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-150
JUDGE William S Thompson

MALLINCKRODT LLC,
a Delaware limited liability corporation, and
SPECGX LLC,
a Delaware limited liability corporation,

Defendants.

COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Defendants Mallinckrodt LLC and SpecGx LLC (hereinafter "Defendants") and alleges as follows:

I. Introduction

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

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

10. 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.

11. 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.

12. In 2007, the cost for treating a NAS baby was approximately $36,000.00; cost for a healthy baby was approximately $3,600.00. 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.

13. 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.

14. 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; see also, R. Califf, *et al.*, A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

15. 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, and pharmacies. The Defendants knew that opioids were dangerous and addictive; nevertheless, they collectively used 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 to endorse and promote the use of opioids. The key opinion leaders 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. The Defendants also supplied the opioids to retail pharmacies without proper protections to prevent diversion.

16. 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.

17. 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

18. 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, including unfair or deceptive acts or practices, W. Va. Code § 46A-6-104, 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).

19. Defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws of Delaware. Mallinckrodt LLC manufactures, sells and distributes opioid medications.

20. Defendant SpecGx LLC is a limited liability company organized and existing under the laws of Delaware. It is headquartered in Webster Groves, Missouri. It is registered as a chemical and pharmaceutical manufacturer with the West Virginia Secretary of State. It is registered as wholesale distributer and manufacturer with the West Virginia Board of Pharmacy with a listed address of 172 Railroad Avenue, Hobart, New York. SpecGx LLC manufactures, sells and distributes opioid medications.

21. Defendants are the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the U.S., based upon volume of prescriptions.

22. The Defendants operate a vertically integrated business in the U.S.: (1) importing raw opium materials; (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York; (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, pharmaceutical benefit managers with mail-order pharmacies, and hospital buying groups; and (4) distributing to retail pharmacies.

23. The Defendants manufactured, distributed, marketed and sold the branded opioids Exalgo, an extended-release hydromorphone sold in 8, 12, 16 and 32 milligram ("mg") dosage strengths, and Xartemis XR ("Xartemis"), an extended release combination of oxycodone and acetaminophen.

24. The Defendants obtained FDA approval for Xartemis in 2014 and discontinued Xartemis in 2016.

25. The Defendants obtained FDA approval for Exalgo in March, 2010. It has since discontinued marketing Exalgo.

26. The Defendants manufacture, distribute, market and sell the branded opioid Roxicodone in 15 mg and 30 mg strengths. The Defendants obtained FDA approval for Roxicodone in 2000.

27. The Defendants promoted its branded opioid products with its own direct sales force.

28. In addition to developing branded opioid products, the Defendants have long been the leading manufacturers of generic opioids. The Defendants report that "in calendar [year] 2018 we estimated that we received approximately 38% of the total DEA quota provided

to the U.S. market for the controlled substances we manufacture."[1]

29. ARCOS data for the years 2006-2012 reports the Defendants as the largest manufacturers of oxycodone and hydrocodone.

30. According to the DEA, hydrocodone is the most frequently prescribed opioid in the United States with more than 136.7 million prescriptions for hydrocodone-containing products dispensed in 2013, and 93.7 million and 83.6 million dispensed recently in 2016 and 2017, respectively (IMS Health™).[2] It is the second most frequently encountered opioid pharmaceutical in drug evidence submitted to federal, state, and local forensic laboratories. Id. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. Id.

31. The Defendants manufacture or have manufactured the following drugs:

Product Name	**Chemical Name**
Exalgo	Hydromorphone hydrochloride (extended release)
Roxicodone	Oxycodone hydrochloride
Xartemis XR	Oxycodone hydrochloride and acetaminophen (extended release)
Methadose	Methadone hydrochloride
Generic MS Contin	Morphine sulfate (extended release)
Generic	Morphine sulfate oral solution
Generic Duragesic	Fentanyl transdermal system
Generic Actiq	Oral transmucosal fentanyl citrate
Generic Percocet	Oxycodone and acetaminophen
Generic Vicodin	Hydrocodone bitartrate and acetaminophen
Generic Dilaudid	Hydromorphone hydrochloride
Generic Exalgo	Hydromorphone hydrochloride (extended release)
Generic Vivitrol	Naltrexone hydrochloridate
Generic Opana	Oxymorphone hydrochloride

[1] Mallinckrodt plc, Annual Report (Form 10-K) for the year ending December 28, 2018, at 8. http://bit.ly/2mSt8P4.

