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IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 19-C-9000**

THIS DOCUMENT APPLIES TO:

STATE OF WEST VIRGINIA ex rel.
PATRICK MORRISEY, Attorney General,

Plaintiff,

v. **CIVIL ACTION NO. 20-C-82 PNM**

WALGREENS BOOTS ALLIANCE, INC.,
a Delaware Corporation;
WALGREEN CO., an Illinois corporation; and
WALGREEN EASTERN CO., INC.,
a New York corporation,

Defendants.

FIRST AMENDED COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Defendants, Walgreens Boots Alliance, Inc.; Walgreen Co.; and Walgreen Eastern Co., Inc. ("Walgreens" or "Defendants"), and alleges as follows:

I. Introduction

1. The State of West Virginia is suffering from a devastating opioid crisis created in part by the Defendants. Opioids may kill as many as 500,000 people in the United States over the next ten years.

2. Opioids are powerful narcotic painkillers that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy. Use of prescription opioids can cause addiction, overdose, and deaths.

3. Opioid addiction has destroyed the lives of tens of thousands of West Virginians and caused immense pain and suffering for families throughout West Virginia.

4. The long-term use of opioids is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve any effect. Patients also quickly become dependent on opioids and will experience often-severe withdrawal symptoms if they stop using the drugs. That makes it very hard for patients to discontinue using opioids after even relatively short periods. The risks of addiction and overdose increase with dose and duration of use. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which can make opioids fatal. It is the interaction of tolerance, dependence, and addiction that makes the use of opioids for chronic pain so lethal.

5. Opioid related deaths may be underreported by as much as 20%, the opioid epidemic is deadlier than the AIDS epidemic at its peak, and West Virginia suffered from the highest opioid mortality rate in the country in 2016.[1]

6. In 2017, over 1,000 West Virginia citizens died as the result of a drug overdose. Eighty-six percent (86%) of these overdose deaths involved an opioid. This is threefold higher than the national rate of 14.6 deaths per 100,000 people.[2]

7. In 2017, West Virginia providers wrote 81.3 opioid prescriptions for every 100 people compared to the national average U.S. rate of 58.76 prescriptions.[3]

8. 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

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[1] Christopher Ingraham, CDC Releases Grim New Opioid Overdose Figures: "We're Talking About More Than an Exponential Increase," Washington Post, Dec. 12, 2017, https://wapo.st/2POdL3m.

[2] *See* Caity Coyne, Number of Fatal Drug Overdoses in 2017 Surpasses 1,000 Mark in West Virginia, Charleston Gazette-Mail, Aug. 30, 2018, https://bit.ly/2yLcxim; *see also*, Christopher Ingram, Drugs are Killing so Many People in West Virginia that the State Can't Keep Up With the Funerals, The Washington Post, Mar. 7, 2017, https://wapo.st/2GI9rk2; Christopher Ingram, Fentanyl Use Drive Drug Overdose Deaths to a Record High in 2017, CDC Estimates, The Washington Post, Aug. 15, 2018, https://wapo.st/2Ozn8b7; *see also* West Virginia Opioid Summary, National Institute on Drug Abuse, March 2019. https://bit.ly/2MzDsGn.

[3] *See* West Virginia Opioid Summary, National Institute on Drug Abuse, March 2019. https://bit.ly/2MzDsGn.

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.

9. As reported in a special issue of the West Virginia Medical Journal, West Virginia has the third highest non-heroin opioid pain reliever ("OPR") treatment rate in the United States.[4]

10. In addition to the number of deaths caused by OPRs such as oxycodone and hydromorphone, there has been an increase in overdose deaths caused by heroin, which dealers cut with fentanyl, an opioid 100 times stronger than morphine.[5]

11. Studies show a direct correlation between OPRs and heroin addiction with 4 out of 5 heroin users reporting their opioid use began with OPRs.[6]

12. Children are especially vulnerable to the opioid epidemic. West Virginia's rate of Neonatal Abstinence Syndrome ("NAS") is five times the national average and results in thousands of children being placed in foster care.[7] In 2017, the overall incidence rate of NAS was 50.6 cases per 1,000 live births for West Virginia residents. The highest incidence rate of NAS was 106.6 cases per 1,000 live births (10.66%) in Lincoln County.

13. In 2007, the cost for treating a NAS baby was approximately $36,000; cost for a healthy baby was approximately $3,600.[8]

14. Between 2006 and 2016, children entering the West Virginia foster care system due to parental addiction rose 124%. About 70% of referrals to Child Protective Services in 2017 had

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[4] Khalid M. Hasan, MD. & Omar K. Hasan, MD, Opiate Addiction and Prescription Drug Abuse: A Pragmatic Approach, West Virginia Medical Journal, Special Ed., Vol. 106, No. 4, p. 84, https://bit.ly/2q0Tqg2.
[5] Dennis Thompson, Drug OD Deaths Nearly Tripled Since 1999, CDC Says, Feb. 24, 2017, CBS News, https://cbsn.ws/2J4n90u.
[6] Andrew Kolodny, et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, p. 560 (Jan. 12, 2015), https://bit.ly/2J5A9Tp.
[7] Proposed Opioid Response Plan for the State of West Virginia, Jan. 10, 2018, p. 20, https://bit.ly/2Oyu48a.
[8] Michael L. Stitely, MD, et al., Prevalence of Drug Use in Pregnant West Virginia Patients, West Virginia Medical Journal, Special Ed., Vol. 106, No. 4, p. 48, https://bit.ly/2q0Tqg2.

a substance abuse component according to the statistics from the Centralized Intake Unit of the West Virginia Bureau for Children and Families. The state court Child Abuse and Neglect (CAN) database indicates that about 80% of referrals from family court and circuit court judges have a substance abuse factor.

15. The State of West Virginia has sustained and continues to suffer massive losses as a result of this opioid epidemic through loss of lives, babies born addicted to opioids, adults unable to work, treatment costs, emergency personnel costs, law enforcement expenses, naloxone costs, medical examiner expenses, foster care expenses, self-funded state insurance costs, and lost tax revenues, among many other costs.

16. The State of West Virginia brings this civil action to hold the Defendants accountable for unconscionably helping to create the State of West Virginia's opioid public health and financial crisis. The Defendants reaped billions of dollars in revenues while causing immense harm to the State of West Virginia and its citizens, and now they should pay for their role in the crisis and act to remediate the problem.

II. Parties

A. Plaintiff

17. The Plaintiff, the State of West Virginia ex rel. Patrick Morrisey, Attorney General, is charged with enforcing the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, *et seq*. ("WVCCPA"). Pursuant to W. Va. Code § 46A-7-108, the Attorney General is authorized to bring a civil action for violations of the WVCCPA and for other appropriate relief. The Attorney General has all common law powers except restricted by statute. Syl. pt. 3, *State ex rel. Discover Financial Services, Inc., et al. v. Nibert*, 744 S.E.2d 625, 231 W. Va. 227 (2013).

