E-FILED | 6/3/2020 2:32 PM CC-40-2020-C-83 Putnam County Circuit Clerk William Mullins

## IN THE CIRCUIT COURT OF PUTNAM COUNTY, WEST VIRGINIA

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

Plaintiff,

v.	CIVIL ACTION NO
	JUDGE:

RITE AID CORPORATION, a Delaware corporation, RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, a Maryland corporation,

Defendant.

### **COMPLAINT**

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Rite Aid Corporation and Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center ("Rite Aid" 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.<sup>1</sup>
- 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.<sup>2</sup>
- 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.<sup>3</sup>
- 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

<sup>&</sup>lt;sup>1</sup> Christopher Ingraham, <u>CDC Releases Grim New Opioid Overdose Figures: "We're Talking About More Than an Exponential Increase,"</u> Washington Post, Dec. 12, 2017, <a href="https://wapo.st/2POdL3m">https://wapo.st/2POdL3m</a>.

<sup>&</sup>lt;sup>2</sup> See Caity Coyne, Number of Fatal Drug Overdoses in 2017 Surpasses 1,000 Mark in West Virginia, Charleston Gazette-Mail, Aug. 30, 2018, <a href="https://bit.ly/2yLcxim">https://bit.ly/2yLcxim</a>; 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, <a href="https://wapo.st/2G19rk2">https://wapo.st/2G19rk2</a>; Christopher Ingram, Fentanyl Use Drive Drug Overdose Deaths to a Record High in 2017, CDC Estimates, The Washington Post, Aug. 15, 2018, <a href="https://wapo.st/2Ozn8b7">https://wapo.st/2Ozn8b7</a>; see also West Virginia Opioid Summary, National Institute on Drug Abuse, March 2019. <a href="https://bit.ly/2MzDsGn">https://bit.ly/2MzDsGn</a>.

<sup>&</sup>lt;sup>3</sup> See West Virginia Opioid Summary, National Institute on Drug Abuse, March 2019. https://bit.ly/2MzDsGn.

of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendant, 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.<sup>4</sup>
- 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.<sup>5</sup>
- 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.<sup>6</sup>
- 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. In 2017, the overall incidence rate of NAS was 50.6 cases per 1,000 live births for West Virginia residents. The highest incidence rate of NAS was 106.6 cases per 1,000 live births (10.66%) in Lincoln County.
- 13. In 2007, the cost for treating a NAS baby was approximately \$36,000; cost for a healthy baby was approximately \$3,600.8
- 14. Between 2006 and 2016, children entering the West Virginia foster care system due to parental addiction rose 124%. About 70% of referrals to Child Protective Services in 2017 had

<sup>&</sup>lt;sup>4</sup> Khalid M. Hasan, MD. & Omar K. Hasan, MD, <u>Opiate Addiction and Prescription Drug Abuse: A Pragmatic Approach</u>, West Virginia Medical Journal, Special Ed., Vol. 106, No. 4, p. 84, https://bit.ly/2q0Tqg2.

<sup>&</sup>lt;sup>5</sup> Dennis Thompson, <u>Drug OD Deaths Nearly Tripled Since 1999, CDC Says</u>, Feb. 24, 2017, CBS News, <a href="https://cbsn.ws/2J4n90u">https://cbsn.ws/2J4n90u</a>.

<sup>&</sup>lt;sup>6</sup> Andrew Kolodny, et al., <u>The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction</u>, Annu. Rev. Public Health 2015, p. 560 (Jan. 12, 2015), <u>https://bit.ly/2J5A9Tp</u>.

<sup>&</sup>lt;sup>7</sup> Proposed Opioid Response Plan for the State of West Virginia, Jan. 10, 2018, p. 20, https://bit.ly/2Oyu48a.

<sup>&</sup>lt;sup>8</sup> Michael L. Stitely, MD, et al., <u>Prevalence of Drug Use in Pregnant West Virginia Patients</u>, West Virginia Medical Journal, Special Ed., Vol. 106, No. 4, p. 48, <a href="https://bit.ly/2q0Tqg2">https://bit.ly/2q0Tqg2</a>.

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.

