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-105
JUDGE WILLIAM S. THOMPSON

JANSSEN PHARMACEUTICALS, INC.,
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.,
JANSSEN PHARMACEUTICA, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.,
and JOHNSON & JOHNSON,

Defendants.

FIRST AMENDED COMPLAINT

Plaintiff, the State of West Virginia, by its Attorney General, Patrick Morrisey, sues Defendants, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson, 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. 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 caused immense pain and suffering for families throughout West Virginia.

4. Originally, doctors prescribed, and patients used, opioids only for short-term acute pain, for cancer, or end-of-life pain. Opioids were seen as too addictive and debilitating to be used long-term, and, for less severe chronic pain conditions, doctors knew that the risks of using opioids dramatically exceeded their benefits.

5. For companies like the Defendants, the market for opioids defined by medical consensus was unacceptably small. Dramatic growth in sales and revenue would come only from the widespread, long-term use of opioids for common and chronic pain conditions like back pain, arthritis, and headaches.

6. To make that happen, the Defendants and other opioid makers had to turn the standard of care on its head—persuading doctors that drugs they had been unwilling to prescribe because of their risk of addiction were more effective and safe enough to use widely and long-term for relatively minor pain conditions. Patients were exposed to the same reassuring messages.

7. The Defendants specifically marketed to doctors and patients in West Virginia and misrepresented that their opioid medications were safer than other alternatives, disseminated misleading statements about opioids, furthered the concept of pseudoaddiction, and misrepresented that opioids were "rarely addictive" when used for chronic (non-cancer) pain. They targeted particularly vulnerable populations, such as the elderly, even though opioid use in this population carries a heightened risk of overdose, injury, and death.

8. The long-term use of opioids is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve any effect. Patients also quickly become dependent on opioids and will experience often-severe withdrawal symptoms if they stop

using the drugs. That makes it very hard for patients to discontinue using opioids after even relatively short periods. The risks of addiction and overdose increase with dose and duration of use. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which can make opioids fatal. It is the interaction of tolerance, dependence, and addiction that makes the use of opioids for chronic pain so lethal.

9. 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 programs.[1]

10. 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.[2]

11. These campaigns also minimized the risks of OPRs and exaggerated the benefits of long-term OPR use. 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." "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."[3]

[1] Andrew Kolodny, *et al.*, The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, p. 562 (Jan. 12, 2015), https://bit.ly/2J5A9Tp.
[2] Id. at 563.
[3] Id.

12. 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.[4]

13. In 2017, over 1,000 West Virginia citizens died as the result of a drug overdose. Eighty-six percent (86%) of these overdose deaths involved an opioid. This is threefold higher than the national rate of 14.6 deaths per 100,000 people.[5]

14. In 2017, West Virginia providers wrote 81.3 opioid prescriptions for every 100 people compared to the national average U.S. rate of 58.76 prescriptions.[6]

15. 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.

16. 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.[7]

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

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

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

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

17. 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.[8]

18. Studies show a direct correlation between OPRs and heroin addiction with 4 out of 5 heroin users reporting their opioid use began with OPRs.[9]

19. 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."[10]

20. Children are especially vulnerable to the opioid epidemic. West Virginia's rate of Neonatal Abstinence Syndrome ("NAS") is five times the national average and results in thousands of children being placed in foster care.[11] In 2017, the overall incidence rate of NAS was 50.6 cases per 1,000 live births for West Virginia residents. The highest incidence rate of NAS was 106.6 cases per 1,000 live births (10.66%) in Lincoln County.

21. In 2007, the cost for treating a NAS baby was approximately $36,000; cost for a healthy baby was approximately $3,600.[12]

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

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

[9] Andrew Kolodny, et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, p. 560 (Jan. 12, 2015), https://bit.ly/2J5A9Tp.

[10] 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.

[11] Proposed Opioid Response Plan for the State of West Virginia, Jan. 10, 2018, p. 20, https://bit.ly/2Oyu48a.

[12] Michael L. Stitely, MD, et al., Prevalence of Drug Use in Pregnant West Virginia Patients, West Virginia Medical Journal, Special Ed., Vol. 106, No. 4, p. 48, https://bit.ly/2q0Tqg2.