B. Walgreens

18. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois.

19. Defendant Walgreen Co. is an Illinois corporation registered with the West Virginia Secretary of State to conduct business in West Virginia. Its principal place of business is located in Deerfield, Illinois. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

20. Walgreen Co. is and was licensed with the West Virginia Board of Pharmacy as a wholesale distributor. Walgreen Co. has active licensed distribution centers in Perrysburg, Ohio, Williamston, South Carolina, and Mount Vernon, Illinois. Walgreen Co. also had a licensed distribution center in Jupiter, Florida. At least between 2006 and 2014, Walgreen Co. distributed opioids from its locations in Jupiter, Florida; Perrysburg, Ohio; and Williamston, South Carolina to Walgreens retail pharmacies located in West Virginia.

21. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

22. Walgreen Eastern Co., Inc. was licensed with the West Virginia Board of Pharmacy as a wholesale distributor with a location in Bethlehem, Pennsylvania. At least between 2006 and 2014, Walgreen Eastern Co., Inc. distributed opioids to Walgreens retail pharmacies in West Virginia.

23. Defendants Walgreens Boots Alliance, Inc., Walgreen Co. and Walgreen Eastern Co., Inc. are collectively referred to as "Walgreens." Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale

distributor. Walgreens distributed prescription opioids throughout the United States, including in West Virginia. These Defendants operated as a licensed wholesale distributor in the State of West Virginia.

24. Walgreens included a captive distributor that supplied pharmaceutical drugs and opioids to Walgreens' pharmacies throughout the country, including West Virginia. Walgreens has traditionally served as a distributor of Schedule III opioids to its own stand-alone pharmacy locations. Walgreens also contracted with outside pharmaceutical wholesale distributors, including, based upon information and belief, Cardinal and AmerisourceBergen, to distribute opioids to Walgreens pharmacy stores. Walgreens operates as a licensed wholesale distributor and, through its various subsidiaries, is registered with the DEA.

25. Walgreens distributed prescription opioids into the stream of commerce in West Virginia while failing to monitor and report suspicious orders, and while failing to detect and warn of diversion of these dangerous drugs for non-medical purposes.

26. At all relevant times, along with retail stores and other business units, Walgreens operated numerous licensed pharmacies with controlled substance permits located in Walgreens retail stores in West Virginia. At all relevant times, Walgreen's licensed pharmacies dispensed prescription opioids in West Virginia.

III. State Court Jurisdiction

27. The causes of action asserted and the remedies sought in this Complaint are based exclusively on West Virginia statutory or common law.

28. In this Complaint, the State references federal statutes, regulations, or actions, but does so only to establish Walgreens' knowledge or to explain how Walgreens' conduct has not been approved by federal regulatory agencies.

29. The mere reference to federal activities in the State's causes of action is not enough to confer federal jurisdiction. *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 813 (1986).

30. The federal Controlled Substances Act ("CSA") does not create a private right of action, *Welch v. Atmore Community Hospital*, 704 Fed. Appx. 813, 817 (11th Cir. 2017), and it does not confer federal question subject matter jurisdiction by the mere regulation of a class of drugs. *Allen v. Endo Pharmaceuticals, Inc.*, No. 5:18-CV-00132-TES, 2018 WL 7352753 at *3 (M.D. Ga. Aug. 23, 2018).

31. Removal to federal court is not warranted for causes of action sounding in state law concerning drug distribution activities where the claims do not necessarily raise or actually dispute a substantial federal issue that is capable of being resolved in federal court without disrupting the federal-state balance. *Gunn v. Minton*, 568 U.S. 251, 258 (2013). *See also, e.g., Mobile County Bd. of Health v. Richard Sackler*, No. 1:19-01007-KD-B, 2020 WL 223618 (S.D. Al. Jan. 15, 2020) (remanded); *New Mexico ex rel. Balderas v. Purdue Pharma, L.P.*, 323 F. Supp. 3d 1242 (D. Nm. 2018) (remanded); *Delaware ex rel. Denn v. Purdue Pharma, L.P.*, No. 1:18-383-RGA, 2018 WL 192363 (D. Del. 2018) (remanded); *West Virginia ex rel. Morrisey v. McKesson Corp.*, No. 16-1773, 2017 WL 357307 (S.D. W. Va. 2017) (remanded).

32. This Complaint does not confer diversity jurisdiction upon federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdictional provisions of the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d). Federal question subject matter jurisdiction under 28 U.S.C. § 1331 is not invoked by this Complaint. Nowhere does the State plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal

law. There is no federal issue important to the federal system, as a whole as set forth in *Gunn v. Minton,* 568 U.S. 251, 258 (2013).

IV. Jurisdiction

33. As a court of general jurisdiction, the circuit court is authorized to hear this matter, based on the WVCCPA and nuisance claims, the amount at issue, and the relief sought pursuant to W. Va. Code § 56-3-33.

34. This court has jurisdiction over Walgreens Boots Alliance, Inc. as it uses its subsidiaries to conduct business in the State of West Virginia. This business relates to the State's claims in this matter and the harm done by Walgreens Boots Alliance, Inc. to the State. Walgreens Boots Alliance, Inc. by its actions and through its subsidiaries, as described herein, transacted business in West Virginia and supplied services or things causing a public nuisance and engaging in unfair and deceptive conduct in West Virginia.

35. At all relevant times, and as the parent company of the Walgreens Subsidiaries, Defendant Walgreens Boots Alliance, Inc. established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States. Walgreens Boots Alliance, Inc. directed and intended that those policies and procedures would be implemented on a nationwide basis, including in West Virginia and specific to West Virginia. At all times relevant to this Complaint, Defendant Walgreens Boots Alliance, Inc. was responsible for directing and implementing policies and procedures governing the distribution of controlled substances by its subsidiaries, including but not limited to the Walgreens Subsidiaries, throughout the United States, including in West Virginia.

36. Walgreens Boots Alliance, Inc. exercised control as a parent over its subsidiaries such that the subsidiaries should be imputed to Walgreens Boots Alliance, Inc. These actions include but are not limited to: owning all or most of the capital stock of the subsidiary; having

common directors and officers; financing subsidiaries; subscribing to all of the capital stock of its subsidiaries and causing their incorporation; being grossly inadequately capitalized; paying salaries, losses, or other expenses of subsidiaries; the subsidiaries having substantially no business or assets except those conveyed by the parent; making statements describing subsidiaries as departments or divisions of the parent; referring to subsidiaries' financial responsibilities as the parent's own; using subsidiary property as its own; subsidiary executives and directors failing to act on the subsidiaries' behalf, but rather on the behalf of the parent; and failing to follow formal requirements of a parent or subsidiary.