#### I. Parties

### A. Plaintiff

17. The Plaintiff, the State of West Virginia ex rel. Patrick Morrisey, Attorney General, is charged with enforcing the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, et seq. ("WVCCPA"). Pursuant to W. Va. Code § 46A-7-108, the Attorney General is authorized to bring a civil action for violations of the WVCCPA and for other appropriate relief. The Attorney General has all common law powers except 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. Rite Aid Corporation is a Delaware corporation located in Camp Hill, Pennsylvania.
- 19. Rite Aid of Maryland, Inc. is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. It is a subsidiary of Rite Aid Corporation and does business under the trade name Rite Aid Mid-Atlantic Customer Support Center. Rite Aid Mid-Atlantic Customer Support Center was licensed by the West Virginia Board of Pharmacy as a wholesale drug distributor.
- 20. In 2017, Rite Aid Corporation was the third largest retail drug store chain with 4,536 stores in 31 states and the District of Columbia. Between 2017 and 2018, Rite Aid Corporation sold 1,651 stores to Walgreens Boots Alliance, including its 104 stores located in West Virginia.
- 21. In 1994, 50.8% of Rite Aid's sales were derived from prescription drug sales. By 2017 that number had increased to 68.3%.

#### III. State Court Jurisdiction

- 22. The causes of action asserted and the remedies sought in this Complaint are based exclusively on West Virginia statutory or common law.
- 23. In this Complaint, the State references federal statutes, regulations, or actions, but does so only to establish Rite Aid's knowledge or to explain how Rite Aid's conduct has not been approved by federal regulatory agencies.
- 24. 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).

- 25. The federal Controlled Substances Act ("CSA") does not create a private right of action, *Welch v. Atmore Community Hospital*, 704 Fed. Appx. 813, 817 (11<sup>th</sup> 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).
- 26. 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).
- 27. 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

28. 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.

#### V. Venue

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

## VI. Factual Allegations

- 30. Rite Aid 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. Acting as a wholesale distributor, Rite Aid 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. Rite Aid shipped and distributed these drugs in West Virginia and failed to report or stop shipments of suspicious orders. Moreover, Rite Aid, 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.
- 31. This Complaint does not assert claims related to Rite Aid's role in dispensing opioids, however the dispensing and claims data from its retail pharmacies were important tools available to Rite Aid to use in its role as a distributor. Upon information and belief, it failed to use this unique knowledge to detect suspicious orders and prevent diversion of opioids.
  - 32. Rite Aid was among the top ten (10) distributors of opioids in West Virginia.<sup>9</sup>

7

<sup>&</sup>lt;sup>9</sup> DEA ARCOS data 2006-2014.

- 33. Between 2006 and 2014, Rite Aid distributed opioids equivalent to 1,305,537,300 milligrams of morphine ("MME") or, stated another way, the equivalent of 87,035,820 10 mg. oxycodone pills, to its 104 retail pharmacies in West Virginia.<sup>10</sup>
- 34. Although Rite Aid was among the top ten distributors to West Virginia, behind McKesson, AmerisourceBergen and Cardinal Health, its "self-distribution" was not enough to fulfill the opioid demand at its retail pharmacy stores.
- 35. Rite Aid's West Virginia pharmacies ordered additional opioids totaling 1,912,430,844 MMEs, the equivalent of 127,495,389 10 mg. oxycodone pills, from McKesson, Anda, Inc., Anda Pharmaceuticals, Inc., and Eckerd Corporation.<sup>11</sup>
- 36. Rite Aid 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.
- 37. The information available to Rite Aid through its distribution centers and retail stores put it on notice that it was meeting more than a legitimate market demand. Rather than report suspicious orders and stop the diversion, Rite Aid continued to sell, ship and profit from these highly dangerous drugs.
  - A. Rite Aid Was Required To Monitor For And Report Suspicious Orders, And Not To Ship Those Orders Unless Due Diligence Disproves The Suspicions.
- 38. Rite Aid was required by law to monitor, report and refuse to ship suspicious orders of controlled substances, unless and until due diligence dispelled the suspicion.

<sup>&</sup>lt;sup>10</sup> 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.

<sup>11</sup> Rite Aid had stores in 49 counties in West Virginia.

- 39. Rite Aid was required to prevent oversupply and diversion into the illicit drug market. Distributors of controlled substances possess specialized and sophisticated knowledge, skills, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.
- 40. Rite Aid was registered as a wholesale distributor with the West Virginia Board of Pharmacy from at least 2004 through 2018.
- 41. The 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).
- 42. The requirements under WVCSA independently parallel and incorporate the requirements of the federal CSA. *See* W.Va. C.S.R. 15-2-3. Rite Aid 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. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74; W. Va. C.S.R. § 15-2-5.3.
- 43. Distributors are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered* by the registrant." 21 C.F.R. § 1301.74(b) (emphasis added). Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual

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

44. Distributors are required to know their customer and the communities they serve. Rite Aid was in a unique position to comply with this requirement as it, essentially, distributed narcotics to itself.

