EFiled: Oct 06 2021 02:45PM EDT
Transaction ID 66994002

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-131 PNM**

CVS PHARMACY, INC., a Rhode Island corporation,
CVS INDIANA, LLC, an Indiana corporation,
CVS RX SERVICES, INC., a New York corporation,
WEST VIRGINIA CVS PHARMACY, LLC and
CVS TN DISTRIBUTION LLC, a Delaware corporation,

Defendants.

FIRST AMENDED COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues CVS Pharmacy, Inc., CVS Indiana, LLC, CVS Rx Services, Inc., West Virginia CVS Pharmacy, LLC and CVS TN Distribution LLC (hereinafter "CVS" 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 Defendant. 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]

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

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 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. This has resulted 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.

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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.
[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.

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 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 §§

[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.

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 those 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. Defendants

18. CVS Health Corporation is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS Health Corporation is included for identification purposes.

19. CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a subsidiary of CVS Health Corporation. CVS Pharmacy, Inc. is registered to do business in West Virginia.

20. CVS Indiana, LLC is an Indiana corporation and a subsidiary of CVS Pharmacy, Inc. Between at least 2006 and 2014, CVS Indiana, LLC was licensed by the West Virginia Board of Pharmacy as a wholesale distributor and distributed opioids to CVS pharmacies in West Virginia.

21. CVS Rx Services, Inc. is a New York corporation and a subsidiary of CVS Pharmacy, Inc. Between at least 2006 and 2014, CVS Rx Services, Inc. was licensed by the West Virginia Board of Pharmacy as a whole sale distributor and distributed opioids to CVS pharmacies in West Virginia.

22. CVS TN Distribution LLC is a Tennessee corporation and a subsidiary of CVS Pharmacy, Inc. Between at least 2006 and 2014, CVS TN Distribution LLC was licensed by the

West Virginia Board of Pharmacy as a wholesale distributor and distributed opioids to CVS pharmacies in West Virginia.

23. West Virginia CVS Pharmacy, LLC, is a West Virginia limited liability company with its principal place of business in Charleston, West Virginia., whose sole member is CVS Pharmacy Inc.

24. Defendants are herein collectively referred to as "CVS."

25. CVS has 9,900 retail pharmacies in the United States with 52 locations in West Virginia, including 38 cities and 24 counties.

26. In 2005, CVS filled over 366 million prescriptions which was 14% of the market. Sales from its retail pharmacies comprised 94% of CVS's consolidated net sales and 91% of its consolidated profit in 2004.

27. During 2019, CVS filled 1.4 billion prescriptions which is approximately 26.6% of the total retail pharmacy prescriptions in the United States.

28. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Between at least 2006 and 2018, CVS distributed prescription opioids to its retail pharmacies located in West Virginia. At all relevant times, CVS operated as a licensed wholesale distributor in the State of West Virginia.

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

III. State Court Jurisdiction

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

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

32. 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).

33. 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.*, 2018 WL 7352753 at *3 (M.D. Ga. 2018).

34. 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*, 1:19-01007-KD-B, 2020 WL 223618 (S.D. Al. 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.*, 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).

35. 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

36. 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.

37. This court has jurisdiction over CVS Health Corporation 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 CVS Health Corporation to the State. CVS Health Corporation, 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.

38. At all relevant times, and as the parent company of the CVS Subsidiaries, Defendant CVS Health Corporation established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States. CVS Health Corporation 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 CVS Health Corporation was responsible for directing and implementing policies and procedures governing the distribution of controlled substances by its

subsidiaries, including but not limited to the CVS Subsidiaries, throughout the United States, including in West Virginia.

39. CVS Health Corporation exercised control as a parent over its subsidiaries such that the subsidiaries should be imputed to CVS Health Corporation. 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, referring to subsidiaries' financial responsibilities as the parent's own, using subsidiary property as one's 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.

40. CVS Health Corporation 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 CVS Subsidiaries. These two entities were directly intermingled and joined in its business activities and practices.

41. CVS Health Corporation consistently oversaw and was involved in the acts of its subsidiaries, including but not limited to CVS Health Corporation, described in this complaint.

42. As alleged below, CVS Health Corporation, through its control over CVS Subsidiaries caused the oversupply and diversion of opioids in West Virginia.

V. Venue

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

VI. Factual Allegations

44. CVS played a dual role in fostering the opioid epidemic by operating pharmacies dispensing opioids to the public and as a wholesale distributor taking orders from and shipping orders to its own pharmacies. CVS distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of drug distributors to detect, warn, and prevent diversion of dangerous drugs. CVS 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, CVS 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 distributor, CVS filled suspicious orders of prescription opioids of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency from its own pharmacies. CVS 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 CVS Health Corporation. Moreover, CVS, 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.