[2] DEA https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf

Product Name	Chemical Name
Generic	Methadone hydrochloride
Generic Roxicodone	Oxycodone hydrochloride
Generic Suboxone	Buprenorphine and naloxone

III. State Court Jurisdiction

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

33. 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).

34. 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. Circuit Court Jurisdiction

35. 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

36. 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.

37. 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.

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

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

40. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day.

41. Different opioids provide varying levels of MMEs. An opioid manufacturer/distributor's contribution to the opioid crisis cannot be calculated by merely counting the number of pills shipped or prescriptions written.

42. Defendants' branded product Exalgo is four times stronger than morphine and was sold in 8, 12, 16 and 32 mg dosage strengths. One 8 mg dose of Exalgo is the equivalent of 32 mg of morphine; 12 mg is the equivalent of 48 mg of morphine, 16 mg the equivalent of 64

mg of morphine and 32 mg the equivalent of 128 mg of morphine.[3]

43. Defendants also manufacture/distribute generic fentanyl, a synthetic opioid that is 100 times stronger than morphine.

44. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids – the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

45. Discontinuing opioids after more than just a few weeks of use will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids depending on how long the opioids were used.

46. The Defendants marketed their branded and generic drugs by misrepresenting their addictive nature and falsely claiming that the drugs could be taken in higher doses without disclosing the greater risks of addiction.

47. The Defendants rely on their sales representatives to convey marketing messages and materials to prescribers in targeted, in-person settings.

48. To ensure that sales representatives delivered the desired messages to prescribers,

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[3] https://go.cms.gov/2oZhqTF

the Defendants 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. Defendants may have provided incentives in the form of bonuses and vacations to increase their sales.

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

50. 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.[4]

51. The Defendants used key opinion leaders, third party groups for which they provided funding, 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.[5]

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

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

[5] 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.

B. The Defendants Misrepresented, Concealed or Omitted Material Facts Regarding Opioids.

53. The Defendants marketed their opioids products by:

a. Making false or misleading claims regarding the risk of addiction;

b. Making false or misleading claims that signs of addictive behavior are actually signs of "pseudoaddiction," requiring more opioids;

c. Misrepresenting, concealing or omitting facts regarding limits and risks of increased dosages;

d. Making false or misleading claims that long-term opioid use improves function or quality of life.

1. Defendants Made False or Misleading Claims Concerning the Risk of Opioid Addiction.

54. Studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose."[6]

55. The Defendants knew their opioids were addictive and an overwhelming number of patients were addicted. This is illustrated in a 2009 email wherein Steven J. Cochran, Vice President of Purchasing for KeySource Medical, Inc. requested a shipment of oxycodone from Victor Borelli, the Defendants' national retail account manager:

Cochran: Keep 'em comin'! Flyin' out of here. Its [sic] like people are addicted to these things or something. Oh, wait, people are . . .

Borelli: Just like Doritos. Keep eating. We'll make more.[7]

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[6] FDA Announces Safety Labeling Changes and Postmarket Study Requirements For Extended-Release and Long-Acting Opioid Analgesics, MagMutual (Aug. 18, 2016).
[7] Cochrane, S. Email to Borelli, V. Jan. 27, 2009, MNK-T1_0000506114.

56. And yet, the Defendants claimed that the potential for addiction from their opioids was relatively small or non-existent, even though there was no scientific evidence to support that claim.

57. As described below, the Defendants promoted their opioid products, both branded and generic, in a campaign that consistently mischaracterized the risk of addiction. They did so through their website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" that it created and led.

58. In 2010, the Defendants created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as a "coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing prescribing habits." The C.A.R.E.S. Alliance itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.), copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance include unbranded publications that do not disclose a link to Mallinckrodt.