### 45. The DEA previously testified that:

- a. DEA registrants are required to block all suspicious orders of prescription opioids. 12
- b. Shipping a suspicious order is a per se violation of federal law.<sup>13</sup>
- 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.<sup>14</sup>
- d. After the fact reporting of suspicious orders has never been in compliance with federal law.<sup>15</sup>
- 46. 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).
- 47. 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

<sup>&</sup>lt;sup>12</sup> Prevosnick Dep. Vol. II, 770:6 to &&1:20, April 18, 2019 (DEA 30(b)(6) designee).

<sup>&</sup>lt;sup>13</sup> *Id.* at 632:7 to 633:2.

<sup>&</sup>lt;sup>14</sup> Id. at 628:24 to 629:15.

<sup>&</sup>lt;sup>15</sup> *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." 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." 17

- 48. In sum, Rite Aid had several requirements with respect to preventing diversion. Rite Aid was required to set up a system designed to detect and reject suspicious orders. Rite Aid 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.
- 49. 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. Reasonably prudent distributors would not fail to meet these requirements, and Rite Aid's failure to exercise appropriate controls foreseeably harms the public health and welfare.

<sup>16</sup> Masters Pharmaceuticals, Inc., Decision and Order, 80 Fed. Reg. 55418-01 at \*55477 (DEA Sept. 15, 2015).

<sup>&</sup>lt;sup>17</sup> 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.

<sup>&</sup>lt;sup>18</sup> 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).

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

## B. Rite Aid Knew Its Obligations To Prevent Diversion And To Report And Take Steps To Halt Suspicious Orders From Its Retail Stores.

- 51. Rite Aid, 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. Rite Aid serves on its board. The Healthcare Distribution Management Association ("HDMA"), now known as Healthcare Distribution Alliance ("HDA"), is a national trade association representing distributors and has partnered with NACDS.
- 52. In 2007 and 2008, the HDA began developing "industry compliance guidelines" ("ICG") that aimed to outline certain best practices for the distributors. The HDA released the ICG in 2008 and emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." <sup>19</sup>

12

<sup>&</sup>lt;sup>19</sup> HDA MDL 000213058

- 53. Rite Aid 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.<sup>20</sup>
- 54. The guidelines, input, and communications from the DEA put Rite Aid on notice of its requirements and obligations.
- 55. The DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances," 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.
- 56. The DEA has repeatedly informed distributors and dispensers, including Rite Aid, about their legal obligations, 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.
- 57. 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

<sup>&</sup>lt;sup>20</sup> HDA MDL 00213212

<sup>&</sup>lt;sup>21</sup> 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.

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.<sup>22</sup>

58. 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." According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained:

[A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program." Another area at issue was whether DEA would take action against a registrant which 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.<sup>24</sup>

59. 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

<sup>&</sup>lt;sup>22</sup> CAH\_MDL2804\_01465723.

<sup>&</sup>lt;sup>23</sup> US-DEA-00025657.

<sup>&</sup>lt;sup>24</sup> US-DEA-00025659.

substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded registrants that, in addition to reporting suspicious orders, they have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The September 27, 2006 letter reminded distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

- 60. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the December 27, 2007 letter referenced the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."
- 61. 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.<sup>25</sup>

<sup>&</sup>lt;sup>25</sup> CAH MDL PRIORPROD DEA07 00877084; CAH MDL PRIORPROD DEA07 01185382.

E-FILED | 6/3/2020 2:32 PM CC-40-2020-C-83 Putnam County Circuit Clerk William Mullins

62. The DEA's regulatory actions against the three largest wholesale distributors

further underscore the fact that distributors such as Rite Aid 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.

63. 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 centrals.

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.

64. Upon information and belief, Rite Aid failed to adhere to the guidance documents,

communications, and other statements issued by the DEA.

16

65. Each failure by Rite Aid 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. Rite Aid Was Uniquely Positioned To Prevent Diversion.

