past order history to determine if an order was suspicious. Instead, Rite Aid distribution centers kept what was called a "Threshold Log," which contained in hard copy only basic information about orders that exceeded the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. Any use of the log to identify potentially

suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

134. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013.

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

136. Rite Aid's dispensing policies and procedures used at all its Rite Aid pharmacies nationally were also deficient in many ways. 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. 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.

137. 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.

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

139. 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. Rite Aid pharmacists also did not have any way to identify pattern prescribing beyond the pharmacist's own personal knowledge. Rite Aid pharmacists could not even look up the prescriptions filled for a prescriber at Rite Aid pharmacies. Rite Aid did not provide any assistance to assist pharmacists to recognize pattern prescribing. Rite Aid pharmacists could also not look up things such as the "top oxycodone/methadone/hydrocodone prescribers" at a pharmacy or a "prescriber's rank in the dispensing quantity, script count and patient out-of-pocket expenses for the base code."

140. Rather than comply with its obligations, Rite Aid drove its pharmacists to fill higher rates of prescriptions across the board, leading up to its 2009 settlement with the DEA (described below), in which it paid $5 million in civil penalties for its improper dispensing practices.

141. Even after the 2009 settlement and civil penalty fine, Rite Aid continued its emphasis on increased prescription fill rates. Rite Aid acknowledged that increasing prescription counts year over year was the top priority Rite Aid placed on each of its pharmacies. Rite Aid's compensation policies provided bonuses that depended on the number of prescriptions—including opioids—dispensed from Rite Aid pharmacies.

142. In 2011, Rite Aid adopted a policy whereby it promised to fill prescriptions in 15 minutes or less. As the chair of the Illinois State Board of Pharmacy said: "This is 180 degrees away from everything we are trying to do in moving the pharmacy profession toward being patient information-focused rather than product-focused. And it's counter to our many efforts to improve patient safety." Similarly, the New Hampshire Board of Pharmacy conducted an analysis into

dispensing errors and found that "contributing factors for errors included high prescription volumes and lack of adequate pharmacist coverage."

Walgreens

143. Acting as both a distributor and a retail pharmacy chain, Walgreens self-distributed opioids to its own individual pharmacies. Although Walgreens had visibility into indicia of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its 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.

144. 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.

145. 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.

146. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient" in a May 2006 Letter of Admonition. The letter cited

Walgreens for controlled substances violations at its Perrysburg, Ohio distribution center, but highlighted problems that went far beyond that particular facility.

147. The 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.

148. 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.

149. 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.

150. In September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at

least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

151. 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 . . . .[5]

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

- "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"

[5] *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).

- "[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 *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]."

153. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations . . . the system is not complete until the data is carefully reviewed and monitored by the registrant."

154. These failures reflect nationwide systemic failures of Walgreens's SOM system that impacted its distribution in New Hampshire. 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 New Hampshire. For example, in connection with Walgreens's Woodland, California distribution center, when Walgreens did submit suspicious order lists to the DEA, it included orders that had already been shipped. The Woodland distribution center also did not have a monitoring process in place to prevent the fulfillment of an order that was deemed suspicious.

155. 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.

156. 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.

157. 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.

158. 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.

159. 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.

160. 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."

161. 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.

162. 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 New Hampshire than could have been expected to serve legitimate medical use, and ignored other indicia of suspicious orders, all of which it concealed from the State. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

163. 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, 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.

164. At the store level, Walgreens did not make any controlled substance metrics available to pharmacists for specific prescribers. Further, despite the fact that at the corporate level Walgreens utilized many tools for descriptive statistics around prescriber patterns, Walgreens was not aware of any consistent reports written using that data. Walgreens did not make this information available to its pharmacists.

165. 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.

5. Defendants delayed a response to the opioid crisis by pretending to cooperate with law enforcement and fraudulently concealed their wrongdoing.

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

167. On September 21, 2017, CVS stated that it had a "broad commitment to fighting the national opioid abuse epidemic" and that its "[p]harmacists will counsel patients about the risk

of dependence and addiction tied to duration of opioid use, the importance of keeping medications secure in the home and methods of proper disposal of unused medication."[6]

168. In reality, *The New York Times* disclosed that a CVS form for staff members to report errors internally asked whether the patient poses "a 'media threat.'" According to the article, the American Psychiatric Association's president observed that "[c]learly it is financially in their best interest to dispense as many pills as they can get paid for[.]"

