IN THE CIRCUIT COURT OF BOONE COUNTY, WEST VIRGINIA

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

Plaintiff,

v.

CIVIL ACTION NO. 19-C-104
JUDGE WILLIAM S. THOMPSON

TEVA PHARMACEUTICAL INDUSTRIES, LTD, TEVA PHARMACEUTICALS USA, INC. CEPHALON, INC.; ALLERGAN FINANCE, LLC, F/K/A/ ACTAVIS, INC., F/K/A WATSON PHARMACEUTICALS, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; WATSON LABORATORIES, INC.; WARNER CHILCOTT COMPANY, LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC; ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC; and ACTAVIS LABORATORIES UT, INC., F/K/A WATSON LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC., F/K/A WATSON LABORATORIES, INC.-FLORIDA;

Defendants.

FIRST AMENDED COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Allergan Finance, LLC f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan

Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc., f/k/a/ Watson Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida, and alleges as follows:

I. Introduction

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

2. Opioids are powerful narcotic painkillers that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy. Use of prescription opioids can cause addiction, overdose, and deaths. Each of the defendants manufacture opioids under a variety of brand names.

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

4. West Virginia has the highest drug overdose rate in the country. In 2017, over 1,000 West Virginia citizens died as the result of a drug overdose. Eighty-six percent of these overdose deaths involved an opioid. *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 Drives Drug Overdose Deaths to a

Record High in 2017, CDC Estimates, *The Washington Post*, Aug. 15, 2018, https://wapo.st/2Ozn8b7.

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

6. Opioid manufacturers are partially responsible for the state's opioid epidemic. Over time, opioid manufacturers overcame physicians' reluctance to prescribe opioid pain relievers ("OPRs") (due to concerns about addiction, tolerance and physiological dependence) through a variety of programs. Andrew Kolodny, *et al.*, The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annual Rev. Public Health 2015, p. 562 (Jan. 12, 2015), https://bit.ly/2J5A9Tp.

7. These programs claimed doctors were confusing addiction with physical dependence and stated that addiction was rare and completely distinct from physical dependence, which was clinically unimportant. Id. at 563.

8. These campaigns minimized the risks of OPRs and exaggerated the benefits of long-term OPR use. Id. In fact, as of 2015, "high-quality long-term clinical trials demonstrating the safety and efficacy of OPRs for chronic non-cancer pain [had] never been conducted." Id. at 563. "Although the number of new nonmedical users has declined, overdose deaths, addiction treatment admissions and other adverse public health outcomes associated with OPR use have increased dramatically." Id. at 563.

9. 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.

10. The opioid epidemic has brought overwhelming suffering to West Virginia and has cost the State a tremendous amount of money. According to the West Virginia Board of Pharmacy's October 2017 report, 30.8% of Boone County residents had an opioid prescription between 2014 and 2016. W.Va. Bd. Of Pharmacy, Prescription Opioid Problematic Prescribing Indicators County Report, Boone County, Oct. 2017, p.10, https://bit.ly/2ysGS5P.

11. As reported in a special issue of the West Virginia Medical Journal, West Virginia has the third highest non-heroin OPR treatment rate in the United States. Khalid M. Hasan, MD. & Omar K. Hasan, MD, Opiate Addiction and Prescription Drug Abuse: A Pragmatic Approach, *West Virginia Medical Journa*l, Special Ed., Vol. 106, No. 4, p. 84, https://bit.ly/2q0Tqg2.

12. West Virginia's rate of Neonatal Abstinence Syndrome ("NAS") is five times the national average and results in thousands of children being placed in foster care. 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. Michael L. Stitely, MD, et al., Prevalence of Drug Use in Pregnant West Virginia Patients, *West Virginia Medical Journal*, Special Ed., Vol. 106, No. 4, p. 48, https://bit.ly/2q0Tqg2.

14. 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. Dennis Thompson, Drug OD Deaths Nearly Tripled Since 1999, CDC Says, Feb. 24, 2017, *CBS News*, https://cbsn.ws/2J4n90u.

15. Studies show a direct correlation between OPRs and heroin addiction with four out of five heroin users reporting their opioid use began with OPRs. Andrew Kolodny, et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annual Rev. Public Health 2015, p. 560 (Jan. 12, 2015), https://bit.ly/2J5A9Tp.