37. Walgreens Boots Alliance, Inc. created policies and procedures for its pharmacies and distribution centers that serviced West Virginia, trained its employees on its centralized, corporate policies and procedures, and dictated the day-to-day operations of Walgreens Boots Alliance, Inc. These two entities were directly intermingled and joined in its business activities and practices.

38. Walgreens Boots Alliance, Inc. consistently oversaw and was involved in the acts of its subsidiaries described in this complaint.

39. As alleged below, Walgreens Boots Alliance, Inc. through its control over its subsidiaries caused the oversupply and diversion of opioids in West Virginia.

V. Venue

40. Venue is proper in Putnam County pursuant to W. Va. Code § 46A-7-114.

VI. Factual Allegations

41. Walgreens played a dual role in fostering the opioid epidemic in West Virginia as both a wholesale distributor taking orders from and shipping orders to its own pharmacies, and as a pharmacy dispensing opioids to the public, ignoring its crucial role in guarding against diversion.

Walgreens distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of drug distributors to detect, warn, and prevent diversion of dangerous drugs. Walgreens failed to comply with West Virginia law, which incorporates federal law, including their duty to maintain effective controls against the diversion of prescription opioids. As a pharmacy, Walgreens failed to create adequate policies for its employees to monitor red flags and prevent diversion; failed to utilize the data available to it to identify and report red flags of diversion; and failed to properly dispense controlled substances and avoid diversion. Acting as a wholesale distributor, Walgreens filled suspicious orders of prescription opioids of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency to its own pharmacies. Walgreens shipped and distributed these drugs in West Virginia and failed to report or stop shipments of suspicious orders. These controlled substances were distributed according to practices and procedures established by Walgreens Boots Alliance, Inc. Moreover, Walgreens, upon information and belief, failed to report or act to stop diversion that was evident to it and supplied far more opioids to their pharmacies than could have served a legitimate market for these drugs. As a dispenser, Walgreens failed to create adequate policies for its employees to monitor for red flags and signs of diversion; failed to utilize the data available to it to identify and report red flags of diversion; and failed to properly dispense controlled substances and detect and prevent diversion.

42. The dispensing and claims data from its retail pharmacies was an important tool available to Walgreens to use in its role as a distributor. Upon information and belief, Walgreens failed to use this unique knowledge to detect suspicious orders and prevent diversion of opioids.

43. Between 2006 and 2014, Walgreens was among the top ten (10) distributors of opioids in West Virginia.[9]

44. Between 2006 and 2014, Walgreens distributed opioids equivalent to 444.6 million (444,629,949) milligrams of morphine ("MME") to its retail pharmacies in West Virginia.[10]

45. During the same period, Walgreens pharmacies in West Virginia bought 707.9 million (707,921,640) MME of opioids.[11]

46. Although Walgreens was among the top ten distributors to West Virginia, behind McKesson, AmerisourceBergen and Cardinal Health, its "self-distribution" was not enough to fulfill the opioid demand at its retail pharmacy stores.

47. In addition to the opioids Walgreens distributed to its pharmacies between 2006 and 2014, its pharmacies also ordered from other wholesale distributors to meet the demand.

48. Walgreens' West Virginia pharmacies ordered additional opioids totaling 263.2 million (263,291,691) MME from third party distributors.

49. The sheer volume of prescription opioids distributed by Walgreens pharmacies in and affecting West Virginia is indicative of potential diversion and required appropriate due diligence.

50. Walgreens knew exactly how many opioids it was distributing to its West Virginia retail pharmacies and how many opioids each of those pharmacies were ordering from other major distributors.

51. The outsized flow of opioids from Walgreens pharmacies far exceeded the needs of the legitimate market, and Walgreens failed to use this knowledge to prevent diversion.

[9] DEA ARCOS data 2006-2014.
[10] Morphine milligram equivalence or MME is the standard value given to an opioid based on its potency in comparison to morphine. For example, a 10 mg. oxycodone tablet is the equivalent of 15 mg. of morphine.
[11] DEA ARCOS 2006-2014.

52. In addition, Walgreens knew or deliberately ignored its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, discovery will reveal that Walgreens had the ability to know that its pharmacies in West Virginia were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions in excessive or dangerous doses and/or lengths of time; (d) filling prescriptions from patients traveling unusual distances; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other prescription "cocktail" drugs frequently abused with opioids, like benzodiazepines, muscle relaxers and/or stimulants; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

53. The information available to Walgreens through its distribution centers and retail stores put it on notice that it was meeting more than a legitimate market demand. Rather than report suspicious orders and stop diversion, Walgreens continued to sell, ship, dispense and profit from these highly dangerous drugs.

A. Walgreens Was Required To Monitor For And Report Suspicious Orders and Prescriptions, Not To Ship Those Orders or Fill those Prescriptions Unless Due Diligence Disproves The Suspicions.

54. Walgreens was required by law to monitor, report and refuse to ship suspicious orders of controlled substances, unless and until due diligence dispelled the suspicion.

55. Walgreens was required to prevent oversupply and diversion into the illicit drug market. Distributors of controlled substances possess specialized and sophisticated knowledge, skills, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

56. Walgreens, through several of its various distribution centers, was registered as a wholesale distributor with the West Virginia Board of Pharmacy from 2005 through 2018.

57. The West Virginia Code and CSA requires manufacturers, distributors, and dispensers of controlled substances to adhere to security, recordkeeping, monitoring, and reporting requirements that are designed to protect against diversion.[12]

58. The WVCSA requires that distributors' operations be consistent with the public interest and also requires the registrant to have established and maintained effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. W. Va. Code § 60A-3-303(a).

59. The requirements under WVCSA independently parallel and incorporate the requirements of the federal CSA. *See* W.Va. C.S.R. 15-2-3. Walgreens was required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C § 823(a)-(b); 21 C.F.R. § 1301.74; W. Va. Code § 60A-3-303(a)(1); W. Va. C.S.R. § 15-2-5.3. This includes the requirements to monitor,

[12] W. Va. C.S.R. § 15-2-4; 21 C.F.R. § 1306.04(a)

detect, report, investigate and refuse to fill suspicious orders. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74; W. Va. C.S.R. § 15-2-5.3; W. Va. C.S.R. § 15-2-8.4.1.

60. Distributors are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered* by the registrant." 21 C.F.R. § 1301.74(b) (emphasis added). Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors." *Id*.