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

23. The Defendants helped fuel 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 touting the benefits of opioid use as if they were independent medical experts, but they actually served as the Defendants' mouthpieces.

24. Moreover, in the mid-1990s, a Johnson & Johnson subsidiary called Tasmanian Alkaloids developed the Norman poppy, a strain of opium poppy high in thebaine, which is used as a starting point in many opioid painkillers, but which did not contain morphine, the precursor to heroin. Noramco, another Johnson & Johnson subsidiary, processed the raw ingredients from Tasmanian Alkaloids into the active pharmacological ingredients ("API") used to produce prescription opioid medications. The introduction of the Norman poppy corresponded with an exploding demand for the baine. A 1998 letter from an executive at Noramco to Purdue Frederick Laboratories (Purdue Pharma) read, "Noramco will work with PF Laboratories to secure its entire, worldwide requirements. This is not a minor point. As we have discussed, access to raw materials is going to be critical to obtaining security of supply." It goes on, "gaining access to raw materials

on a worldwide basis…simply cannot be provided by any other company." Noramco purportedly became the nation's top supplier of the active pharmaceutical ingredient used to manufacture prescription opioid medication.

25. Noramco, along with Tasmanian Alkaloids, were part of the Johnson & Johnson Family of Companies[13] and were important to Johnson and Johnson's "pain management franchise."[14] Through these subsidiaries, Johnson & Johnson's global manufacturing network for opioids was among the largest narcotic API suppliers in the United States. Noramco supplied opioid API, including oxycodone, hydrocodone, and fentanyl,[15] to other drug manufacturers, including Teva, Endo, Purdue, and Mallinckrodt, and it capitalized on brand to generic switches. As of 2015, 80% of Noramco's sales were through long-term supply agreements or majority controlled substance share with all seven of the top U.S. generic companies.[16] As a result, Johnson & Johnson profited from, and was incentivized to foster, increased sales of both unbranded and branded opioids.

26. 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.

27. 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

[13] https://www.noramco.com/our-capabilities/.
[14] Oklahoma Judgment after Non-Jury Trial at 5.
[15] PAR_OPIOID_MDL_002024206.
[16] PAR_OPIOID_MDL_0002024217.

harm to the State of West Virginia and its citizens, and now they should pay for their role in the crisis and act to remediate the problem.

II. Parties

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

29. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey. Janssen Pharmaceuticals, Inc. formally was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn formally was known as Janssen Pharmaceutica, Inc. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson, which controls the sale and development of Janssen Pharmaceuticals, Inc.'s drugs. Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit.

30. Documents posted on Johnson & Johnson's and Janssen's websites confirm Johnson & Johnson's control of the development and marketing of opioids by Janssen. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a Johnson & Johnson company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical

Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. Further, the "Ethical Code for the Conduct of Research and Development" is on Janssen's website, but it is Johnson & Johnson's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

31. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

32. Defendant Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

33. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey.

34. Collectively, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. and Johnson & Johnson are hereinafter referred to collectively as "Janssen" or "the Defendants."

35. In August 2004, the State of West Virginia sued Johnson & Johnson, Janssen Pharmaceutica Products, L.P., and Janssen Pharmaceutica, Inc. in the Circuit Court of Brooke County, West Virginia, Civil Action No. 04-C-156-MJG, for violations of the WVCCPA in connection with the sale and branded marketing of the drugs Risperdal® and Duragesic®. The parties entered into a settlement agreement with respect to the State's claims regarding Duragesic® which was approved by Final Order dated December 23, 2010 ("2010 Settlement"). Pursuant to the 2010 Settlement agreement, the State agreed to "release[ ] and forever discharge[ ]" Johnson & Johnson and Janssen Pharmaceutica Products, L.P. "from all manner of claims, demands,

actions, suits, causes of action, damages whenever incurred, liabilities of any nature whatsoever . . . arising out of or relating in any way to any conduct of any Released Party regarding the prescription drug Duragesic prior to dismissal of [Civil Action No. 04-C-156-MJG] and concerning any claims or matters alleged in the Amended Complaint . . . ." The State does not violate the 2010 Settlement by bringing this action against the Defendants for violations of state law in the marketing and sale of Duragesic occurring after the dismissal date of Civil Action No. 04-C-156-MJG. In addition, the 2010 Settlement does not bar the State from bringing an action against the Defendants regarding unlawful conduct with respect to other opioid medications marketed and sold by the Defendants, or for the Defendants' unlawful conduct in promoting opioids in general through unbranded marketing or third-party promotion.