16. According to Dr. Rahul Gupta, former West Virginia Commissioner of Public Health, if you are a West Virginia resident who is a single, male, blue collar worker between the ages of 35-54 with less than a high school education you are at a "very, very high risk of overdosing." Brianna Ehley, The Immigrant Doctor Who's Solving West Virginia's Opioids Crisis, *Politico*, May 2, 2018 *quoting* Dr. Rahul Gupta, https://politi.co/2IbE2Ze.

17. The Defendants helped cause the opioid epidemic by engaging in strategic campaigns of misrepresentations about the risks and benefits of opioid use to physicians, other prescribers, consumers, pharmacies, and state governmental agencies. The Defendants knew that opioids were dangerous and addictive; nevertheless, they collectively used front organizations that they funded to disseminate misinformation about the use of opioids for chronic pain treatment. The Defendants also employed medical professionals known as key opinion leaders ("KOLs") to endorse and promote the use of opioids. The KOLs wrote articles and gave speeches, based at least in part, upon information provided to them by the Defendants, touting the benefits of opioid use (and omitting information as to adverse effects) as if they were independent medical experts, but they actually served as the Defendants' mouthpieces.

18. 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.

19. 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 should pay for their role in the crisis and act to remediate the problem.

II. Parties

20. 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 as 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).

21. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania.

22. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

23. Both Teva USA and Cephalon, Inc. are wholly owned subsidiaries of Defendant Teva Pharmaceutical Industries Ltd ("Teva Ltd."), a company based in Israel. Since Teva Ltd.

acquired Cephalon, Inc. in 2011, Cephalon's United States sales and marketing activities have been conducted by Teva USA.

24. The close connection between Teva Ltd. and its U.S. subsidiaries, as well as the blurred distinction between them, is shown in Teva's websites. For example, on Teva USA's website is a page entitled "Teva Pharmaceutical Industries Limited," on a page labeled "intended for US residents only," which includes the following: "Teva improves health in the US every day, every minute, every second. One in every six prescriptions dispensed in the US is a Teva product. Approximately 22 prescriptions in the US are filled by Teva products every second . . . Teva is the world's largest maker of generic pharmaceutical products."[1] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales . . . ." [2] The United States is the largest of Teva Ltd.'s global markets, and it represents nearly half of its total revenue.[3]

25. Other publicly available information demonstrates Teva Ltd.'s control over Cephalon's operations: For example, immediately after acquiring Cephalon, Teva Ltd. caused Cephalon to increase its product prices up to twenty-five percent.[4] The two companies combined sales forces[5], product pipelines, and research and development efforts.[6]

---

[1] https ://www.tevausa.com/Company. aspx
[2] New Yorker; Fact Sheet Teva Pharmaceutical Industries Ltd. Annual Report (Form 20-F) (Feb. 12, 2013) at 62.
[3] *Id.* at 62-64.
[4] Tracy Staton, *Teva jacks up prices on Cephalon legacy brands* (Dec. 7, 2011), http://wwW.fiercepharma.com/story/tevajacks-prices-cephalon-legacy -brands/2011 -12-07.

[5] *NASDAQ OMX 27th Investor Program Conference Call,* Teva Pharm. Indus. Ltd. (Dec. 6, 2011, 5:15 AM), http ://seekingalpha.com/article/315684-teva-pharmaceuticals-management-presents-at-nasdaq-omx-27th-investor-program-transcript?page=4.
[6] *See generally, Teva Pharmaceuticals Industries ' Management Presents at Citi Global Health Care Conference (Transcript)* (Mara 8, 2012), http://seekingalpha.com/article/419471-

26. Teva Ltd., Teva USA, and Cephalon, Inc. are collectively referred to herein as "Teva."

27. Teva manufactures, promotes, sells, and distributes branded opioids Actiq, a fentanyl lollipop, and Fentora, a dissolving fentanyl pill, throughout the United States and West Virginia. Actiq and Fentora have been approved by the FDA only for the management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

28. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading off-label promotion of Actiq and two other drugs and agreed to pay $425 million.

29. Teva also sells generic opioids through the United States and West Virginia, including generic opioids previously sold by Allergan plc, whose generics business Teva's parent company acquired in August 2016. Generics sold by Teva include oxymorphone and hydrocodone.

30. Allergan plc (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis,

Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

31. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share.[7] Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions.[8] Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date."[9]

32. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc.

33. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

---

[7] *See City of Chicago v. Purdue Pharma L.P., et al.* (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.

[8] *See id.*

[9] *See id.*

34. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

35. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

36. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

37. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

38. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

39. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

40. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

41. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

42. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva

Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

43. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

44. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

45. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

46. Each of these defendants and entities currently is or was previously owned by Allergan plc, which uses them to market and sell its drugs in the United States.

Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

47. Actavis manufactures or has manufactured generic opioids, including but not limited to generic versions of Kadian, Duragesic, and Opana in the United States.

48. Teva and Actavis are at times referred to collectively herein as "Defendants."

III. State Court Jurisdiction

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

50. 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).

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

IV. Jurisdiction

52. 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 § 56-3-33a.

V. Venue

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

VI. Factual Allegations

A. Opioids are Dangerous and Highly Addictive Narcotics.

54. Opioids are highly addictive narcotics. The risk of becoming addicted for people taking prescription opioids for pain is very high.

55. High-dose and long-term prescription of opioids for chronic pain present particular dangers. Risks of opioid usage include overdose, respiratory depression, hyperalgesia, hormonal dysfunction, neonatal abstinence syndrome, decline in immune function, confusion, dizziness (with increased falls and fractures in the elderly), and potentially fatal interactions with alcohol or benzodiazepines. People who become addicted to prescription opioids are at higher risk of becoming addicted to drugs that have no lawful uses, including heroin.

56. Opioids can interact dangerously with benzodiazepines, a common treatment for veterans with PTSD.

57. Because many people become addicted to opioids, they are at risk of being diverted from lawful, controlled medical uses into the illegal drug market.

58. Teva relies on sales representatives to convey marketing messages and materials to prescribers in targeted, in-person settings.

59. Teva sales representatives visited prescribers in West Virginia, including, upon information and belief, prescribers whom they had reason to suspect were engaged in diversion.

60. To ensure that sales representatives delivered the desired messages to prescribers, Teva directed and monitored all of its sales representatives through detailed action plans, training, and review of those sales representatives' notes from each visit. It further ensured nationwide marketing consistency through sales representative training.

61. Upon information and belief, the marketing strategies, scripted messages and materials delivered by Teva's sales forces in West Virginia are consistent with its nationwide campaign.

62. Research on different marketing practices, including visits by sales representatives (also known as "detailing"), medical journal advertisements, and direct-to-consumer advertising shows that visits by sales representatives have the strongest impact on driving drug utilization. Moreover, doctor prescribing practices are directly related to meetings with sales representatives.[10]

63. Teva also used "key opinion leaders" ("KOLs") – doctors who were especially influential because of their reputations and seeming objectivity – to deliver paid talks and continuing medical education programs ("CMEs") that provided information through third party organizations about treating pain and the risks, benefits, and use of opioids. This gave Teva considerable influence over the messenger, the message, and the distribution of the program.

---

[10]Larkin, et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, May 2, 2017, http://bit.ly/31i27TR.

64. In addition to talks and CMEs, Teva's KOLs served on the boards of patient advocacy groups and professional associations, such as the American Academy of Pain Medicine, that were influential because of their seeming independence. Teva exerted influence and control over such groups by providing funding directly to them. As a result, these third-party groups created unbranded patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits and understating their risks.

65. Teva used KOLs and unbranded patient education materials and treatment guidelines to influence the message that it disseminated and shape the views of physicians and how those views are applied in practice.[11]

66. Teva executed its marketing strategies in concert with these KOLs and front-groups and other manufacturers who similarly sponsored these front groups and KOLs.

67. The FDA does not regulate third-party unbranded materials, marketing messages or scripts followed by Teva's sales representatives and none of these materials were reviewed or approved by the FDA.

68. Unbranded marketing materials promote the benefits of opioids as a class, which in turn aid in the sale of generic opioids.

B. Teva Deceptively Marketed Actiq and Fentora for Off-Label Use.

69. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Actiq delivers fentanyl into the bloodstream via a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." *See* John

---

[11] Sismondo S., How to make opinion leaders and influence people [published online ahead of print, 2015 Jul 6]. *CMAJ*. 2015;187(10):759–760. doi:10.1503/cmaj.150032, http://bit.ly/2YvU7C0.

Carreyrou, Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs, *The Wall Street Journal* (Nov. 3, 2006), https://on.wsj.com/2ZzuBbr. Fentora, a tablet, is administered by placing it in the mouth until it dissolves. Both are rapid-onset opioids that take effect within 10-15 minutes, but last only a short time. Neither is approved for, nor has either been shown to be safe or effective for, treating chronic pain. These drugs are approved solely for breakthrough cancer pain in patients who are tolerant to opioid therapy.

70. In fact, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of serious and life-threatening adverse events and abuse which are greatest in non-cancer patients.