61. Distributors and pharmacies are required to know their customer and the communities they serve. Walgreens was in a unique position to comply with this requirement as it distributed narcotics to itself.

62. The DEA previously testified that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.[13]

b. Shipping a suspicious order is a per se violation of federal law.[14]

c. If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.[15]

d. After the fact reporting of suspicious orders has never been in compliance with federal law.[16]

63. To comply with the law, companies that distribute opioids 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 distributor's relations with its

[13] Prevosnick Dep. Vol. II, 770:6 to &&1:20, April 18, 2019 (DEA 30(b)(6) designee).
[14] *Id*. at 632:7 to 633:2.
[15] *Id*. at 628:24 to 629:15.
[16] *Id*. at 673:7 to 674:13, 679:20 to 680.8.

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). The distributor cannot ignore information that raises serious doubt as to the legality of a potential or existing customer's business practices. *Southwood Pharms., Inc.*, 72 Fed. Reg. 36,487, 36,498 (DEA July 3, 2007).

64. Due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA] about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[17] Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[18]

65. In sum, Walgreens had several requirements with respect to preventing diversion. Walgreens was required to set up a system designed to detect and reject suspicious orders. Walgreens was required to recognize red flags signaling illegal conduct and to use the information available to it to identify, report, and not fill suspicious orders. This included reviewing its own data, relying on its observations of its own pharmacies, and following up on reports or concerns of potential diversion.

66. The law requires that all suspicious conduct must be reported to appropriate enforcement authorities. It also prohibits the fulfillment or shipment of any suspicious order unless

[17] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).
[18] *Masters Pharmaceuticals*, 861 F.3d at 212. The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.

the distributor has conducted an adequate investigation and determined that the order is not likely to be diverted into illegal channels.[19] Walgreens failed to meet these requirements, and Walgreens' failure to exercise appropriate controls foreseeably harms the public health and welfare.

67. Walgreens has legal duties specifically with respect to its dispensing practices: "[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."[20]

68. Further, under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). All dispensers are required to check 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); W. Va. C.S.R. § 15-2-8.4.1. The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."[21]

69. The CSA does not require separate registrations for practitioners affiliated with registered institutions or agents of registrants to obtain a separate registration. It is the pharmacy, not the individual pharmacist, which is a registrant under the WVCSA and CSA. For this reason, individual pharmacists are agents of the pharmacy and the duty to ensure the proper dispensing of controlled substances lie with the pharmacy entity, and not the individual pharmacist alone.[22]

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[19] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).
[20] 21 C.F.R. § 1306.04(a)
[21] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf
[22] *Id.*; W. Va. Code § 60A-3-302.

70. The law also requires Walgreens to maintain effective controls and procedures to prevent diversion of controlled substances at its retail pharmacies.

71. The WVCSA requires that pharmacies be registered to dispense any controlled substances. *See* W. Va. Code § 60A-3-303(c); W. Va. Code § 60A-3-302(a); W. Va. C.S.R. 15-2-4.1.1.

72. Walgreens pharmacies were registered to dispense prescription opioids with the West Virginia Board of Pharmacy from at least 2003 through 2018.

73. The requirements under the WVCSA incorporate the requirements of the CSA. *See* W.Va. C.S.R. 15-2-3.

74. Under the CSA, "[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." 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."[23]

75. The CSA requires pharmacy registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). All dispensers are required to check 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. *See* 21 C.F.R. § 1306.04(a). The DEA construes these regulations to include the duty not to fill prescriptions until "red flags" indicative of illegitimacy and diversion have been resolved, such as pattern prescriptions like the same types of drugs in the same quantities from the same prescriber. *See, e.g.*, *Medic-Aid Pharmacy*, 55 FR 30,043, 30,044, 1990 WL 328750 (DEA

[23] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf

July 24, 1990) ("[A] pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose."); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 (Oct. 12, 2012) (noting that certain red flags, such as "the red flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be prescribed lawfully, see 21 U.S.C. 812(b)(2), and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions").

76. Each failure by Walgreens to abide by requirements of laws or rules enacted to protect the consuming public or to promote a public interest constitutes an unfair or deceptive act or practice and violates the WVCCPA, W. Va. Code § 46A-6-104, *see also Final Order, State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General vs. David McCuskey et al.*, Kanawha County Circuit Court, Civil Action No. 01-C-3041, Mar. 13, 2003. *See also Pabon v. Recko*, 122 F. Supp.2d 311, 314 (D. Conn 2000); *Lemelledo v. Beneficial Management Corp. of America*, 674 A.2d 582 (N.J. Super. Ct., App. Div. 1996); *Winston Realty Co., Inc. v. G.H.G., Inc.*, 331 S.E.2d 677 (N.C. 1985).

B. Walgreens Knew Its Obligations To Prevent Diversion And To Report And Take Steps To Halt Suspicious Orders

77. Walgreens, in its capacity as a wholesale drug distributor and as a mass merchant with pharmacies, has been active in various trade organizations for decades. The National Association of Chain Drug Stores ("NACDS") is one such organization. Walgreens serves on its board. The Healthcare Distribution Management Association ("HDMA"), now known as Healthcare Distribution Alliance ("HDA"), is a national trade association representing distributors and has partnered with NACDS.

78. In 2006, the NACDS issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs.[24] The Model Compliance Manual notes that a retail pharmacy may:

> "[G]enerate and review reports for its own purposes" and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:
>
> - Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
>
> - Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.
>
> - Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

79. In 2007 and 2008, the HDA began developing "industry compliance guidelines" ("ICG") that aimed to outline certain best practices for the distributors. The HDA released the ICG in 2008 and emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[25]

80. Walgreens received repeated and detailed guidelines from the DEA concerning, for example, their obligations to know their customers and the communities they serve. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to

[24] CAH_MDL2804_00842870.
[25] HDA_MDL_000213058

distributors on what to look for in assessing their customers' trustworthiness. As part of its development of the ICG, the HDA met with the DEA on at least three occasions.[26]

81. The guidelines, input, and communications from the DEA put Walgreens on notice of its requirements and obligations.

82. The DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,"[27] which suggests that distributors examine, among other things, the ratio of controlled vs. non-controlled orders placed by the pharmacy; the methods of payment accepted; whether, why, and to what extent the pharmacy also orders from other distributors; and the ratio of controlled substances the distributor will be shipping relative to other suppliers.

83. The pharmacies have repeatedly received extensive guidance from the DEA about their duties under the CSA. For example, the DEA has provided guidance in the form of its "Pharmacist's Manual: An Information Outline for the Controlled Substances Act of 1970" which outlines the "requirements set up under the Controlled Substances Act of 1970 [*et seq*.] as they affect pharmacy practice."