- 66. As vertically-integrated pharmacies and distributors, Rite Aid had access to additional information that would allow it to identify and prevent diversion, unlike third-party wholesale distributors. Rite Aid 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.
- 67. At the pharmacy level, Rite Aid 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.
- 68. 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 Rite Aid 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.

- 69. Rite Aid 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, Rite Aid 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.
- 70. Upon information and belief, Rite Aid failed to use the dearth of information it possessed to detect, prevent, or report suspicious orders. An internal Rite Aid document discloses that, as of late 2013, Rite Aid had not yet developed a suspicious order monitoring system to detect or report suspicious orders by analyzing data from individual Rite Aid pharmacies. <sup>26</sup> Instead, Rite Aid used a "blanket" threshold for all of its stores nationwide of 5,000 dosage units per individual drug per week per store, regardless of dispensing volume or trends. <sup>27</sup>
- 71. Rite Aid knew that its blanket threshold failed to meet its anti-diversion requirements under law. Upon information and belief, in late 2013, Rite Aid was motivated to create a suspicious order monitoring program that looked at data at the pharmacy level because the "DEA has stated numerous times controlled substance distributors must have a protocol to identify

<sup>&</sup>lt;sup>26</sup> Project Initiation for Suspicious Order Monitoring (MDL Doc. # 3016-36).

<sup>&</sup>lt;sup>27</sup> Id.; see also Janet Hart Depo. at 235:6-24 (MDL Doc. #: 325-54).

and report suspicious orders based on individual pharmacy volume, not generic limits for all [Rite Aid pharmacies]."<sup>28</sup> Another motivating factor was a lawsuit filed by McDowell County, West Virginia, against three Rite Aid pharmacy locations. The lawsuit, which was later withdrawn, included, among other things, "language concerning suspicious orders to the Rite Aid pharmacies, how identified, how resolved, and end outcome."<sup>29</sup> Rite Aid also knew many of the opioids it was supplying to its pharmacies were being diverted. For example, Rite Aid entered into a settlement with the Department of Justice ("DOJ") after a DOJ investigation of Rite Aid pharmacies in eight (8) states revealed multiple violations of the CSA, including filling prescriptions for controlled substances that were not issued for a legitimate medical purpose and failure to properly account for Schedule II and III controlled substances. Specifically, the DOJ found significant shortages and surpluses of oxycodone and hydrocodone products "reflecting a pattern of non-compliance with the requirements of the CSA..."

## D. Rite Aid Failed to Maintain Effective Controls Against Diversion and Contributed to the Oversupply of Opioids into West Virginia.

72. According to data from the ARCOS database, between 2006 and 2014, Rite Aid distributed the equivalent of over 87 million 10mg oxycodone pills to its retail pharmacy locations in West Virginia, a state with a population of less than 2 million people. This volume of opioids, which does not include the additional opioids its pharmacies ordered from McKesson, should have raised a red flag with Rite Aid that not all of the prescriptions being ordered could be for legitimate medical uses, and, as such, that many of the opioids Rite Aid distributed to its retail stores were being diverted.

<sup>&</sup>lt;sup>28</sup> Project Initiation for Suspicious Order Monitoring (MDL Doc. # 3016-36 at 10).

<sup>&</sup>lt;sup>29</sup> *Id.*; see also County Commission of McDowell County v. Black Diamond Pharmacy, LLC, et al, 13-C-148-S (McDowell County, WV, Aug. 21, 2013).

<sup>&</sup>lt;sup>30</sup> https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations

- 73. For years, per capita opioid prescriptions in West Virginia far exceeded the national average and increased in ways that should have alerted Rite Aid to potential diversion. Indeed, as a vertically-integrated, national retail pharmacy chain, Rite Aid 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.
- 74. 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, Rite Aid 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.
- 75. Despite its compliance obligations and requirements, Rite Aid shipped far more opioids into West Virginia than could have been expected to serve legitimate uses. Rite Aid 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 laws enacted to protect the public.
- 76. 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).

- 77. Rite Aid's failure to abide by a requirement of a law or rule 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.
- 78. Rite Aid 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.