59. By 2012, the Defendants, through the C.A.R.E.S. Alliance, promoted and distributed Defeat Chronic Pain Now!.[8] This book is still available online. The false claims and misrepresentations in this book include the following statements:

a. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."[9]

b. "When chronic pain patients take opioids to treat their pain, they rarely

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[8] C. Argoff, et al., Defeat Chronic Pain Now!: Ground Breaking Strategies for Eliminating the Pain of Arthritis, Back and Neck Conditions, Migraines, Diabetic Neuropathy and Chronic Illness (Dec. 1, 2010) (Kindle Ed.)

[9] Id. at p. 173.

develop a true addiction and drug craving."[10]

c. "Only a minority of chronic pain patients who are taking long-term opioids develop a tolerance."[11]

d. "**The bottom line**: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."[12]

e. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."[13]

f. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."[14]

60. The author of Defeat Chronic Pain Now!, Charles Argoff, M.D., is the president of the American Academy of Pain Medicine Foundation (AAPMF). AAPMF and individuals affiliated with AAPMF received over $600,000.00 from various opioid manufacturers between 2012 and 2017.[15]

61. The Defendants also included Argoff's book in its sales force training materials as a patient education tool.[16]

62. The Defendants distributed this book to consumers through its C.A.R.E.S. Alliance.[17]

63. Between 2013 and at least June 2018 online, Mallinckrodt Pharmaceuticals Policy

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[10] Id. at p. 175.
[11] Id. at p. 177.
[12] Id.
[13] Id. at p. 178.
[14] Id.
[15] Id.
[16] MNK-NC01320579, p. 18.
[17] LaRue, L. Email to Saake, L., et al. Mar. 11, 2013, MNK_NC00508525.

Statement Regarding the Treatment of Pain and Control of Opioid Abuse, stated that "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cited to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

2. Defendants Misrepresented that Signs of Addiction Were Untreated or Under-treated Pain ("Pseudoaddiction").

64. The Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated or undertreated pain and that the appropriate response was to prescribe more opioids.

65. 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. The report 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 . . . ." [18]

66. The Defendants informed doctors and patients that people on prescription opioids who exhibited classic signs of addiction – requesting more and higher dosages of opioids – were not addicted, but were suffering from the under-treatment of their pain.

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[18] 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/

67. The Defendants made these representations in outreach materials they produced, sponsored or controlled.

68. For example, the FAQs section of www.pain-topics.org, a now defunct website to which the Defendants provided funding, contained misleading information about addiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking'."[19]

69. Defendants recommended that this "undertreated pain" or "pseudoaddiction" should be treated with increased strengths of dosages of opioids.

3. Defendants Misrepresented, Omitted or Concealed Facts Regarding Limits and Risks of Increased Dosage.

70. In materials they produced, sponsored, or controlled, the Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief, based upon the Defendants' representations that their drugs had no ceiling dose. These claims were deceptive because they omitted or concealed the danger of adverse effects that occur at higher doses that were confirmed by scientific evidence.

71. Patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are more likely to remain on opioids for a longer period of time.

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[19] https://web.archive.org/web/20080630030443/http://pain-topics.org/faqs/index1.php#tolerance

72. Defendants' sales representatives were trained to aggressively push doctors to prescribe stronger doses of opioids. For example, the Defendants created "X Brand Radio" as a motivational tool for its sales teams.

73. An email dated May 11, 2012, with the subject "Get INSPIRED with EXALGO X Brand Radio," asked the sales team to listen to the first installment of the show featuring "today's hit song – Propah Dose."[20]

74. The chorus to "Propah Dose," a song performed in reggae style, tells sales representatives that:

> So when you start at the middle
> Or you start at the top
> Or you start at a little
> Make sure you just don't stop
> Cause your patient needs relief, mon
> So do what you should
> When you convert and titrate
> Make sure EXAAALGOOD[21]

75. The email instructed that the song was for "your ears only and should NOT be shared with customers or others outside the Specialty Pharmaceuticals team. Happy Listening and Good Selling!" See. n. 20.

76. Opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day; 33 mg of oxycodone is the equivalent of 50 MME.

77. Taking opioids for longer periods of time or in higher doses increases the risk of addiction, overdose and death.[22]

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[20] MNK-NCO2869604
[21] MNK_NCO4261780.
[22] https://www.cdc.gov/vitalsigns/opioids/index.html

4. Defendants Misrepresented that Long-Term Opioid Use Improves Function.

78. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Defendants consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome the risks.

79. The Defendants' website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[23]

80. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[24]

81. Substantial evidence exists that demonstrates opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in function outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed [sic] that opioids for chronic pain may actually worsen pain and function . . ." along with general health, mental health, and social function.[25]

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[23] http://www.mallinckrodt.com/corporate-responsibility/responsible-use/ (last accessed Oct. 3, 2019).
[24] CDC Guideline at 20.
[25] T. Frieden, Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline, 374 N. Eng. J. Med. 1501-1504 (Apr. 21, 2016). http://bit.ly/352a0j1.

82. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, and substance abuse), increased psychological distress and greater health care utilization. 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 opioid use are clearer and significant."[26] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[27]

83. Research such as a 2008 study in the journal Spine has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[28] Another study demonstrated that injured workers who received a prescription opioid for more than seven (7) days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[29]

C. Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels.

84. The Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States and in West Virginia. They deployed seemingly unbiased and independent third parties that they controlled to spread

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[26] CDC Guideline at 2, 18.
[27] CDC Guideline, n. 27.
[28] J. Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, Spine: Sept. 15, 2008 – Vol. 33- Issue 20 – p. 2219-27. http://bit.ly/30Gnai7.
[29] GM Franklin, Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort, Spine: January 15, 2008 - Volume 33 - Issue 2 - p 199-204. http://bit.ly/2oMCi0o.

their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the country, including West Virginia.

85. The Defendants' sales representatives made 9,844 sales visits to doctors and other medical professionals in West Virginia from April 1, 2010 through October 31, 2013.

86. In addition to direct marketing sales representatives and key opinion leaders, the Defendants funded patient advocacy and professional organizations that appear independent from the Defendants, but were not, and distributed branded and unbranded advertising and publications to promote opioids to doctors and patients.

87. The Defendants distributed publications that understated the risks and overstated the benefits of long-term opioid use, appeared to be the result of independent, objective research, and were calculated to shape the perceptions of prescribers and patients. This literature was distributed to prescribers and patients and served to further the Defendants' marketing goals, rather than scientific standards, and were intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

88. To accomplish their goal, the Defendants, through sales representatives and through its C.A.R.E.S. Alliance, distributed publications such as the book Defeat Chronic Pain Now! to patients, and Responsible Opioid Prescribing by Dr. Scott Fishman, a former president of the American Academy of Pain Medicine, to its doctors.

89. Dr. Fishman's book asserted that pain is undertreated and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful.[30] It also promoted long-term opioid treatment as viable and a safe option for treating chronic pain.

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[30] Fishman, Scott, Responsible Opioid Prescribing: A Physician's Guide (Waterford Life Sciences 2007).

90. Defendants also distributed its "Opioid Safe Use and Handling Guide" to patients. This guide informs patients that "Addiction does not often develop when taking opioid pain medication as prescribed by a healthcare provider . . ." and that "[p]hysical dependence is not the same as addiction."[31]

D. Defendant SpecGx LLC Failed to Report Suspicious Orders.

91. Violations of laws enacted to protect the public are unfair or deceptive acts or practices. *State ex rel. McGraw v. McCuskey, et al.*, 2003 WL 25570573 (W. Va. Cir. Ct.) (Trial Order), *citing 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), and *Winston Realty Co., Inc. v. G.H.G., Inc.*, 331 S.E.2d 677 (N.C. 1985).

92. The purpose of Uniform Controlled Substances Act ("UCSA"), W. Va. Code § 60A-1-101, *et seq.*, is to protect the health and safety of the citizens of West Virginia.

93. The Board of Pharmacy promulgated legislative rules for the UCSA, 15 C.S.R. 2, relating to the distribution of controlled substances with the State of West Virginia pursuant to W. Va. Code § 60A-3-301.