84. The DEA's guidance emphasizes: "The role of the pharmacist in the proper dispensing of controlled substances is critical both to the health of patients and to safeguard society against drug abuse and illicit diversion. The pharmacist's adherence to the law, together with voluntary service of its objectives, constitute a powerful resource for protecting the public health and safety. . . . The pharmacist is in a pivotal position because it is the pharmacist who dispenses the prescription medication to the ultimate consumer."

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[26] HDA_MDL_00213212

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

85. However, "[p]harmacists must be aware of the various methods and activities employed to divert controlled substances. The primary method is falsified prescription orders. Other methods for diverting controlled substances are: theft from a pharmacy, theft of prescription blanks, and willful and intentional diversion by pharmacists." The following non-exhaustive list of red flags as indicators of possible illegal and/or fraudulent prescription orders are provided in the Manual:

a. Prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area;
b. Prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis;
c. Prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time;
d. Numbers of people who present similar prescription orders from the same practitioners;
e. People who are not regular patrons presenting prescription orders from the same physician
f. A dramatic increase in the purchases of controlled substances.

86. "The DEA also expects that pharmacists will make a reasonable effort to determine the identity of the prescriber – if the prescriber is not known to the dispensing pharmacist."

87. Finally, if a pharmacy finds evidence of prescription diversion, the Manual indicates that the local Board of Pharmacy and DEA must be contacted.

88. Despite its obligation to implement systems to prevent diversion as required to comply with the WVCSA and CSA, Walgreens failed to create and/or implement necessary policies and procedures to ensure that its pharmacists could and did identify and report red flags of potential diversion. As a result, Walgreens facilitated the widespread diversion of opioids in West Virginia by: (1) failing to monitor and report suspicious orders and (2) dispensing prescriptions it knew or should have known were for the purpose of illegal diversion.

89. The DEA has repeatedly informed distributors and dispensers, including Walgreens, about their legal obligations, as described above, including obligations that were so obvious that they required no clarification. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

90. The requirement to report suspicious orders at the time—not after the fact—has always been clear. As early as 1984, correspondence between the National Wholesale Druggists' Association ("NWDA"), now the HDA, and the DEA illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting "**DEA has interpreted 'orders' to mean prior to shipment.**" Consistent with that understanding, the NWDA's 1984 Guidelines repeated the same directive.[28]

91. In addition, in April 1987, the DEA sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers."[29] According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained:

> [A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program." Another area at issue was whether DEA would take action against a registrant which

[28] CAH_MDL2804_01465723.
[29] US-DEA-00025657.

> reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.[30]

92. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly. . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as. . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded registrants that, in addition to reporting suspicious orders, they have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The September 27, 2006 letter reminded distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

93. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 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

[30] US-DEA-00025659.

merely transmitting data to the DEA). Finally, the December 27, 2007 letter referenced the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

94. In September 2007, members of the NACDS, among others, attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders.[31]

95. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Walgreens were well aware of the legal requirements. 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. 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. Most recently, in January 2017, McKesson entered into an Administrative Memorandum Agreement ("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.

96. The DEA also brought actions against Walgreens for pharmacy related violations. Indeed, 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

[31] CAH_MDL_PRIORPROD_DEA07_00877084; CAH_MDL_PRIORPROD_DEA07_01185382.

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. These actions demonstrate Walgreens's knowledge of, and disregard for, its obligations to prevent diversion.

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

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

98. Upon information and belief, Walgreens failed to adhere to the guidance documents, communications, and other statements issued by the DEA.

99. Each failure by Walgreens to abide by requirements of laws or rules enacted to protect the consuming public or to promote a public interest constitutes an unfair or deceptive act or practice and violates the WVCCPA, W. Va. Code § 46A-6-104, *see also Final Order, State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General vs. David McCuskey et al.*, Kanawha County Circuit Court, Civil Action No. 01-C-3041, Mar. 13, 2003. *See also Pabon v. Recko,* 122 F. Supp.2d 311, 314 (D. Conn 2000); *Lemelledo v. Beneficial Management Corp. of America,* 674 A.2d 582 (N.J. Super. Ct., App. Div. 1996); *Winston Realty Co., Inc. v. G.H.G., Inc.,* 331 S.E.2d 677 (N.C. 1985).

C. Walgreens Is Uniquely Positioned To Prevent Diversion.

100. As a vertically-integrated pharmacy and distributor, Walgreens has access to additional information that would allow it to identify and prevent diversion, unlike third-party wholesale distributors. Walgreens possessed such detailed and valuable information regarding its retail stores' orders, prescriptions, prescribers, and customers that companies known as "data vendors" were willing to pay for it.

101. At the pharmacy level, Walgreens has information on customers with insurance coverage making cash payments. It could also identify customers filling prescriptions at multiple pharmacy branches or from different doctors, or patterns of unusual or suspicious prescribing from a particular medical provider. For example, Walgreens was able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.

102. Walgreens, notably, could, and did, use "[d]ata mining . . . [a]cross Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive . . . ." in setting ceilings for its stores.[32]

103. Further, a customer's order data and the data of other similar customers provide detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion. As with the other wholesalers, these data points give Walgreens insight into prescribing and dispensing conduct that would have enabled it to play a valuable role in preventing diversion and fulfilling its obligations to guard against diversion.

[32] WAGMDL00757776.

104. Walgreens had complete access to all prescription opioid dispensing data related to its pharmacies in West Virginia, 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. It likewise had complete access to information revealing the opioid prescriptions dispensed by its pharmacies in and around the state. Further, Walgreens 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, including the size, frequency, dose, and combinations of prescriptions written by specific doctors and filled by its pharmacies in and around the state.

105. Upon information and belief, Walgreens by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

D. Walgreens Delayed Developing a SOMS Program, Instead it Relied on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags.

106. Though Walgreens had access to significant information about red flags due to its vertical integration with its retail stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

107. 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.

108. 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.

109. 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,"[33] via a 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.

110. In the May 2006 Letter, the DEA reminded Walgreens that it's suspicious ordering "formula should be based on (size, pattern, frequency),"[34] though Walgreens failed to even 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.

111. Even with its ample threshold, Walgreens identified thousands of suspicious orders placed by pharmacies and listed them on the Suspicious Control Drug Order report. Even then, however, as noted above, a store would not necessarily be reported for a violation, as Walgreens

[33] WAGMDL00709508.
[34] WAGMDL00709508.

required two consecutive months of exceeding thresholds to trigger reporting.[35] The Suspicious Control Drug Order report was generated on a nationwide basis and each report could be thousands of pages or more in length. This directly contravenes the regulatory requirement that suspicious orders be reported when discovered. 21 C.F.R. 1301.74(b).

112. 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.

113. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until after the orders were already filled and shipped. Walgreens sent the post-shipment Suspicious Control Drug Order report to the DEA on a monthly basis. In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, when an order exceeded the three times multiplier for more than one month in a given time period.

114. In September 2012, the DEA issued an immediate suspension order ("ISO") for Walgreens' Schedule II distribution center in Jupiter, Florida, finding Walgreens' distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The ISO contained a "statement of [the DEA's] findings regarding the danger to public health or safety" posed by Walgreens' distribution practices. Therein, the DEA specifically considered the Suspicious Control Drug Order reports and made the following findings of fact and conclusions of law regarding the reports and Walgreens' suspicious order monitoring system—applicable across Walgreens' operations:

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

[35] WAGMDL00400357 (April 3, 2007)

- "[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'] 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."

- "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 Respondent's customer pharmacies. *See* 21 C.F.R. § 1301.74(b); *see also Southwood Pharm., Inc.,* 72 Fed. Reg. 36,487 (2007)."

- "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'] 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."

115. Upon information and belief, in early 2013, Walgreens expected that its Perrysburg, Ohio distribution center would also be shuttered by the DEA for the same reasons. In anticipation of such an event, Walgreens asked Mallinckrodt to reroute its direct Schedule II purchases to other wholesale distributors. This "proactive" step would help maintain the level of potent opioids flowing to its retail stores.[36]

E. Walgreens Knew its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

116. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In 1988, the DEA specifically advised Walgreens "[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."

117. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. One of the managers for Walgreens' Pharmaceutical Integrity ("RX Integrity") Department stated

[36] MNK-T1_005639179

that, when he was with the Loss Prevention Department, he "basically burned the data on a CD and sent it off. I didn't dive into each individual report or CD" and that he "would look at it briefly, but just to see if the data transferred to the CD, but that's about the extent."[37] In a document submitted in connection with a deposition in the MDL, Walgreens acknowledged that it "is currently unaware of due diligence that was performed based on orders being flagged . . ."[38]

118. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

119. Moreover, in September 2007, three Walgreens' senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas.[39] Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact."[40]

120. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders." They go on to state that "[j]ust reporting these orders is not good enough – need to document what happened."[41]

[37] E. Stahmann Dep. at 287: 16-23.
[38] See E. Bratton 30(b)(6) Deposition Erratum No. 3, Ex. 333.
[39] CAH_MDL_PRIORPROD_DEA07_01185382. at CAH_MDL_PRIORPROD_DEA07_01185404-5.
[40] CAH_MDL_PRIORPROD_DEA12_00011059; HDS_MDL_00002032 at 2040. No federal law is being invoked. West Virginia requires compliance with the provisions that are set forth in the CSA.
[41] WAGMDL006558242.

121. Internally, Walgreens admitted that its pre-2009 suspicious order procedures were insufficient. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance:

> In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:
>
> DC-wide:
>
> - suspicious controlled drug order processing and reporting;
> - controlled drug reporting, specifically receiving record information;
> - lack of formalized CII controlled substance policies and procedures.

122. The Internal Audit goes on to state that "Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery." It also notes that while "Walgreens produces monthly Suspicious Controlled Drug Orders report," the audit team recommended discussions continue across multiple departments within Walgreens regarding "reporting suspicious control drug orders" and an "Updated Suspicious Control Drug Order Identification Methodology," with an "Estimated Completion Date for the New Reporting" of "June 30 2009." In this respect, too, it makes clear that the failures described are systemic. The audit also underlined Walgreens' lack of urgency in addressing the problems, indicating that the next "Cross-Functional Meeting" to

address the "Updated Suspicious Controlled Drug Order Identification Methodology" would not occur for more than five months, at the end of May 2009.[42]

F. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.

123. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

124. The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

125. MDL testimony from a Walgreens Director of Pharmacy Purchasing and Rx Supply Chain revealed that even as late as 2012, Walgreen's Pharmaceutical Integrity Department, which as of that time was charged with overseeing Walgreens' suspicious order monitoring (SOM) system, viewed the SOM system as an inventory control mechanism:

[42] WAGMDL00757193

> Q: Now, Walgreens' system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?
>
> A: It was put in place to ensure that the stores had the proper quantities. Not necessarily to . . . detect a red flag. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.

126. The second aspect of this DC level procedures required "pickers," the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

127. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

128. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens' distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

129. Walgreens' documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring ["SOM"] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program.[43] The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide.

130. From 2009 through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens' "three times" test, showing

[43] WAGMDL00660331; WAGMDL00709395.

that Walgreens' post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

G. Walgreens' New SOM Program Was Woefully Inadequate.

131. The SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

132. The new SOM system also allowed Walgreens' stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into store analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

133. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy" prompted an internal email from an employee in Walgreens' Loss Prevention Department, to Walgreens' Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance

activity.[44] The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week," and asked if his department had "a resource available" to assist.[45]

134. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens' new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens' policy of reducing and then filling and shipping suspicious orders without reporting them violated the CSA:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders,* not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood,* is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

135. Walgreens post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

136. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled

[44] WAGMDL00660331.
[45] Id.

nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not "make sense" to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor, and did not have any authority to take "direct action" on an order.

137. In a series of emails from January 10-11, 2011, between Ms. Martin and a Walgreens DC employee, the DC employee noted that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis," stating, regarding one store in Port Richey, Florida, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per week, stating, "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)." Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject."

138. In its investigation into this Port Richey store, the DEA found that "none of these orders were reported as suspicious and there appears to have been no other inquiries conducted into the circumstances of the enormous amount of narcotics being shipped." Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month,

Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

139. In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone. She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and couldn't take any "direct action." Approximately 18 months after this email exchange, as a result of DEA action, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin reviewed as part of her exemplary "due diligence."

140. In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges: "Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy." The DEA further found regarding this purported "due diligence," that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels." DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."

141. These failures were not limited to the specific Florida pharmacies and distribution center described above; instead, they reflect systemic failures of Walgreens' SOM system that impacted its distribution in West Virginia, as well.

142. Still, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Rather, at that time, the program began to

automatically reduce orders that violated ceiling thresholds.[46] There also is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

143. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped. With fewer than 5 people in the entire RX Integrity department, Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances."

144. Walgreens admitted to failures in suspicious order monitoring prior to 2012, and states that as a result of the DEA investigation and settlement, it formed the Pharmaceutical Integrity Team, to make sure those types of failures did not happen again. As summarized by one of Walgreens' Pharmaceutical Integrity Managers in August 2013:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override . . . The purpose for this is to ensure we have performed adequate review before sending in additional inventory.

145. Even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

146. Walgreens never properly equipped its distribution operations to properly monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the

[46] WAGMDL00667938.

financial impact of no longer... [self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."