45. CVS had unique knowledge typically unavailable to wholesale drug distributors because it had dispensing and claims data from its pharmacies throughout West Virginia and across the country to alert it to suspicious orders and the diversion of opioids. CVS used its nationwide data to investigate and monitor patients and prescribers.[9] "Analyses of aggregated data like ours

[9] Betses, M., & Brennan, T. (2013). Abusive prescribing of controlled substances—A pharmacy view. *New England Journal of Medicine, 369,* 989–991.

can also target patterns of abuse by both prescribers and patients. Given the growing use of controlled substances and the resulting illness and deaths, more innovative use of transparent data is only prudent."[10] In spite of these aspirations, CVS failed to adequately review its data to assist with its distribution due diligence responsibilities.

46. Moreover, when such prescribers were identified, CVS did not alert authorities in West Virginia or the Drug Enforcement Administration (DEA). CVS failed to implement any monitoring and reporting system related to controlled substances it purchased from third-party distributors. Not only did it fail to monitor, but on the off-chance it would discover a suspicious order shipped from a third-party distributor, CVS directed employees not to notify the DEA:

> "[controlled substance] orders that are placed to an Outside Vendor that we identify as an order deviating from the normal size, frequency, and/or buying pattern and deemed to not be for a legitimate purposes or are at risk of being diverted are not required to be reported to the DEA."[11]

47. CVS was among the top ten (10) distributors of opioids in West Virginia.[12]

48. Between 2006 and 2014, CVS distributed opioids equivalent to over 730.5 million (730,553,422) milligrams of morphine ("MME") to its 52 retail pharmacies in West Virginia.[13]

49. Although CVS was among the top ten distributors to West Virginia, its "self-distribution" was not enough to fulfill the opioid demand at its retail pharmacy stores.

50. Between 2006 and 2014, CVS's West Virginia pharmacies ordered additional opioids totaling 1.7 billion (1,675,864,781) MMEs from third-party distributor Cardinal Health.[14]

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[10] *Id.* at 991.
[11] Craig Schiavo Dep. (Jan. 17, 2019), at 257:9-258:1. See also Schiavo Ex. 16 at CVS MDLT1-000078060-78069 at 78068.
[12] DEA ARCOS 2006-2012.
[13] 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.
[14] DEA ARCOS 2006-2014.

51. During that same period, CVS pharmacies in West Virginia bought over 2.4 billion (2,406,418,203) MMEs of opioids to dispense in West Virginia.[15]

52. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in West Virginia is indicative of potential diversion and required appropriate due diligence.

53. CVS is a vertically integrated distributor and dispenser of prescription opioids. Based both on its distribution to its own CVS stores in West Virginia, and the dispensing by those stores, CVS had the information showing that an excessive volume of pills was being sold into West Virginia and ultimately, onto its streets.

54. CVS 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.

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

56. At the pharmacy level, upon information and belief, based upon CVS's distribution outside of West Virginia and the operation of pill mills in the state, CVS 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 of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently

[15] DEA ARCOS 2006-2014.

abused with opioids, like benzodiazepines, or prescription "cocktails";[16] (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. CVS 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.

57. The information available to CVS through its distribution centers and retail stores put it on notice that it was exceeding legitimate market demand. Rather than report suspicious orders and stop diversion, CVS continued to dispense, sell, ship, dispense and profit from these highly dangerous drugs. CVS never reported a single suspicious order from its distribution centers related to any opioids distributed in West Virginia.[17]

A. CVS Was Required To Monitor For And Report Suspicious Orders, Not To Ship Those Orders Unless Due Diligence Disproved The Suspicions.

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

59. CVS was required by law 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

[16] According to definitions applied by CVS for suspicious order monitoring purposes, "cocktails for opioids are methadone, muscle relaxants, stimulants and benzodiazepines."
[17] Mark Nicastro Dep. (Dec. 6, 2018), at 206:3-209:9, CVS-MDLT1-000000409-0000420 at 417; CVS-MDLT1-000000421-00000422.

of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

60. CVS was registered as a wholesale distributor with the West Virginia Board of Pharmacy from 2003 through 2017.

61. 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.[18]

62. CVS 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."[19]

63. 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."[20]

64. 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,

[18] W. Va. C.S.R. § 15-2-4; 21 C.F.R. § 1306.04(a)
[19] 21 C.F.R. § 1306.04(a)
[20] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf

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.[21]

65. Thus, in addition to its duties as a distributor, CVS also had a duty to design and implement systems to prevent diversion of controlled substances in its retail pharmacy operations. CVS had the ability, and the obligation, to look for red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions suggestive of potential diversion.