## E. Rite Aid's Conduct Has Injured the State of West Virginia and Its Citizens.

- 79. 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.
- 80. 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.
- 81. The opioid crisis has also impacted some of West Virginia's most vulnerable demographics, such as the elderly. The AARP reports that elderly Americans have faced a 500% increase in hospitalization rates related to opioids over the last twenty years. In 2015, "physicians prescribed opioid painkillers to almost one-third of all Medicare patients, or nearly 12 million people. In the same year, 2.7 million Americans over age 50 took painkillers in amounts—or for reasons—beyond what their physicians prescribed." Hospitalization rates due to opioid abuse has quintupled for those 65 and older in the past two decades.<sup>31</sup>

<sup>&</sup>lt;sup>31</sup> See https://www.aarp.org/health/drugs-supplements/info-2017/opioid-drug-addiction-pain-pills.html.

- 82. Rite Aid's actions alleged in this Complaint have caused numerous societal injuries to the State of West Virginia. Rite Aid'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.
- 83. Rite Aid's actions alleged in this Complaint have caused numerous economic injuries to the State of West Virginia. Rite Aid'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

- 84. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 83 of this Complaint as if fully set forth herein.
- 85. Rite Aid distributed opioid products to the State of West Virginia and its governmental entities, businesses, and consumers within West Virginia.
- 86. Rite Aid's distribution of opioid products in the State of West Virginia involves trade or commerce within the meaning of the WVCCPA.
- 87. 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).

- 88. Rite Aid's actions, as detailed above, constitute unfair or deceptive acts or practices that are prohibited by the WVCCPA.
- 89. Each occurrence of a failure to abide by a requirement of 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.
- 90. Rite Aid'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.
- 91. 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.
- 92. As part of its WVCCPA action, the State expressly does not raise claims nor seek any damages attributable the Medicaid or Medicare programs or any other federal programs. Additionally, as part of its WVCCPA action, the State expressly does not raise claims or seek any damages for the State's workers' compensation program, nor does it raise claims or seek damages on behalf of any state agencies.

## COUNT II Common Law Public Nuisance

93. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 83 of this Complaint as if fully set forth herein.

- 94. Through the actions described above, Rite Aid 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.
- 95. While Rite Aid'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.
- 96. Through the actions described above, Rite Aid 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.
- 97. Rite Aid 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 and shipping orders it knew were suspicious.
- 98. Opioid use, abuse, addiction, and overdose deaths increased dramatically in West Virginia as a result of Rite Aid's conduct. The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources.
- 99. Rite Aid's actions described above were a substantial factor in opioids becoming widely available, used, and abused.
- 100. Rite Aid'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.

Rite Aid's actions have and will continue to injure and harm the citizens and the State of West Virginia for many years to come.

- 101. 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 Rite Aid, which knew or should have known that its unfair and deceptive business practices as described herein were creating a public nuisance.
- 102. While tort-based standards are not applicable to a public nuisance suit brought by the State, a reasonable person in Rite Aid's position would foresee the widespread problems of opioid addiction and abuse that resulted from the drastic oversupply of opioids in this state.
- 103. Rite Aid was on notice and aware of the broader use of opioids that were causing the kinds of harm described in this Complaint.
- 104. 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. Rite Aid's conduct interfered in the enjoyment of these public rights.
- 105. As part of its nuisance action, the State expressly does not raise any claim nor seek any damages attributable the Medicaid or Medicare programs or any other federal programs. Additionally, as part of its nuisance action, the State expressly does not raise claims or seek any damages for the State's workers' compensation program, nor does it raise claims or seek damages on behalf of any state agencies.

## Prayer for Relief

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

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

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

unlawful conduct;

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

d. Civil penalties of up to \$5,000.00 for each repeated and willful violation of

W. Va. Code § 46A-6-104, pursuant to W. Va. Code § 46A-7-111(2);

e. Pre- and post-judgment interest;

f. Costs and reasonable attorneys' fees; and,

g. Such other relief, fees and costs as shall be available under the West

Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101, et seq.;

h. An order abating the public nuisance and ordering any injunctive relief that

the Court finds appropriate under law; and

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

appropriate.

STATE OF WEST VIRGINIA ex rel.

PATRICK MORRISEY,

Attorney General

By Counsel

ANN L. HAIGHT (WVSB No. 1527)

Deputy Attorney General

VAUGHN T. SIZEMORE (WVSB No. 8231)

Deputy Attorney General

MICHELLE L. BRADLEY (WVSB No. 10129)

Assistant Attorney General
ABBY G. CUNNINGHAM (WVSB No. 13388)
Assistant Attorney General
Consumer Protection Division
812 Quarrier Street, First Floor
Post Office Box 1789
Charleston, West Virginia 25326-1789

Telephone: 304-558-8986 Fax: 304-558-0184