H. Walgreens Failed to Put into Place Adequate Policies to Guard Against Diversion at the Pharmacy Level

147. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

148. 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, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being held responsible for "excessive c2 rx dispensing," her district supervisor instructed her "not [to] refuse script for large quantities" but simply to "call the MD's, document it on the hard copy[,] and that is all that is needed to protect your license." Despite internally recognizing that "a prescriber of a controlled

substance prescription [may be] involved in diversion", Walgreens's GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

149. In 2012, Walgreens finally removed the "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.

150. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present. To be clear, this required no inquiry into whether an opioid prescription was the proper treatment for a particular patient; instead, as a registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to identify and address signs of diversion.

151. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, 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 law or protecting public health.

152. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement 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."

153. Walgreens would also make more promises in a 2013 Memorandum with the DEA, described further below, related to failures to that lead to the ISOs described above.

154. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, "traditionally, we've always treated a controlled substance like any other, [a] widget's a widget to the system."[47]

155. Further, after the GFD "relaunch" in April 2014, a Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[48]

156. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each

[47] *See* D. Murray Dep., 31:20-22 (Jan. 15, 2019).
[48] Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

157. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens's supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure.[49]

158. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance … [with] regulatory requirements in… pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

[49] *Id.*

159. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware the GFD procedures or had been told by supervisors to disregard them.

160. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

I. Multiple Enforcement Actions Against Walgreens Confirm its Compliance Failures.

161. Governmental agencies and regulators have repeatedly penalized Walgreens for its serious and flagrant violations of the CSA in distributing and dispensing opioids. These actions demonstrate Walgreens' knowledge of, and disregard for, its obligations to prevent diversion.

162. On September 30, 2009, the DEA issued an Order to Show Cause 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 West Virginia pharmacies would not have been exempt.

163. Walgreens's settlement with the DEA stemmed from the DEA's investigation into Walgreens's distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens's corporate headquarters pushed to increase the number of oxycodone sales to Walgreens's Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center, a distribution center that also distributed into West Virginia.

164. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 MOA") with the DEA in relation to its San Diego facility and expressly agreed that it would "maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations."

165. On September 14, 2012, however, the DEA also issued an *Order to Show Cause and Immediate Suspension Order* ("ISO"), described above against Walgreens' Distribution Center in Jupiter, Florida, as well as ISOs related to certain Walgreens pharmacies. Evidencing the existence of systemic failures, the ISO stated that, "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration]."

166. 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 Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens' "alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."[50] 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.

167. 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."[51] 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.[52]

168. 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.

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[50] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[51] WAGMDL00490963 at WAGMDL00490964.

[52] *Id.* at WAGMDL00490968.

169. 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 not only turned a blind eye, but also provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. Yet Walgreens corporate officers ignored these abuses. In fact, the long term Controlled Substance Compliance Officer[53] 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.[54]

170. An August 2013 email shows Walgreens understood the consequences of its actions, explaining that Walgreens' "previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing products like Oxycodone."[55]

171. 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.

172. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the

[53] WAGMDL00815828; WAGFLDEA00000127.
[54] WAGFLDEA00001890.
[55] WAGMDL00021425

context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

173. The actions against Walgreens as a distributor and dispenser of opioids 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.

J. Walgreens Failed to Maintain Effective Controls Against Diversion in Distributing and Dispensing Opioids in West Virginia.

174. As discussed above and further below, Walgreens ignored red flags of diversion in West Virginia. Indeed, with respect to Walgreens suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOMs system in that litigation. *See* Order [Denying Walgreen's Motion for Summary Judgment], MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

175. According to ARCOS data, between 2006 and 2014, Walgreens self-distributed 444.6 million (444,629,949) opioid MME, the equivalent of 44.4 million 10mg hydrocodone tablets, to its retail pharmacy locations in West Virginia, a state with less than 2 million residents. This volume of opioids should have raised a red flag that not all of the prescriptions being ordered could be for legitimate medical uses and, as such, that many of the opioids Walgreens distributed to its retail stores were being diverted.

176. Walgreens self-distributed 444.6 million (444,629,949) MME of opioids from 2006 to 2014 to its pharmacies in West Virginia. Walgreens pharmacies in West Virginia bought an additional 263.2 million (263,291,691) MME of opioids from third party distributors.

177. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

178. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution and use of prescription opioids in West Virginia. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion, but it did not.

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

K. Defendants Worked with Opioid Manufacturers to Promote Opioids and Bolster Their Profits at the Expense of Communities Like West Virginia

180. Walgreens was not merely the distributor and dispenser of opioids marketed and prescribed by other players in the supply chain. Walgreens also worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

181. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow to tragic proportions.

182. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren't "turning away good customers" and encouraging stores to utilize continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

L. Walgreens Failed to Monitor for, Report, and Halt Suspicious Orders in West Virginia.

183. Walgreens failed to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion; and (e) protect against diversion at Walgreens pharmacies.

184. The volume of opioids Walgreens shipped into West Virginia and dispensed from its retail pharmacies was so high that it should have recognized that not all of the opioid prescriptions distributed to and dispensed from its retail pharmacies were for a legitimate purpose.

185. Yet, according to information from the DEA, Walgreens failed to report a single suspicious order in West Virginia between 2007 and 2014 – the period in which the DEA provided data. Despite the fact that Walgreens failed to report suspicious orders of its own customers, Walgreens' outside distributors reported 121 suspicious orders involving Walgreens pharmacies in West Virginia between March 3, 2013 and December 29, 2014.

186. Walgreens funneled far more opioids into West Virginia than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to distributors and dispensers such as

Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

187. Walgreens, therefore, was aware of the suspicious orders and prescriptions that flowed from its distribution facilities and retail pharmacies. Walgreens refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Walgreens failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into West Virginia and dispensed from Walgreens pharmacies.

188. Upon information and belief, Walgreens failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sale relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

M. Walgreens' Conduct Has Injured the State of West Virginia and Its Citizens.

189. Between 1999 and 2014, sales of opioids nearly quadrupled, according to the CDC. Nearly 259 million opioid prescriptions were written in the United States in 2012 alone. This equates to more than one opioid prescription for every American adult. Many tens of thousands of West Virginians are currently addicted to opioids.

190. Deaths from opioid overdoses do not fully capture the breadth of the harm suffered by West Virginia citizens. Opioid use results in thousands of hospitalizations and emergency room visits as well. The State of West Virginia often bears the cost of treatment.