36. Janssen manufactures the opioids Duragesic, Tapentadol IR, Ultram, Ultracet, and Ultram ER, and previously manufactured the opioids Nucynta and Nucynta ER. Janssen promotes, markets, advertises, and sells opioids in West Virginia, including Duragesic, Ultram, Ultracet, Ultram ER, and Tapentadol IR. Until 2015, Janssen promoted, marketed, advertised, and sold the opioids Nucynta and Nucynta ER in West Virginia.

III. State Court Jurisdiction

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

38. 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).

39. 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

40. 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

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

VI. Factual Allegations

A. Janssen Falsely Trivialized, Mischaracterized, and Failed to Disclose the Known, Serious Risk of Addiction

42. Janssen spent millions of dollars on promotional activities and materials, including advertising, websites, and in-person sales calls, that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. It also relied upon seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were unsupported and misleading, but seemed independent and therefore credible.

43. Janssen relies heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings.

44. Janssen's sales representatives visited prescribers in West Virginia, including, upon information and belief, prescribers whom Janssen had reason to suspect were engaged in diversion.

45. Upon information and belief, Janssen understood the effectiveness of sales representatives' visits to doctors and used sales representatives to market its opioids because it knew that sales representatives influence prescribers to increase its sales.

46. To ensure that sales representatives deliver the desired messages to prescribers, Janssen directs and monitors them through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (known as "call notes") from each visit. Janssen likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the companies. It ensured marketing consistency nationwide through national and regional sales representative training. Thus, the company's sales forces in West Virginia carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

47. Janssen also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were clearly the wrong thing to do.

48. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Society, that were also able to

exert greater influence because of their seeming independence. Janssen exerted influence over these groups by providing major funding directly to them as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Janssen distributed these publications to prescribers or posted them on their websites.

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

50. Neither these unbranded third-party materials, nor the marketing messages and scripts relied on by Janssen's sales representatives, were reviewed or approved by the FDA.

51. Upon information and belief, all of the messages described below were disseminated to West Virginia prescribers and patients.

1. Minimizing or Mischaracterizing the Risk of Addiction

52. To convince prescribers and patients that opioids are safe, Janssen directly, through its influence of third parties, and/or by aiding and abetting third parties, deceptively represented that the risk of abuse and addiction is modest, manageable, and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

53. On information and belief, Janssen sales representatives also told doctors that Nucynta was less likely to be addictive than other opioids.

54. Janssen also undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. Upon information and belief, Janssen encouraged doctors in West Virginia to prescribe their opioids to the "right" patients or

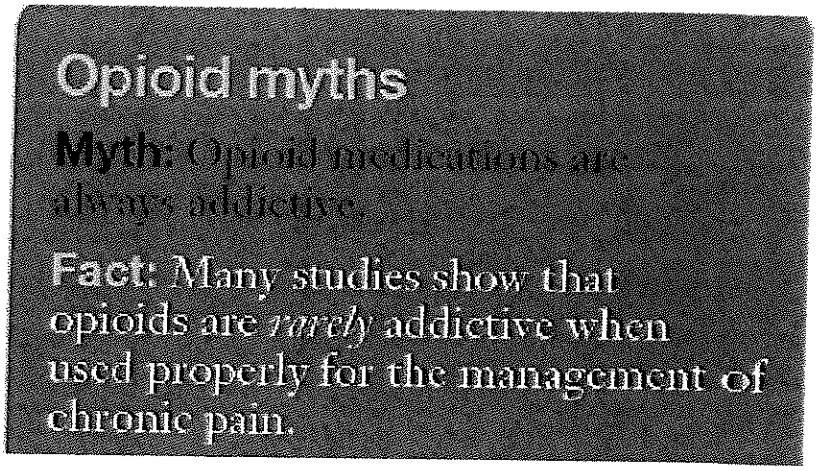
"appropriate" patients, which was meant, and understood, to mean patients who were not likely to become addicted, notwithstanding the fact that a low-risk population did not exist or could not be ascertained.