71. In 2008, the Department of Justice ("DOJ") accused Cephalon of promoting Actiq, along with two non-opioid drugs, for uses the FDA had not approved. Cephalon agreed to settle the charges for $425 million. The DOJ charged that Cephalon promoted Actiq to non-cancer patients for conditions such as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy.[12] The DOJ also accused Cephalon of promoting Actiq for patients who were not opioid-tolerant, "for whom it could have life-threatening results." The DOJ outlined Cephalon's sales tactics as follows:

> Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain . . . . Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label

[12] Press Release, Department of Justice, Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008).

> uses . . . . Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq . . . . The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

See n. 4, infra p. 14

72. Acting U.S. Attorney Laurie Magid stated that Cephalon had violated the very process meant to protect the public from harm in order to boost its bottom line and noted, "[p]eople have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved." Id.

73. Despite the multi-million dollar fine and admonitions from the DOJ and the FDA, Teva conducted and continued to conduct a campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe, effective, and appropriate for treating non-cancer pain.

74. For example, Teva sponsored a CME, "Opioid-Based Management of Persistent and Breakthrough Pain," published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

75. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to *Anesthesiology News*,

Clinical Oncology News, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for multiple causes of pain and not just cancer pain.

76. The similarity of reports from sales representatives from different states across the country demonstrates that the sales messages and practices were part of Teva's nationwide marketing strategy. The representations discussed below were a part of Teva's national strategy for the sale and marketing of its opioid products that included West Virginia.

a. Teva sales representatives primarily marketed to prescribers who were non-oncologists. Although sales representatives knew Actiq was for cancer patients, Teva's management dictated sales goals that required the representatives to detail prescribers other than oncologists or specialists treating cancer patients. Had the sales representatives done otherwise, they could not meet their sales goals.

b. Teva's management instructed sales representatives to target pain clinics, even though these doctors did not treat cancer patients. Teva targeted promotion of Fentora to pain specialists to increase prescription sales because oncologists were not prescribing the drug.

77. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs included mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses – and patients must already be opioid-tolerant and taking high doses of opioids to be prescribed Actiq and Fentora. However, according to a former Fentora and Actiq sales representative, even

after the TIRF REMS program was implemented, he continued to market to the same prescribers who prescribed Actiq and Fentora to non-cancer patients, and his promotional messages regarding Actiq and Fentora did not change.

C. Teva Misrepresented, Concealed and Failed to Disclose the Known, Serious Risk of Addiction to Their Products.

78. To convince prescribers and patients that opioids should be widely prescribed for the long-term treatment of chronic pain conditions, Teva deceptively represented that the risks of abuse and addiction were modest, manageable, and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impression that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted; (2) patients with the greatest risk of addiction could be identified; and (3) all other patients could safely be prescribed opioids.

79. Teva sponsored American Pain Foundation's ("APF") guide Treatment Options: A Guide for People Living with Pain (2007), which stated that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. Additionally, the guide recommended against restricting access to opioids to prevent opioid abuse and stated, "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."[13] The guide also stigmatizes the term "narcotics" by associating the term with illegal drugs such as cocaine and heroin, while promoting opioids. The guide states that referring to opioids as narcotics "reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance or their use as pain medicines."[14]

---

[13] https://ce4less.com/Tests/Materials/E019Materials.pdf at p. 15 (site last visited 8/5/2019)
[14] https://ce4less.com/Tests/Materials/E019Materials.pdf at p. 11. (site last visited 8/5/19)

80. In addition, a 2003 Teva-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape in February 2003, taught doctors that:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population . . . . The continued stigmatization of the opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under-treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[15]

81. Teva also deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called 'pseudoaddiction'. This concept was invented to foster the misconception that signs of addiction, such as drug-seeking behavior, actually reflected undertreated pain that should be addressed with more opioids – the medical equivalent of fighting fire by adding fuel.

82. Teva, acting in concert with other opioid manufacturers, promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for Teva and other opioid manufacturers. Dr. Portenoy popularized the concept and falsely claimed that pseudoaddiction was substantiated by scientific evidence.