66. The West Virginia Uniform Controlled Substances Act (WVCSA) requires that distributors' operations be consistent with the public interest and also requires registrants 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).

67. The requirements under WVCSA independently parallel and incorporate the requirements of the federal Controlled Substances Act (CSA). *See* W.Va. C.S.R. § 15-2-3. CVS 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, detect, report, investigate and refuse to fill suspicious orders and prescriptions. *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. § 15-2-7.

68. Distributors are not entitled to be passive observers, but rather "shall inform the Field Division Office of the (Drug Enforcement) 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

[21] *Id.;* W. Va. Code § 60A-3-302.

unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

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

70. The DEA previously testified that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.[22]

b. Shipping a suspicious order is a per se violation of federal law.[23]

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.[24]

d. After the fact reporting of suspicious orders has never been in compliance with federal law.[25]

71. 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 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).

72. 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

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

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."[26] 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."[27]

73. In sum, CVS had several requirements with respect to preventing diversion. CVS was required to set up a system designed to detect and reject suspicious orders. CVS 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.

74. 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 the distributor has conducted an adequate investigation and determined that the order is not likely to be diverted into illegal channels.[28] CVS failed to meet these requirements, and CVS's failure to exercise appropriate controls foreseeably harms the public health and welfare.

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

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[26] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).

[27] *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*.

[28] *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).

76. 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.

77. CVS's pharmacies were registered to dispense prescription opioids with the West Virginia Board of Pharmacy from at least 2001 through 2018.

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

79. 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."[29]

80. 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 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*

[29] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf

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").

81. Each failure by CVS 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)

82. CVS never reported a single suspicious order to authorities in West Virginia or the DEA regarding its distribution of opioids in West Virginia.[30]

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

83. CVS, 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. CVS serves on its board. The Healthcare Distribution Management Association ("HDMA"), now known as Healthcare

[30] Mark Nicastro Dep. (Dec. 6, 2018), at 206:3-209:9, CVS-MDLT1-000000409-0000420 at 417; CVS-MDLT1-000000421-00000422.

Distribution Alliance ("HDA"), is a national trade association representing distributors and has partnered with NACDS. CVS also was a member of the HDA.

84. In 2006, the NACDS issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs.[31] 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.

85. In 2007 and 2008, the HDA began developing "industry compliance guidelines" ("ICG") that aimed to outline certain best practices for drug 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."[32]

[31] CAH_MDL2804_00842870.
[32] HDA_MDL_000213058.

86. CVS 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 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.[33]

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

88. The DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,"[34] 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.

89. 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."

90. 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

[33] HDA_MDL_00213212.

[34] 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.

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."

91. 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.

92. "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."

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

94. Despite its obligation to implement and maintain systems to prevent diversion as required to comply with the WVCSA and CSA, CVS 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, CVS 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.

95. The DEA has repeatedly informed distributors and dispensers, including CVS, 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.

96. 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.[35]

97. 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."[36] 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

[35] CAH_MDL2804_01465723.
[36] US-DEA-00025657.

> 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 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.[37]

98. 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 reminds 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 warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

99. 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,

[37] US-DEA-00025659.

report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the December 27, 2007 letter references 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."

100. 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.[38]

101. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as CVS 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.

102. The DEA also brought actions against CVS for pharmacy related violations. For example, an investigation by the U.S. Attorney's Office for the District of Rhode Island found that

[38] CAH_MDL_PRIORPROD_DEA07_00877084; CAH_MDL_PRIORPROD_DEA07_01185382.

CVS retail pharmacies filled 39 prescriptions for Percocet that CVS pharmacists had reason to know were forged, in violation of the CSA. On April 16, 2019 CVS paid $535,000 for filling invalid prescriptions in Rhode Island pharmacies.[39]

103. Another example of a DEA action against CVS for pharmacy activities arose out of two pharmacies in Florida. A CVS Pharmacist-in-Charge admitted to filling prescriptions for a large number of customers who presented the same "cocktail" of combination drugs known to signal abuse or diversion. She said that the majority of the diagnostic codes listed by the prescribing physician for these patients was the same. Twenty of the doctors whose prescriptions were being filled by these two CVS pharmacies in Florida had been the subject of civil and criminal disciplinary actions by the DEA for their prescribing practices. All but 4 of the 20 doctors' offices were over 200 miles away from the CVS pharmacies filling prescriptions. Pharmacists admitted to filling prescriptions for patients that they believed were not medically necessary. In fact, one Pharmacist-in-Charge stated that she would hide some of her pharmacies' supply of OxyContin 30mg pills for "the real pain patients."[40]