169. 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."[7]

170. In 2019, Walgreens Boots Alliance, Inc. issued a Board Report in which it represented: "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

[6] Press Release, CVS Health, *CVS Health Fighting National Opioid Abuse Epidemic With Enterprise Initiatives* (Sept. 21, 2017), https://www.cvshealth.com/newsroom/press-releases/cvs-health-fighting-national-opioid-abuse-epidemic-with-enterprise-initiatives

[7] Aaron C. Davis & Jenn Abelson, *Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales*, The 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.

with federal and state legal requirements."[8] 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."[9]

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

172. 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."[10]

173. Through the above statements and, upon information and belief, other similar statements assuring their compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but further affirmed that their

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[8] Walgreens Boots Alliance, Inc., *Board Report on Oversight of Risk Related to Opioids*, http://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf

[9] *Id.*

[10] Rite Aid, *Medication Safety & Disposal*, https://www.riteaid.com/pharmacy/drug-information/medication-disposal-and-safety (last visited June 21, 2022).

conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic and concealed their own roles in contributing to it.

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

174. 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, 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 New Hampshire.

CVS

175. Enforcement actions against CVS are legion. By way of example, in 2013, CVS agreed to pay $11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using "dummy" DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

176. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

177. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records.

178. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that, from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA by filling prescriptions with no legitimate medical purpose.

179. In June 2016, CVS Pharmacy, Inc. paid $3.5 million to resolve allegations made by the District of Massachusetts' U.S. Attorney's Office that 50 of its stores violated the CSA by filling forged prescriptions—mostly addictive painkillers—more than 500 times between 2011 and 2014. Among other things, the DEA identified forged prescriptions filled 403 times at 40 CVS stores in Massachusetts and New Hampshire. In addition, CVS entered into a three-year compliance agreement with the DEA that required CVS to maintain and enhance programs for detecting and preventing diversion of controlled substances.

180. In connection with the settlement, U.S. Attorney Carmen M. Ortiz stated: "When pharmacies ignore red flags that a prescription is fraudulent, they miss a critical opportunity to prevent prescription drugs from entering the stream of illegal opiates on the black market. Diverted painkillers are contributing to the devastating opioid epidemic in our Commonwealth."

181. In 2017, CVS Pharmacy, Inc. paid $5 million to resolve allegations that its pharmacies in the Eastern District of California failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. In addition to the settlement payment, CVS agreed to an administrative compliance plan with the DEA. The payment and plan resolved the United States' allegations that during the period from April 30, 2011, through April 30, 2013, CVS pharmacies failed to provide effective controls and procedures to guard against diversion.

182. In March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription."

183. When CVS acquired Omnicare, CVS was fully aware the DEA had previously investigated Omnicare for "alleged errors and deficiencies in paperwork requirements for controlled-substances dispensing at several of the company's pharmacies in Ohio." Omnicare publicly acknowledged the DEA's Ohio investigation in its 2010 SEC filings, which Omnicare later settled for $50 million in 2012. CVS was also aware the DEA had previously investigated Omnicare in 2007 for countrywide violations of the CSA that also led to a settlement with the DEA.

184. Since its acquisition by CVS, Omnicare has continued to violate the CSA. In May 2020, Omnicare settled additional charges made by the DEA and paid $15.3 million. The DEA found that Omnicare again violated the CSA:

> [I]n its handling of emergency prescriptions, its controls over the emergency kits, and its processing of written prescriptions that had missing elements. The federal investigation found that Omnicare failed to control emergency kits by improperly permitting long-term care facilities to remove opioids and other controlled substances from emergency kits days before doctors provided a valid prescription. The investigation also revealed that Omnicare had repeated failures in its documentation and reporting of oral emergency prescriptions of Schedule II controlled substances.

185. Many of the recent allegations made by the DEA repeat precisely those violations Omnicare engaged in before 2012. The Acting Administrator of the DEA stated: "Omnicare failed

in its responsibility to ensure proper controls of medications used to treat some of the most vulnerable among us."

186. CVS, fully aware of the past compliance failures and fully aware of the enormous danger posed to the public from the diversion of opioids, failed to monitor and create a corporate system through which it could ensure that its subsidiaries, including Omnicare, complied with the CSA.