---

[15] Michael J. Brennan et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape (Feb. 26, 2003). https://www.medscape.org/viewarticle/449803_2

83. The term "pseudoaddiction" originated in 1989 based upon a single case report of a 17 year old leukemia patient whom Dr. David Haddox (who would later become Purdue Pharma's vice president of health policy) determined was exhibiting behaviors associated with opioid addiction – requesting medication before scheduled dosing time and complaining of pain. It referred to patients who exhibited drug-seeking behavior due to undertreated or uncontrolled pain, as opposed to addiction. This concept has "not been empirically verified. No evidence supports its existence . . . ." [16]

84. Teva further promoted pseudoaddiction through its CME, Pharmacologic Management of Breakthrough or Incident Pain. According to the CME, pseudoaddiction is a term which refers to "drug-seeking behavior in patients who have severe unrelieved pain and who have not received effective pain therapy." *See* n. 8. Additionally, it promotes the continued use of opioids by stating that "such behavior disappears when adequate analgesic treatment, including increased opioid dosing, is given." Id.

85. Teva's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. In March 2016, the FDA emphasized the "serious risk [] of . . . addiction" of opioids."[17] That same month, after a "systemic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain ("the CDC Guideline"). The CDC Guideline noted that "[o]pioid pain

---

[16] Greene MS, Chambers RA. *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature. Curr Addict Rep.* 2015;2(4):310–317. doi:10.1007/s40429-015-0074-7 (Oct. 1, 2015) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/

[17] U.S. Food & Drug Admin., FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-release and Long-acting Opioid Analgesics (Sept. 10, 2013); *see also* U.S. Food & Drug Admin., FDA Announces Enhanced Warnings for Immediate-release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death (Mar. 22, 2016), http://bit.ly/31ksSqQ.

medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction). CDC Guideline at 2. The CDC also emphasized that "continuing therapy for 3 months substantially increases risk for opioid use disorder." CDC Guideline at 21.

D. Teva Misrepresented the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use.

86. Teva sought to convince prescribers and patients that there were significant benefits in treating chronic pain with long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[18] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed.

87. Teva touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Upon information and belief, Teva exercised influence over two prominent professional medical membership organizations regarding their position on opioids. The American Academy of Pain Medicine's ("AAPM"), along with the American Pain Society ("APS"), issued a consensus statement in 1997, The Use of Opioids for the Treatment of Chronic Pain, which endorsed opioids to treat chronic pain and claimed that patients' risk of becoming addicted to opioids was low. Teva KOL, Dr. Russell Portenoy, was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down after a doctor complained.

[18] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval. & Research to Andrew Kolodny, M.D. (Sept. 10, 2013).

88. AAPM, along with APS, continued to recommend the use of opioids to treat chronic pain by issuing treatment guidelines in 2009 ("AAPM/APS Guidelines").[19] Treatment guidelines such as these are particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors, who have no specific training in treating chronic pain. Some panel members who drafted the AAPM/APS Guidelines received income or research funding from Teva.

89. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality evidence" and concluded that the risk of addiction was manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, who was at that time a Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions made by drug companies, including Teva, to sponsoring organizations and committee members.[20]

90. The AAPM/APS Guidelines are still available online, were reprinted in the Journal of Pain and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

E. Overstating Opioids' Effect on Patients' Function and Quality of Life

---

[19]Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. (Feb. 2009) http://bit.ly/2MGYTFi.

[20] Fauber, John, Networking Fuels Painkiller Boom, *Milwaukee Journal Sentinel* (Feb. 19, 2012) http://bit.ly/31tL7ub

91. Upon information and belief, Teva also claimed to West Virginia doctors, without evidence, that long-term opioid use would improve patients' quality of life.

92. A former Fentora sales representative who visited prescribers has described being trained by Teva to tell prescribers that Fentora would improve patients' quality of life. The representative was instructed to use, and did use, messaging that focused on Fentora improving patients' function, allowing patients to spend more time with the family or to return to a normal work pattern. Similarly, another former Teva sales representative promoted Actiq and Fentora by stating that they could "improve patients' quality of life, by letting them get back to their normal functions." Upon information and belief, similar messages regarding the improvement of patient function were provided to prescribers in West Virginia by Teva sales representatives.

93. In addition, Responsible Opioid Prescribing: A Physician's Guide (2007) by Scott M. Fishman, M.D., a physician guide sponsored and distributed by Teva, taught that relief of pain by opioids alone improved patients' function. The book remains for sale online.

94. Teva's claims that the use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of opioid use beyond 12 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

95. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social

functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[21] Studies of patients who suffer from pain have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.

96. The CDC has noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." *See* CDC Guideline at 2. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term use are clearer and significant." *See* CDC Guideline at 18. According to the CDC, "for the vast majority of patients, the known, serious, and to-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]." CDC Guideline at 18.