104. Nationally, CVS has been investigated for alleged violations of the CSA and entered into settlement agreements with the DEA to resolve a number of investigations occurring between 2013 and 2019. The allegations range from 1) filling prescriptions from doctors who were not licensed to prescribe Schedule II drugs; 2) failure to timely report significant thefts of controlled substances; 3) failure to have adequate policies and procedures in place to prevent stolen narcotics; 4) failure of CVS pharmacies to abide by its corresponding responsibilities. These prior actions include:

[39] https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions
[40] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 38-41 (D.D.C. Feb. 24, 2012).

a. In 2018, CVS paid a civil penalty of $1.5 million relating to its failure to timely report the loss or theft of controlled substances in certain of its New York stores, as well as a penalty of $1 million relating to record keeping violations in certain of its Alabama stores.

b. In 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[41]

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

d. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

e. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

f. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

g. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

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

[41] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

i. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

j. In April 2013, CVS paid $11 million in civil charges relating to allegations that its Oklahoma retail pharmacies created fake DEA license numbers, filled prescriptions for doctors without valid licenses, and improperly labeled prescription vials. A few months later, in August 2013, CVS was also fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

k. In 2010, CVS admitted to illegally selling pseudoephedrine to criminals who made methamphetamine and agreed to pay $77.6 million to resolve the government investigation.

l. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere were found to have intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

105. These enforcement actions and settlements across the country over more than a decade are the product of policies and procedures that were implemented at a national level and would have impacted CVS's operations in West Virginia.

106. 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**.

107. The DEA has also repeatedly emphasized that retail pharmacies, like the CVS pharmacies, are required to implement systems that detect and prevent diversion and must monitor for red flags of diversion.

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

109. Each failure by CVS 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. CVS Was Uniquely Positioned To Prevent Diversion.

110. As vertically-integrated pharmacy and distributor, CVS had access to additional information that would allow it to identify and prevent diversion, unlike third-party wholesale distributors. CVS 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.

111. Illustrating the value of this information, CVS Caremark's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber

level data, drug level data, plan level data, [and] de-identified patient data." Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).

112. At the pharmacy level, CVS had 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.

113. 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 gave CVS 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.

114. CVS 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, CVS 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.

115. CVS knew the opioids it was supplying to its pharmacies were being diverted. Between 2010 and 2019, CVS paid civil penalties totaling $131,292,500.00 for various violations of the Controlled Substances Act. These violations included filling prescriptions written by a doctor without a valid registration number, filling prescriptions that were not issued for a legitimate medical purpose, filling forged prescriptions for addictive painkillers, filling invalid prescriptions, failing to monitor drug use patterns or use professional judgment when dispensing controlled substances, and failing to install equipment to allow pharmacists to check patients' prescription histories.[42]

116. As acknowledged in an article CVS published in the New England Journal of Medicine, "[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular." Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12, 2013, at 989-991. The DEA has identified "both pharmaceutical distributors and chain pharmacies as part of the problem" contributing to opioid abuse and related deaths.

117. CVS has a particular "advantage" in meeting their obligations under the CSA because these entities can use "aggregated information on all prescriptions filled at the chain" in order to examine "patterns" of opioids and other "high-risk drugs" and target "inappropriate prescribing." *Id*. at 990. For example, a chain pharmacy should properly use its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash payment, ages of patients, and

[42] https://violationtracker.goodjobsfirst.org/prog.php?parent=cvs-health&page=1.

the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances." *Id*. This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." *Id*. Accordingly, as CVS touts, "innovative use of transparent data is only prudent." *Id*.

118. As CVS counseled, Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

D. CVS Failed to Maintain Effective Suspicious Order Monitoring System or to Complete Necessary Due Diligence.

i. CVS Lacked Necessary Policies and Procedures Needed to Prevent Diversion

119. CVS did not, for the relevant time period, provide adequate guidance and training materials to its pharmacists to detect and prevent the diversion of opioids at its pharmacies nationwide, including West Virginia, as mandated by the CSA.