55. Upon information and belief, Janssen told West Virginia prescribers that patients were less likely to suffer from withdrawal, and that their drugs had less of a withdrawal effect than other opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

56. Janssen also disseminated misleading information about opioids and addiction. Janssen was a sponsor of the Let's Talk Pain Coalition, which was founded by the American Pain Foundation ("APF") and other advocacy groups. Upon information and belief, the Coalition's *Let's Talk Pain* website stated, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." The website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."[17]

57. In addition, Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.

[17] Let's Talk Pain website is no longer available to view online. This website was accessible online until May 2012.



58. The American Geriatrics Society ("AGS"), a nonprofit organization which serves health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). Janssen contracted with AGS to disseminate the 2009 AGS Guidelines and create CMEs based on them. Janssen was aware of the content of the 2009 AGS guidelines when it agreed to provide funding for these projects.

59. Treatment guidelines, like those produced by AGS, are especially influential with primary care physicians and family doctors to whom Janssen promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the U.S. Centers for Disease Control and Prevention has recognized that treatment guidelines can change prescribing practices.

60. Janssen's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized

the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[18] That same month, after a "systematic 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 noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[19] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[20]

2. Janssen Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

61. Janssen, along with other opioid manufacturers, covered up the occurrence of addiction by attributing it to a made-up condition called "pseudoaddiction." Pseudoaddiction meant that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

62. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

63. Janssen, acting in concert g with other opioid manufacturers, also promoted the concept of pseudoaddiction by its involvement and contracting with Dr. Russell Portenoy, a leading KOL for opioid manufacturers. He popularized the concept and falsely claimed that

[18] FDA announces safety labeling changes and post-market study requirements for extended-release and long-acting opioid analgesics, FDA (Sep. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.
[19] 2016 CDC Guideline at 2.
[20] Id. at 21.

pseudoaddiction is substantiated by scientific evidence. Dr. Portenoy later admitted that the concept of pseudoaddiction in chronic pain was not supported by the evidence and stated, "[t]he term has taken on a bit of life of its own. That's a mistake."[21]

B. Janssen Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use

1. Mischaracterizing the Benefits of and Evidence for Long-Term Use

64. To convince prescribers and patients that opioids should be used to treat chronic pain, Janssen had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[22] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[23] The FDA, too, has recognized the lack of evidence to support 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."[24] As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

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[21] Green MS, Chambers RA, Pseudoaddiction: Fact or Fiction? An investigation of the Medical Literature, Curr Addic Rep. 2015;2(4):310-317. Doi:10.1007/s40429-015-0074 (October 1, 2015), https://www.ncbi.

[22] CDC Guideline at 10.

[23] Id. at 9.

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

65. On information and belief, Janssen 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, Janssen failed to disclose the lack of evidence for long-term opioid therapy in the treatment of chronic pain to West Virginia prescribers.

66. Upon information and belief, Janssen exercised influence over two prominent professional and medical membership organizations regarding their positions on opioids. Both organizations 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 the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for an opioid manufacturer and later became its senior executive. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on the American Academy of Pain Medicine's ("AAPM") website until 2011 and was removed from AAPM's website only after a doctor complained.

67. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for opioid manufacturers, stated that he would place the organization "at the forefront" of teaching that "*the risks of addiction* are there, but they are *small and can be managed*." (Emphasis added.)

68. AAPM and the American Pain Society ("APS") issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Janssen and the other opioid manufacturers 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. Nine of the twenty-one panel members who drafted the

AAPM/APS Guidelines received support from Janssen, and many of the other panel members received support from other opioid manufacturers.

69. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, 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 inappropriately by drug companies, including Janssen.[25]

70. 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.