F. Teva Told Doctors that Opioids Could be Taken in Ever Higher Doses Without Disclosing Their Greater Risks.

97. Teva falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Upon information and belief, Teva needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribing opioids for more frequent dosing.

---

[21] Andrea Rubinstein, Are We Making Pain Patients Worse?, Sonoma Med. (fall 2009).

98. Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that, unlike NSAIDs, opioids have no "ceiling dose" and are therefore more appropriate treatment for severe pain. The publication inaccurately attributed 10,000-20,000 deaths annually to NSAIDs. The actual figure was 3,200, far fewer than deaths from opioids.[22] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication omitted known risks of opioid therapy while emphasizing the risks of competing products so that prescribers and patients would be more likely to choose opioids over other therapies such as over-the-counter acetaminophen or NSAIDs.

99. Teva also reinforced its message of the lack of a ceiling dose for opioids through its sales representatives. According to a former Actiq and Fentora representative, he told doctors that there was no ceiling dose for either opioid.

100. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic

[22]Ask the Expert: Do NSAIDs Cause More Deaths Than Opioids (Nov./Dec. 2013)(citations in article) http://bit.ly/2yFpxq3.

pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent.[23] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED. *See* CDC Guideline at 16

101. Teva's misrepresentations effectively increased opioid sales. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 19.3% to 29.1% of visits while NSAID and acetaminophen prescriptions fell from 36.9% to 29.1%. Accordingly, Teva's deceptive marketing of opioids as a class benefited their generics business, as well as their branded products.

G. Defendants Violated Laws Requiring Them to Guard Against Diversion of Opioids

102. West Virginia's Uniform Controlled Substances Act ("WVUCSA") and the legislative rules promulgated pursuant to the Act, 15 C.S.R. 2, require the Defendants to provide effective controls and procedures to guard against theft and diversion of controlled substances, among other requirements. W. Va. Code § 60A-1-101, *et seq.*, W. Va. C.S.R. § 15-2-5.

103. Defendants' knowledge of diversion and of suspicious orders suggesting diversion came from observations of sales representatives on the ground in West Virginia, as well as from information concerning prescribing activities acquired by vendors, and virtually real-time information concerning prescription fills in the form of "chargeback" data.

---

[23] CDC Guideline at 19. The 1016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013 the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

104. Defendants' knowledge of criminal diversion included, upon information and belief, knowledge of rogue prescribers and pharmacies inside West Virginia, as well as knowledge of the diversion of opioids from other states.

105. Defendants' obligations to provide effective controls and procedures to guard against diversion would necessarily include procedures to report diversion or suspicious orders suggesting diversion.[24] But both Teva and Actavis failed to comply with these requirements. Teva failed to have any suspicious order monitoring program for years, and did not implement a written suspicious monitoring ("SOM") system until 2014. Even this system merely reviewed whether customers were registered with the DEA and were credit worthy.

106. Further, the key investigatory role for suspicious orders was in the hands of Teva's Sales Department. The Sales Department would direct customer service to contact the customer for an initial investigation and to gather information, and to send a sales rep to the customer if the response was not satisfactory. The conflicts of interest inherent in this system are obvious. Furthermore, as of 2015, the decision to release orders rested with one individual, which exposed the system to the risk of mistaken releases.

107. The inadequacy of Teva's system is confirmed by the fact that even after it implemented a written SOM policy, it reported and stopped very few suspicious orders. For example, Teva reported its first ever suspicious order to the DEA on February 13, 2013. In total, from 2013 through 2016, nationally, Teva reported only 6 suspicious orders out of 600,000 total line orders (and not all were opioid products).

---

[24] In addition, W. Va. C.S.R. § 15-2-5 specifically requires a "wholesale drug distributor" to inform the Board of Pharmacy of suspicious orders of controlled substances. Teva Pharmaceuticals USA, Inc. is registered in West Virginia as a wholesale drug distributor and several of the Actavis entities previously held such a license.

108. The Actavis SOM system included separate systems operated by Watson Pharmaceuticals, Inc. ("Watson") and Actavis, Inc. ("Actavis"), which Watson bought in 2012-2013, and by Allergan, Inc., which the merged companies then bought in 2015. Neither of the two prior companies, nor the merged group, maintained effective controls against diversion.