120. In June of 2011, CVS developed a policy related to forged or altered prescriptions that contained some of the "red flags" suggested by the DEA in evaluating prescriptions for Schedule II drugs.[43] These guidelines include but are not limited to, verifying legitimacy of a prescription before dispensing by verifying the identity of the patient, reviewing the patient's profile before filling a prescription for a controlled substance, contacting the prescriber with any

[43] Suspected Forged or Altered Prescriptions, Document ID: ROPP-0059, June 30, 2011, CVSMDLT1-0000815521558.

concerns about the type, dosage frequency or amount of medication prescribed, and documenting those communications.[44]

121. It was not until 2012, however, that CVS generated a written policy entitled the *Guidelines for Dispensing Controlled Substances,* which explains in more detail the "red flags" or cautionary signals that CVS pharmacists should monitor to prevent diversion and to fulfill their corresponding responsibility to ensure that all controlled substances are dispensed for a legitimate medical purpose.[45]

122. Some of the red flags include prescriptions from practitioners for multiple patients in the same dosage, preprinted or stamped prescriptions, patients who pay in cash, suspected forged or altered prescriptions or patients that seem visibly intoxicated or incoherent.[46]

123. The 2012 Guidelines advise pharmacists to contact the practitioner with any concerns about the type and quantity of medication and, when dispensing a controlled substance medication such as oxycodone, hydrocodone, "where you have no relationship with the patient and/or the prescriber, you should verify with the practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined." The 2012 Guidelines continues, "Note that this verification process is but one step that a pharmacist should take to ensure that a prescription is issued for a legitimate medical purpose."[47]

124. In 2014, CVS established a written policy entitled "Federal Regulations and CVS Pharmacy Guidelines for Controlled Substances" that includes additional guidance on dispensing

[44] *Id*.
[45] Guidelines for Dispensing Controlled Substances, Document ID ROPP-0061, January 4, 2012, CVSMDLT1-000055548 – 55550.
[46] *Id*.
[47] Id. CVS-MDLT1-000055549

controlled substances, including DEA regulations that require "that controlled substance prescriptions must be issued for a legitimate medical purpose and the regulations place "corresponding responsibility" on the Pharmacist who fills the prescription."[48]

125. The 2014 Guidelines also refers the CVS pharmacy employee to the 2012 Guidelines.

126. Even as they evolved over time. CVS lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion. Not until 2012—years after the opioid epidemic in West Virginia was in full force—did CVS put in place guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and comply with the law.

127. CVS's conduct, and the volume it dispensed in West Virginia, indicates that its policies were not applied or effective.

128. In addition, CVS had performance metrics in place that pressured pharmacists to fill prescriptions, and to fill them quickly, putting profits ahead of safety.

129. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any meaningful measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists were calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013, and after that time,

[48] Federal Regulations and CVS Pharmacy Guidelines for Controlled Substances, Document ID: ROPP-047561, May 2, 2018, CVS-NH0000018-38.

the pressure from the metrics' focus on profitability remained. These policies remained in place even as the epidemic raged. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics' focus on profitability remained. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[49]

130. Former pharmacists at CVS have publicly complained about pressure to put speed ahead of safety. Concerning the metrics at CVS, one pharmacist commented, "You get stressed, and it takes your mind away from the actual prescriptions." Another former CVS pharmacist recalled that "[e]very prescription [wa]s timed," and a backlog would pop up in color on pharmacists computer screens if they fell behind.[50] Additionally, CVS has faced discrimination complaints alleging that the company's "Metrics" system set unobtainable goals — or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists' professional responsibilities, edging out older pharmacists.

131. More recently, a former CVS pharmacist in North Carolina described being driven to leave his position and open his own pharmacy, where he could work safely. He described working a 13-hour shift with no breaks for lunch or dinner at CVS the day before he left in December 2018; a day on which he filled "552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through." In departing, he let his manager know that he would not "work in a situation that is unsafe." One

[49] *See* Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html

[50] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

pharmacist was so alarmed that he wrote anonymously to the Texas State Board of Pharmacy to caution: "I am a danger to the public working for CVS."[51]

132. It is difficult to contemplate how any pharmacist could and/or would be able to meaningfully comply with any corporate policy regarding red flag analyses or any anti-diversion analysis under such draconian pressures.

133. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

134. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[52]

135. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially

[51] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html

[52] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/.

decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[53]

136. Still, according to a 2016 investigation by the Chicago Tribune, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews — or skip them altogether," missing dangerous drug combinations in the process.[54] A pharmacist too rushed to check for a potentially deadly drug interaction is also likely to be too rushed to check for red flags of diversion, such as prescription "cocktails" or other combinations of highly abused drugs.

137. The culture CVS created undermined its pharmacists' and technicians' ability to adequately prevent diversion. CVS's quest for increased sales substantially contributed to the public nuisance in West Virginia. CVS's corporate headquarters knew these outrageous sales numbers and failed to stop the excessive flow of opioids into the state.

ii. CVS Lacked A Genuine Suspicious Order Monitoring System for Much of the Relevant Time.

138. CVS distribution centers, along with outside vendors, supplied opioids to CVS pharmacy stores until 2014.

139. Before 2009, CVS lacked any meaningful suspicious order monitoring ("SOM"). Instead, CVS relied on gut instincts of "Pickers and Packers" of the drugs in the distribution center to identify "really big" orders that they believed were simply too large.[55] This was not an effective, or legally compliant, SOM system – or a system at all.