191. The opioid crisis has also impacted some of West Virginia's most vulnerable demographics, such as the elderly. The AARP reports that elderly Americans have faced a 500% increase in hospitalization rates related to opioids over the last twenty years. In 2015, "physicians prescribed opioid painkillers to almost one-third of all Medicare patients, or nearly 12 million

people. In the same year, 2.7 million Americans over age 50 took painkillers in amounts—or for reasons—beyond what their physicians prescribed." Hospitalization rates due to opioid abuse has quintupled for those 65 and older in the past two decades.[56]

192. Walgreens' actions alleged in this Complaint have caused numerous societal injuries to the State of West Virginia. Walgreens' conduct has contributed to deaths, drug addiction, personal injuries, child neglect, children placed in foster care, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and lost productivity, among others. The State of West Virginia is expending its resources to address these and other social problems resulting from the opioid crisis and will continue to expend resources addressing these problems.

193. Walgreens' actions alleged in this Complaint have caused numerous economic injuries to the State of West Virginia. Walgreens' conduct has caused economic losses for medical treatment, rehabilitation costs, hospital stays, emergency room visits, emergency personnel costs, law enforcement costs, substance abuse prevention costs, costs for displaced children, naloxone costs, medical examiner expenses, self-funded state insurance costs, and lost tax revenues, among others.

COUNT I
Violation of the West Virginia Consumer Credit and Protection Act

194. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 193 of this Complaint as if fully set forth herein.

195. Walgreens distributed and dispensed opioid products to the State of West Virginia and its governmental entities, businesses, and consumers within West Virginia.

[56] *See* https://www.aarp.org/health/drugs-supplements/info-2017/opioid-drug-addiction-pain-pills.html.

196. Walgreens' distribution and dispensing of opioid products in the State of West Virginia involves trade or commerce within the meaning of the WVCCPA.

197. Violations of statutes enacted to protect the consuming public or to promote a public interest are unfair or deceptive acts or practices. *See Final Order, State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General vs. David McCuskey et al.*, Kanawha County Circuit Court, Civil Action No. 01-C-3041, Mar. 13, 2003. *See also Pabon v. Recko*, 122 F. Supp.2d 311, 314 (D. Conn 2000); *Lemelledo v. Beneficial Management Corp. of America*, 674 A.2d 582 (N.J. Super. Ct., App. Div. 1996); *Winston Realty Co., Inc. v. G.H.G., Inc.*, 331 S.E.2d 677 (N.C. 1985).

198. Walgreens' actions, as detailed above, constitute unfair or deceptive acts or practices that are prohibited by the WVCCPA.

199. Each occurrence of a failure to abide by laws and rules enacted to protect the consuming public or to promote a public interest constitutes an unfair or deceptive act or practice in violation of the WVCCPA, *See* W. Va. Code § 46A-6-104.

200. Walgreens' unfair, deceptive, and unconscionable acts or practices, or the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined.

201. Consequently, the State of West Virginia seeks all available relief under the WVCCPA, including but not limited to disgorgement, restitution, civil penalties, equitable relief, injunctive relief, and attorneys' fees and costs.

202. As part of its WVCCPA action, the State expressly does not raise claims nor seek any damages attributable the Medicaid or Medicare programs or any other federal programs. Additionally, as part of its WVCCPA action, the State expressly does not raise claims or seek any

damages for the State's workers' compensation program, nor does it raise claims or seek damages on behalf of any state agencies.

COUNT II
Common Law Public Nuisance

203. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 193 of this Complaint as if fully set forth herein .

204. Through the actions described above, Walgreens has contributed to and/or assisted in creating and maintaining a condition that has interfered with the operation of the commercial market, interfered with public health, and endangered the lives and health of West Virginia residents.

205. While Walgreens' degree of care is not relevant in a common law nuisance suit brought by the sovereign State, it behaved negligently, recklessly, or intentionally as set forth above.

206. Through the actions described above, Walgreens contributed to and/or assisted in creating and maintaining a condition that causes enormous public harm, endangers the life or health of West Virginia residents, and unreasonably interferes with or obstructs rights common to the public.

207. Walgreens expanded the market for prescription opioids by failing to implement effective controls and procedures to guard against diversion, including but not limited to failing to report their knowledge of suspicious orders to relevant authorities, shipping orders it knew were suspicious, and failing to protect against diversion at Walgreens pharmacies.

208. Opioid use, abuse, addiction, and overdose deaths increased dramatically in West Virginia as a result of Walgreens' conduct. The greater demand for emergency services, law

enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources.

209. Walgreens' actions described above were a substantial factor in opioids becoming widely available, used and abused.

210. Walgreens' actions significantly contributed to the widespread use of opioids and to the enormous public health hazards of opioid overuse, abuse, addiction, and death that now exists. Walgreens' actions have and will continue to injure and harm the citizens and the State of West Virginia for many years to come.

211. While tort-based standards are not applicable to a public nuisance suit brought by the State, the public nuisance and associated financial and economic losses were foreseeable to Walgreens, which knew or should have known that its unfair and deceptive business practices as described herein were creating a public nuisance.

212. While tort-based standards are not applicable to a public nuisance suit brought by the State, a reasonable person in Walgreens' position would foresee the widespread problems of opioid addiction and abuse that resulted from the drastic oversupply of opioids in this state.

213. Walgreens was on notice and aware of the broader use of opioids that were causing the kinds of harm described in this Complaint.

214. The health and safety of West Virginia residents, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State. West Virginians have a right to be free from conduct that endangers their health and safety and that interferes with the commercial marketplace. Walgreens' conduct interfered in the enjoyment of these public rights.

215. As part of its nuisance action, the State expressly does not raise any claim nor seek any damages attributable the Medicaid or Medicare programs or any other federal programs. Additionally, as part of its nuisance action, the State expressly does not raise claims or seek any damages for the State's workers' compensation program, nor does it raise claims or seek damages on behalf of any state agencies.

Prayer for Relief

WHEREFORE, Plaintiff State of West Virginia prays for the following relief:

a. Judgment against the Defendants in favor of the State;

b. Temporary relief, a preliminary injunction and permanent injunction ordering the Defendants to comply with W. Va. Code § 46A-6-104 and to cease the unlawful conduct;

c. Equitable relief, including, but not limited to, restitution and disgorgement;

d. Civil penalties of up to $5,000.00 for each repeated and willful violation of W. Va. Code § 46A-6-104, pursuant to W. Va. Code § 46A-7-111(2);

e. Pre- and post-judgment interest;

f. Costs and reasonable attorneys' fees; and,

g. Such other relief, fees and costs as shall be available under the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101, *et seq.*;

h. An order abating the public nuisance and ordering any injunctive relief that the Court finds appropriate under law; and

i. An order awarding such other and further relief as the Court deems appropriate.

STATE OF WEST VIRGINIA ex rel.
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Attorney General

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