109. Before the 2012 merger, Actavis produced twelve different generic opioids including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and a generic version of Janssen's Duragesic. However, from November 2000 through October 2012 the company maintained a rudimentary threshold-based SOM system.[25] This system only flagged orders unusual in size; it did not flag orders unusual in frequency or pattern in real time. It did not utilize any customer information available to Actavis, did not differentiate among NDC codes for drugs with a higher risk of diversion, nor did it automatically stop orders from shipping.

110. Similarly, the core of the pre-merger Watson SOM system, like the early pre-merger Actavis system, dated to the early 2000s.[26] This system, however, was even more rudimentary and was understaffed. Between 2009 and 2012, the Watson Call Center/Customer Relations Operation added no new staff to handle SOM validations, even though the number of validations increased by approximately 350% during that time. Furthermore, the Watson system affirmatively allowed customers to get around violations by canceling orders, or cutting their quantity.[27] According to its then-CEO, Actavis Group allowed customers to resubmit

---

[25] *See* Allergan_MDL_02081243; Allergan_MDL_02128514.
[26] Allergan_MDL_01844864.

[27] Allergan_MDL_01838989.

unjustifiable suspicious orders in smaller amounts so as to fall below their arithmetic suspicious order monitoring threshold, thereby avoiding reporting.

111. In 2015, the company, now known as Allergan plc, announced it was selling all of its generic drugs and various corporate subsidiaries to Teva, a sale it would complete in 2016. It ceased operating even the deficient Watson SOM program at that time. Regarding the transition, Thomas Napoli, Watson's (and then post-merger Actavis's) DEA Compliance Chief, testified in the *In re: National Prescription Opiate Litigation* ("MDL") that Teva "already had their own program in place for Suspicious Order Monitoring," and he was laid off after the sale.[28]

112. Upon information and belief, Teva and Actavis also targeted prescribers in West Virginia and elsewhere whom they had reason to know were engaged in diversion, contributing to the oversupply of non-medical opioids in the State and nationally. Both Teva's and Actavis' marketing plans called for the targeting of high volume prescribers.

113. Teva and Actavis therefore failed to comply with their obligations under the Uniform Controlled Substances Act, including their obligation to guard against diversion of controlled substances, which contributed to the illegal secondary opioid market in West Virginia and nationwide.

H. Teva and Actavis Deceptively Concealed Their Misconduct

114. Teva knew its marketing was false and misleading and profited from those misrepresentations. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids are highly addictive and responsible for a long list of very

[28] Napoli Deposition at 324:3-12 & 325:19.

serious adverse outcomes. Teva had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing evidence that conclusively exposes the known falsity of these misrepresentations.

115. Teva's and Actavis' failure to guard against diversion and report their knowledge of suspicious orders and suspicious and unlawful prescribing further concealed their misconduct in contributing to the opioid epidemic.

116. Notwithstanding this knowledge, at all times relevant to this Complaint, Teva and Actavis took steps to avoid detection of and to conceal their deceptive marketing and/or unlawful conduct. Teva disguised its roles in the deceptive marketing of chronic opioid therapy by funding and working through unbranded marketing, and/or third party advocates and professional associations.

I. Defendants' Conduct Has Injured the State of West Virginia and Its Citizens.

117. Opioids became a common treatment for chronic pain, in part, because of the Defendants' campaign of misrepresentations. As a result, opioid usage rates—and opioid abuse rates—have skyrocketed in West Virginia and in the United States. 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. At the same time, diagnoses of opioid addiction increased nearly 500% from 2010 to 2016. Many tens of thousands of West Virginians are currently addicted to opioids.

118. Opioid users often resort to heroin when they run out of opioids. Heroin is cheaper and more readily available. According to the National Survey on Drug Use and Health, four out of five current heroin users report that their drug use began with an opioid pain reliever.

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

120. Another result of Defendants' actions is the upsurge of the sober home[29] crisis in West Virginia. The opioid epidemic has created a market of thousands of people with opioid dependence. Instead of helping those with addiction problems recover, many sober homes have become hotbeds of opioid distribution and have distorted the character of once-peaceful neighborhoods.

121. The opioid crisis 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."

122. The Defendants' actions alleged in this Complaint have caused numerous societal injuries to the State of West Virginia. The Defendants' conduct has contributed to deaths, drug addiction, personal injuries, child neglect, children placed in foster care, babies born addicted to

[29] A "sober home", sometimes called a "halfway house", is a sober, safe, and healthy living environment that promotes recovery from alcohol and other drug use and associated problems. Sober homes provide alcoholics and addicts a place to transition to everyday life after leaving inpatient facilities.

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.