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[53] *Id*.
[54] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html.
[55] *See* Deposition testimony of CVS employee Sherri Hinkle (January 25, 2019), *In re: National Prescription Opiate Litigation*, 1:17-MD-2804 at 75:8.

140. Moreover, CVS lacked a training program to prepare its Pickers and Packers to identify orders of unusual size, frequency, or pattern. In a deposition, a CVS employee testified that CVS did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations. And, there were no formal qualifications or training to be employed as a Picker and Packer.[56]

141. CVS did not even begin to design a rudimentary SOM program until 2007.[57] Then, with the help of an outside consultant, CVS began work on a Standard Operating Procedure Manual ["SOP"] that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring.[58] However, by November, 2007 neither the final manual nor the suspicious order monitoring ("SOM") section was complete. Internal documents from that time acknowledge that CVS was "still in the process of writing the Suspicious Order Monitoring Section of the SOP."[59] During the same deposition described above, CVS's corporate representative testified that he did not "believe that there was a suspicious order monitoring policy put into place as of that date."[60]

142. Drafts of the SOP demonstrate that CVS understood, or should have understood, that the lack of a suspicious order monitoring policy was unacceptable. The draft SOP provides that: "CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else."[61] Despite this acknowledgement,

[56] *See* Deposition testimony of CVS employee Sherri Hinkle, Hinkle dated January 25, 2019 at 75:8 Vernazza Dep. Tr. 197:1-9; 198:3-199:2.
[57] Expert Report of Whitelaw, MDL 2804, filed at Doc. 1999-25.
[58] Expert Report of Whitelaw, MDL 2804, filed at Doc. 1999-25 *See* CVS-MDLT1-000109199; CVS-MDLT1-000025204 at CVS-MDLT1-000025206 ["2007 DEA SOP"].
[59] *See also* Email from A.L. Brown to A. Brumfield, et al., New RX DEA SOP (Nov. 27, 2007), CVS-MDLT1-000025204.
[60] Vernazza Dep. Tr. 214:22-215:10; Vernazza Dep. Tr. 221:5-13.
[61] CVS-MDLT1-000025206 at 207.

when the first version of the SOP was finally issued in December 2007, the SOM section still remained incomplete.[62] As of April 2009, it remained so.[63]

143. As John Mortelliti, CVS's Director of Loss Prevention, wrote in November 2009, this had become "a big issue with CVS and the DEA," and he was "trying to get a rough draft SOM SOP" before a DEA meeting.[64] Ultimately, CVS did not incorporate the final missing section until the end of August 2010, and even then, evidently did so only because of the need to fulfill an apparent promise to provide it to the DEA.[65]

144. In a September 2010 e-mail, Mr. Mortelliti circulated an August 27, 2010 document titled "Suspicious Order Monitoring for PSE/Control Drugs: Summary of Key Concepts & Procedures," which he described as "final approved speaking points for the DEA" should DEA agents question suspicious order monitoring at a CVS facility. In the correspondence, he asked that the recipients "be sure [their team] understands [the material] before presenting so it doesn't look like a prop instead of a tool."[66]

145. As of November 2011, CVS had a "CVS DEA compliance coordinator" in name only. A former CVS employee who held the position at that time has said that this was only "for reference in SOPs," not her real job. For "personnel purposes," she was never considered the CVS DEA compliance coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than "updating the SOP with what was provided for the program."[67]

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[62] *See* RX-01(2009).
[63] *See* Email from A. Propatier to W. McDaniels, et al., Updated DEA SOP (Apr. 3, 2009) (A. Propatier was formerly A.L. Brown), CVS-MDLT1-000066574.
Vernazza Dep. Tr. 235:14-23.
[64] *See* Email from J. Mortelliti to C. Knight, RE: November 10, 2009 (Nov. 5, 2009), CVS-MDLT1-000087889.
[65] *See* RX-01(2010); *See also* Email from A. Propatier to A. Lamoureux, DEA SOP 08-25-10.doc (Aug. 26, 2010), CVS-MDLT1- 000088956; Email from J. Mortelliti to F. Devlin, et al., RE: DEA SOP (Aug. 23, 2010) (referencing Mr. Devlin's earlier email to him stating "we promised this to DEA by Wednesday."), CVS-MDLT1-000089188.
[66] Email from J. Mortelliti to P. Hinkle et al. (Sept. 1, 2010) (CVS-MDLT1-0000075299-75312,).
[67] *Id.*

iii. CVS Failed to Remedy Fatal Flaws in the System it Slowly Developed.