Rite Aid

187. Rite Aid also has a long history of violating the CSA. For example, in 2009, Rite Aid Corporation and nine of its subsidiaries in eight states agreed to pay $5 million in civil penalties to settle allegations of violations of the CSA by the DOJ. In addition to the $5 million penalty, Rite Aid and its subsidiaries agreed to a compliance plan with the DEA to ensure compliance with all requirements of the CSA and applicable DEA regulations and to prevent diversion of controlled substances.

188. As part of its investigation, the DEA conducted accountability audits of controlled substances at 25 of the 53 stores investigated to determine whether Rite Aid could properly account for Schedule II and III controlled substances purchased and dispensed. The results of the accountability audits revealed significant shortages or surpluses of the most highly abused drugs, including oxycodone and hydrocodone products, reflecting a pattern of non-compliance with the requirements of the CSA and federal regulations that led to the diversion of controlled substances in and around the communities of the Rite Aid pharmacies investigated.

189. Rite Aid's violations extend to New Hampshire. In 2019, Maxi Drug North, Inc. d/b/a Rite Aid agreed to pay a penalty of $22,500 to resolve allegations by the DOJ that it had

filled fraudulent prescriptions for controlled substances at its location in Concord between December 1, 2013, and June 30, 2014.

190. In 2022, Rite Aid agreed to pay $30,000 in a settlement to resolve allegations brought by the U.S. Attorney's Office in New Hampshire that its pharmacists at a Manchester Maxi Drug North, Inc. d/b/a Rite Aid pharmacy filled prescriptions they should have known were not valid under the CSA between October 2016 and March 2018.

Walgreens

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

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

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

194. On September 14, 2012, however, the DEA also issued an Order to Show Cause and Immediate Suspension Order ("ISO"), described above, against Walgreens's distribution

center in Jupiter, Florida, as well as 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]."

195. In 2013, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. The DOJ, in describing the settlement, explained that 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."

196. 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.

197. 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.

198. 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.

199. 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.

200. 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.

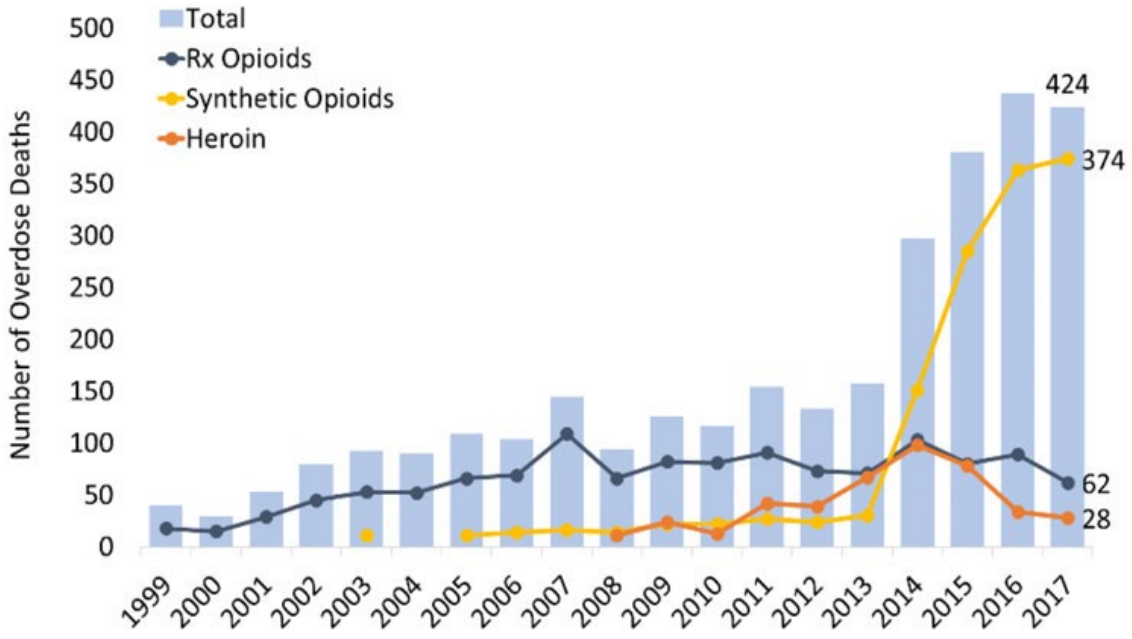
201. More recently, on May 4, 2022, Walgreens entered into a settlement agreement with the Florida Attorney General in connection with allegations for public nuisance, negligence,

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 those claims.