123. The Defendants' actions alleged in this Complaint have caused numerous economic injuries to the State of West Virginia. The Defendants' 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
Violations of the West Virginia Consumer Credit and Protection Act

124. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

125. Defendants' acts or practices alleged herein are unfair, deceptive, and/or unconscionable in violation of the WVCCPA.

126. Defendants' sale, promotion, marketing, advertising of opioid products in the State of West Virginia involves "trade" or "commerce" within the meaning of the WVCCPA.

127. Defendants sold, promoted, marketed, and advertised opioid products to the State of West Virginia and its governmental entities, businesses, and consumers within West Virginia.

128. The Defendants' misrepresentations and omissions of material facts, as detailed above, constitute deceptive act or practices that are prohibited by the WVCCPA.

129. In addition, Defendants' violated the WVUCSA by failing to implement effective

controls and procedures to guard against diversion, including but not limited to targeting prescribers and pharmacies whom they knew or should have known were potentially engaged in diversion, and failing to report their knowledge of suspicious orders and prescribers to relevant authorities.

130. Defendants' violation of the WVUCSA, a law whose purpose is to protect the health and safety of the public, is an unfair or deceptive act or practice prohibited by the WVCCPA.

131. Defendants' 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.

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

133. 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

134. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

135. Through the actions described above, the Defendants have 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.

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

137. Through the actions described above, the Defendants 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.

138. The expansion of the market for prescription opioids because of the Defendants' misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with actual or signs indicative of abuse or diversion, created an overabundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

139. Defendants further expanded the market for prescription opioids by failing to implement effective controls and procedures to guard against diversion, including but not limited to targeting prescribers and pharmacies whom they knew or should have known were potentially engaged in diversion, and failing to report their knowledge of suspicious orders and prescribers to relevant authorities.

140. Opioid use, abuse, addiction, and overdose deaths have increased dramatically in West Virginia as a result of the Defendants' conduct. The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources including the State and its political subdivisions.

141. The Defendants' actions described above were a substantial factor in opioids becoming widely available, used, and abused.

142. But for the Defendants' actions, opioid use would not have become so widespread and the enormous public health hazards of opioid overuse, abuse, addiction, and death that now exists would have been averted. The Defendants' actions have and will continue to injure and harm the citizens and the State of West Virginia for many years to come.

143. While tort-based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance and associated financial and economic losses were foreseeable to the Defendants, who knew or should have known that its unfair and deceptive business practices regarding the safety, purported benefits, and comparative superiority or equivalency of its opioid products, its continued sales targeting of providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion of opioids, and its other conduct described herein were creating a public nuisance.

144. The Defendants intended health care providers to prescribe their opioids for long-term use and for patients to fill those prescriptions and to keep filling those prescriptions at higher and higher doses. A reasonable person in the Defendants' position would foresee not only an expanded market but the other likely and foreseeable result of the Defendants' conduct - the widespread problems of opioid addiction and abuse, particularly given the easy manipulation of its prior formulation and its popularity among opioid abusers and those addicted.

145. The Defendants were on notice and aware of signs both that health care providers were prescribing unreasonably high numbers of opioids and that the broader use of opioids were causing the kinds of harm described in this Complaint.

146. The Defendants' business practices generated a new and very profitable circular market with the promotion of opioids—providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand to buy more.

147. The Defendants acted without express authority of a statute in misrepresenting the safety, comparative superiority or equivalence of its opioids to other products, and benefits of its opioid products, failing to disclose the increased risk of addiction at higher doses, and failing to disclose the lack of substantiation for long-term use of opioids among other conduct.

148. 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. Teva's conduct interfered in the enjoyment of these public rights.

149. As part of its nuisance 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.

Prayer for Relief

WHEREFORE, the State prays that the Court grant the following relief:

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

2. 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;

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

4. 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);

5. Pre- and post-judgment interest;

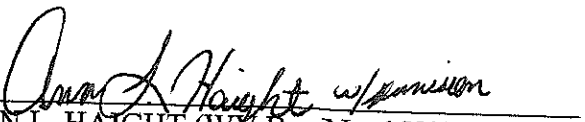
6. Costs and reasonable attorneys' fees; and

7. 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.*

STATE OF WEST VIRGINIA ex rel.

PATRICK MORRISEY,
Attorney General

By Counsel



ANN L. HAIGHT (WV Bar No. 1527)
Deputy Attorney General
VAUGHN T. SIZEMORE (WV Bar No. 8231)
Deputy Attorney General
ABBY G. CUNNINGHAM (WV Bar 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