146. In 2009, CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. The automated program was delivered by an outside vendor to CVS in December of 2008.[68]

147. CVS called the output of the flagged orders an Item Review Report ("IRR").

148. IRRs were the primary SOM process. As CVS's corporate representative explained in the MDL on behalf of the company, "for the most part," if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order.[69] Yet, CVS neglected to provide written instructions for how to perform that critical review until February 29, 2012. Further, the IRR system was deficient and failed to meet CVS's obligations as a distributor in many respects.

149. CVS also learned in 2010 that its SOM algorithm was not working properly because it monitored by drug, not active ingredient, meaning that changes in a drug's description or name caused historical data, necessary for valid calculations, to be lost.[70]

150. CVS's SOMS algorithm also failed to consider outside vendors orders, meaning that CVS's SOM system would not track how many opioids CVS was ordering from third party distributors when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under [the] radar."[71] It also knew that waiting to consider outside vendor data until later in the process meant CVS "may ship a potentially reportable suspicious

[68] Expert Report of Whitelaw, MDL 2804, filed at Doc. 1999-25.
[69] Vernazza Dep. Tr. 392:20-393:7.
[70] CVS-MDLT1-29864-29866
Mortelliti Depo., 129:11 – 131:11, Ex, 16; Vernazza Depo., pp. 400 – 455.
[71] MDL Doc #: 2208-10.

order from [its] DC."[72] Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time."[73] This deficiency is particularly glaring because CVS had full access to the orders its pharmacies placed to outside vendors.

151. Recognizing the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system.[74]

152. Still, as late as July 2013, internal e-mails reflect that CVS's primary tool for investigations used stale data that made any analysis, "for the most part, irrelevant and pointless."[75]

153. Not until mid to late 2014 did CVS fully implement the new SOM system.[76] That same year, CVS stopped distributing opioids at the wholesale level.

iv. CVS Failed to Perform Due Diligence.

154. All orders that appeared on the IRR should have been subjected to a thorough due diligence investigation, but only a very small percentage were subjected to appropriate due diligence investigation. From early/mid-2009 through March 2011, one employee, Henry "John" Mortelliti, "was taking the first pass through the IRR himself."[77] According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and conduct review and due diligence as he deemed appropriate."[78] At select times in 2012 and 2013, CVS had only one

[72] CVS-MDLT1-000103327-000103328, at 28.
[73] *Id.*
[74] Expert Report of Robert L. Hill, May 31, 2019, MDL-2804, Doc. 3122-2; CVS-MDLT1-000125136.
[75] CVS-MDLT1-78116.
[76] Baker Dep. Tr. 259:16–262:19; Ex. 27; Ex. 29.
[77] Vernazza Dep. Tr. 365:6-13, Ex. 385. *See also id.* at 368:9-14.
[78] Vernazza Dep. Tr. 371:15-23.

employee reviewing all potentially suspicious orders for every pharmacy in the country.[79] The Suspicious Order Monitoring system would select certain orders based on a number of factors and "pend" the order. If an order was selected, the CVS SOM manager would review the orders and conduct an "in depth" dive on select orders. Even though the SOM program would identify between 200 and 500 suspicious orders a day, the CVS employee would only have time to do a "deep dive" on 5-6 orders per day. A single employee was responsible for reviewing for IRR one half of the country over a period covering twelve days ranging from June 14, 2012 to September 6, 2012, during which time CVS investigated a total of seven control substance orders.[80] As of November 21, 2013, CVS reported only 7 suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States.[81] The first suspicious order CVS ever reported to the DEA was on February 29, 2012. CVS reported no suspicious orders in West Virginia.

E. CVS Worked with Opioid Manufacturers to Promote Opioids and Bolster Its Profits, Fostering the Opioid Epidemic in West Virginia

155. CVS was not merely the distributor and dispenser of opioids marketed and prescribed by other players in the supply chain. CVS partnered with opioid manufacturers to disseminate false messaging surrounding the treatment of pain and the addictive nature of opioids and to provide adherence and discount programs that would encourage patients to start and stay on opioids.

156. Purdue worked with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for Purdue's

[79] CVS-MDLT1-000076114-76117, at 76115.
[80] Burtner Dep. Tr. 340–371; 505; Ex. 500.
[81] *See*, e-mail from Mark Nicastro, CVS Distribution Center Manager in Indianapolis to DEA Agent Daniel Gillen on November 21, 2013 subject matter was closing meeting, Nicastro attaches a chart of all suspicious orders reported to the DEA, CVS-MDLT1-000000409-420.

2007 criminal guilty plea and $600 million fine for misleading the public about Oxycontin's risk of addiction and its potential for abuse.