202. 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.

V. THE EFFECTS OF THE OPIOID EPIDEMIC IN NEW HAMPSHIRE

203. New Hampshire has been among the top five states with the highest rate of opioid-involved deaths. According to the National Institute on Drug Abuse, there were 424 drug overdose deaths involving opioids in New Hampshire—an age-adjusted rate of 34.0 deaths per 100,000 persons—in 2017. This was more than twice the average national rate of 14.6 deaths per 100,000 persons. A significant increase was seen in cases involving synthetic opioids other than methadone (mainly fentanyl), with a rise from 30 deaths in 2013 to 374 deaths in 2017.



204. These harms have not abated. In 2020, the State had an opioid overdose death rate of 26.9 per 100,000, significantly higher than the national average of 21.4 deaths per 100,000.

205. According to the University of New Hampshire's Carsey School of Public Policy, in the ten years from 2005 to 2015, the number of infants diagnosed with neonatal abstinence syndrome ("NAS") increased from 52 to 269. NAS births accounted for 24.4 per 1,000 live hospital births in New Hampshire in 2015. This number may be an underestimate, because hospitals may report NAS differently depending on provider documentation and coding of diagnosis, and also issues of data quality. New Hampshire newborns diagnosed with NAS remained in the hospital 12 days on average, compared to three days for newborns not exposed. In 2015, the total discharge amount for all births coded with an NAS diagnosis in New Hampshire averaged $33,700, compared to $7,800 for those not diagnosed with NAS.

206. The University of New Hampshire's Carsey School of Public Policy also reported that there were 2,632 female and 3,452 male opioid-related emergency departments in 2016, which were most prevalent among 20-29-year-olds and 30-39-year-olds.

207. Diseases connected to injecting drugs, including HIV and hepatitis C, are another side effect of opioid and heroin addiction (largely through intravenous drug use). In 2019, there were over 1,300 people in New Hampshire living with HIV. From 2014 to 2016, the Catholic Medical Center in Manchester, New Hampshire saw the number of hepatitis C cases in patients who were drug users rise from 157 to 289. Treatment for hepatitis C costs about $65,000 to $100,000 per patient.

208. Across the country there is a significant increase in children being abused, neglected, and eventually separated from their parents due to opioid addiction. New Hampshire is no exception. The University of New Hampshire's Carsey School of Public Policy reported that "[c]oncurrent with the rise of the opioid epidemic is a 21 percent increase in the number of child abuse and neglect reports accepted for assessment by the [New Hampshire Division for Children, Youth, and Families], from 9,248 in 2013 to 11,197 in 2016."

209. The number of child abuse and neglect reports assessed by the New Hampshire Division for Children, Youth, and Families increased by 21 percent between 2013 and 2016, from 9,248 to 11,197. Substance-use-related issues are increasingly present in the lives of the children and youth who are removed from parental care. For example, 60 percent of children or youth removed from parental care in 2016 had a substance-related allegation in their assessment, double the percentage in 2012 (30 percent).

210. The full cost of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. The New Hampshire

Charitable Foundation reported that substance use costs New Hampshire $2 billion annually in lost worker productivity and earnings, healthcare costs, public safety and criminal justice expenses. Furthermore, while more than 100,000 people are in need of treatment for the disease of addiction in New Hampshire, only between four and six percent get that treatment.

VI. CAUSE OF ACTION

CLAIM FOR RELIEF
(Public Nuisance)

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

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

213. 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 New Hampshire.

214. 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.

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

216. Here, Defendants' conduct is prescribed by statutes and regulations, including the CSA and regulations incorporated therein.

217. Defendants violated the standard of conduct set forth in the CSA by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids.

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

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

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

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

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

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

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

225. Defendants' actions were, at the very least, a substantial factor in the public health crisis that followed and has reached a state of emergency. Defendants controlled those actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or much less severe.

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

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

PRAYER FOR RELIEF

WHEREFORE, the State prays for an order:

a. awarding judgment in its favor and against Defendants on the cause of action asserted in the Complaint;

b. requiring Defendants to abate the public nuisance their conduct has created;

c. requiring Defendants to pay the costs of the suit, including attorneys' fees; and

d. awarding such other, further, and different relief as this Court may deem just.

Dated: July 22, 2022

Respectfully submitted,

THE STATE OF NEW HAMPSHIRE

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