94. A violation of the UCSA or related rules is an unfair or deceptive act or practice and violates W. Va. Code § 46A-6-104.

95. The Defendant SpecGx LLC is a distributor of controlled substances and must comply with the laws of West Virginia.

96. "A wholesale distributor shall inform the Office of the Board of suspicious orders

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[31] "Opioid Safe Use and Handling," MNK_NC002284036.

of controlled substances when discovered by the wholesale drug distributor." "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 15 C.S.R. 2.5.3.

97. Defendant SpecGx regularly distributed large quantities of commonly-abused, highly addictive controlled substances to clients who were serving a customer base comprised of individuals who were abusing prescription medications, many of whom were addicted and who could reasonably be expected to become addicted or to engage in illicit drug transactions.

98. Defendant SpecGx knew its customers, customer base, the population base served by a particular pharmacy or drug store, and the average prescriptions filled each day, as well as other information that would identify an order as suspicious and subject to reporting under the rule.

99. Defendant SpecGx's failed to adequately design and operate a system to disclose suspicious orders of controlled substances, and failed to inform the State of suspicious orders when they were discovered.

100. Defendant SpecGx facilitated the dispensing of controlled substances for non-legitimate medical purposes and fueled a prescription drug abuse epidemic in West Virginia.

101. The Defendant SpecGx contributed to the epidemic prescription drug abuse problem in the State of West Virginia through its repeated violations of 15 C.S.R. 2.5.3.

102. The Defendant SpecGx LLC's failure to comply with 15 C.S.R. 2.5.3 is an unfair or deceptive act or practice.

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

103. 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.

104. 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.

105. The number of 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.

106. Another result of Defendants' actions is the upsurge of the sober home[32] 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.

107. 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

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[32] 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.

reasons—beyond what their physicians prescribed."

108. The Defendants' actions alleged in this Complaint have caused numerous societal and economic 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 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.

Count I
Violations of the West Virginia Consumer Credit and Protection Act

109. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 108 above as if fully set forth herein.

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

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

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

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

114. 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.

115. 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.

116. As part of this action, the State expressly does not raise any conduct related to, nor seek any damages attributable to, the Medicare or Medicaid programs. As to manufacturers, the state reserves the right to file a separate action to claim damages attributable to the Medicare or Medicaid programs.

Count II
Common Law Public Nuisance

117. Plaintiff State of West Virginia adopts, realleges, and incorporates by reference paragraphs 1 through 108 above as if fully set forth herein.

118. 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.

119. 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.

120. 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.

121. 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.

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

123. 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.

124. 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.

125. The Defendants intended health care providers to prescribe their opioids, including their extended release 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.

126. 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.

127. 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.

128. 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.

129. 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. Defendants' conduct interfered in the enjoyment of these public rights.

130. As part of this action, the State expressly does not raise any conduct related to, nor seek any damages attributable to, the Medicare or Medicaid programs. As to manufacturers, the state reserves the right to file a separate action to claim damages attributable to the Medicare or Medicaid programs.

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

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VERIFICATION

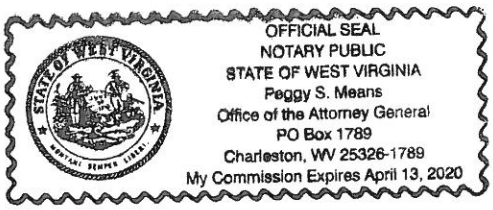
STATE OF WEST VIRGINIA,
COUNTY OF KANAWHA, TO-WIT:

I, Vaughn T. Sizemore, Deputy Attorney General, being duly sworn, depose and say that I am the counsel of record for Plaintiff in the foregoing styled civil action; that I am familiar with the contents of the foregoing **COMPLAINT** and that the facts and allegations contained therein are true, except such as are therein stated upon information and belief, and that as to such allegations I believe them to be true.

VAUGHN T. SIZEMORE (WV State Bar # 8231)
DEPUTY ATTORNEY GENERAL

Taken, subscribed, and sworn to before me in the County and State aforesaid this 19th day of November, 2019.

My commission expires April 13, 2020



Peggy S Means
NOTARY PUBLIC