157. CVS also collaborated with other opioid manufacturers. CVS sent letters to the patients' homes to encourage them to stay on Opana, an opioid made by Endo, which was sued separately by the State for its conduct in marketing and distributing opioids, even though prolonged use of opioids increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications.

158. CVS likewise helped Actavis, also sued separately by the State, to promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and discounts on the drugs, with the aim being to "move [] product."

159. These marketing programs were designed to make pharmacists comfortable with opioids, so that they would counsel patients to fill prescriptions for opioids, and not discourage their use, and to make it more likely that patients would initiate and refill their opioid prescriptions, thus increasing the use of opioids and the harms that followed.

F. CVS Failed to Maintain Effective Controls Against Diversion and Contributed to the Oversupply of Opioids into West Virginia.

160. According to data from the ARCOS database, between 2006 and 2014, CVS distributed over 730.5 million (730,553,422) MME of opioids to its retail pharmacy locations in West Virginia, a state with a population of less than 2 million people. This volume of opioids does not include the additional opioids its pharmacies ordered from a third-party distributor which added over 1.7 billion (1,675,864,781) MMEs. In total, CVS purchased and dispensed over 2.4 billion (2,406,418,203) MMEs of opioids in West Virginia from 2006-2014. This volume alone should have raised a red flag with CVS that not all of the prescriptions being ordered could be for

legitimate medical uses, and, as such, that many of the opioids CVS distributed to its retail stores were being diverted.

161. For years, per capita opioid prescriptions in West Virginia far exceeded the national average and increased in ways that should have alerted CVS to potential diversion. Indeed, as a vertically-integrated, national retail pharmacy chain, CVS had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from its own retail pharmacy locations.

162. Given the volume and pattern of opioids it distributed in West Virginia, and its knowledge of the orders for opioids its pharmacies placed with other distributors, CVS knew that it was oversupplying opioids to its pharmacies in West Virginia and should have detected, reported, and rejected suspicious orders. Upon information and belief, it did not.

163. Despite its compliance obligations and requirements, CVS shipped far more opioids into West Virginia than could have been expected to serve legitimate uses. CVS ignored red flags of diversion, failed to investigate its retail pharmacies, failed to detect suspicious orders, and chose not to report or reject suspicious orders in violation of the laws and rules enacted to protect the public.

164. 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).

165. CVS's failure to abide by 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.

166. CVS dramatically contributed to the oversupply of opioids into the State in violation of West Virginia law and shares in the responsibility for the current epidemic of opioid addiction and death.

G. CVS Failed to Monitor for, Report, and Halt Suspicious Orders in West Virginia.

167. CVS 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 CVS pharmacies.

168. The volume of opioids CVS 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.

169. Yet, according to information from the DEA, CVS 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 CVS failed to report suspicious orders of its own customers, its outside distributors reported 166 suspicious orders involving CVS pharmacies between December 8, 2012 and December 1, 2014.

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

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

172. Upon information and belief, CVS 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.

H. CVS's Conduct Has Injured the State of West Virginia and Its Citizens.

173. 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.

174. 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.

175. The opioid crisis also has 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.[82]

176. CVS's actions alleged in this Complaint have caused numerous societal injuries to the State of West Virginia. CVS's 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.

177. CVS's actions alleged in this Complaint have caused numerous economic injuries to the State of West Virginia. CVS's 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

178. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 177 of this Complaint as if fully set forth herein.

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

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

181. CVS's actions, as detailed above, constitute unfair or deceptive acts or practices that are prohibited by the WVCCPA.

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

182. 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).

183. 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, W. Va. Code § 46A-6-104.

184. CVS's 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.

185. 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.

186. As part of its WVCCPA action, the State expressly does not raise claims nor seek any damages attributable to 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

187. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 177 of this Complaint as if fully set forth herein.

188. Through the actions described above, CVS 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.

189. While CVS's 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.

190. Through the actions described above, CVS 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.

191. CVS 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 CVS pharmacies.

192. Opioid use, abuse, addiction, and overdose deaths increased dramatically in West Virginia as a result of CVS's conduct. The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources.

193. CVS's actions described above were a substantial factor in opioids becoming widely available, used, and abused.

194. CVS's 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

would have been averted. CVS's actions have and will continue to injure and harm the citizens and the State of West Virginia for many years to come.

195. 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 CVS, which knew or should have known that its unfair and deceptive business practices as described herein were creating a public nuisance.

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

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

198. 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. CVS's conduct interfered in the enjoyment of these public rights.

199. As part of its nuisance action, the State expressly does not raise any claim nor seek any damages attributable to 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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