71. The use of third-party, unbranded marketing not only created the false impression that materials requested, reviewed, edited, and distributed by Janssen came from objective and disinterested sources, it allowed Janssen to minimize regulatory scrutiny, as such materials typically are not reviewed by the FDA.

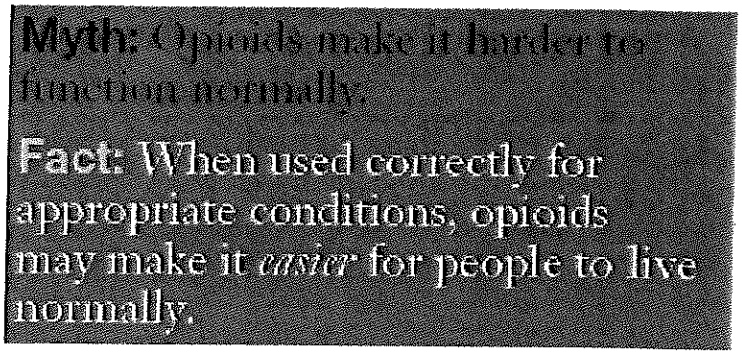
2. Overstating Opioids' Positive Effect on Patients' Function and Quality of Life

72. Janssen also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Upon information and belief, Janssen sales representatives

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

promoted the ability of opioids to improve patients' function and quality of life during visits in West Virginia.

73. Janssen's materials that were distributed or made available in West Virginia, reinforced this message. Janssen's patient education guide, *Finding Relief: Pain Management for Older Adults* (2009), states as a "fact" that "opioids may make it easier for people to live normally."



The guide goes on to list expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

74. Janssen's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids 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.

75. As 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."[26]

76. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[27] The CDC Guideline, following a "systematic review of the best available evidence," 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."[28] According to the director of 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]."[29] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[30]

3. Omitting or Mischaracterizing Adverse Effects of Opioids

77. In materials Janssen produced, sponsored, or controlled, Janssen omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that

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[26] Andrea Rubinstein, Are We Making Pain Patients Worse?, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[27] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[28] CDC Guildeline for Prescribing Opioids for Chronic Pain – United States, at 2, 18 (March 18, 2016).

[29] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief – The CDC Opioid-Prescribing Guidline" at 1503 (April 2, 2016).

[30] *Id.*

prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

78. In addition to failing to disclose the risks of addiction, abuse, overdose, and death in promotional materials, Janssen routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[31] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

79. Janssen and other opioid manufacturers frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs, and deceptively described the risks from NSAIDs while failing to disclose the risks from opioids. For example, *Finding Relief: Pain Management for Older Adults*, a Janssen-sponsored patient education guide, stated that NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, while opioids could cause temporary "upset stomach or sleepiness" and constipation.

80. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients who were administered opioids orally dropped out of the trials because of the intolerable effects of opioids.[32]

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[31] U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Staff Report, Fueling an Epidemic, Report Two, at 4.

[32] Meredith Noble M, *et al.*, Long- Term Opioid Management for Chronic Noncancer Pain (Review), Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

81. Again, Janssen's misrepresentations were effective. 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 24.5%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

C. Janssen Continued to Tell Doctors that Opioids Could be Taken in Ever-Higher Doses Without Disclosing their Greater Risks

82. Janssen 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. Janssen needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

83. The Janssen sponsored patient education guide, *Finding Relief: Pain Management for Older Adults* (2009), was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is no longer available online.

84. 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 approximately nine times more likely to suffer overdose from opioid- related causes than those on low doses.[33] 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

[33] Dunn KM, Saunders KW, Rutter CM, et al. Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study. *Ann Intern Med.* 2010; 152(2):85-92. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000551/pdf/ukmss-32216.pdf.

escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.[34]

85. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic 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."[35] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[36]

86. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.[37]

D. Janssen Deceptively Capitalized on Tramadol as an Unscheduled Drug Despite Knowing its Potential for Addiction, Abuse, and Diversion

87. In March 1995, the US FDA approved tramadol as a non-controlled, centrally acting opioid analgesic under the trade name Ultram.[38] Subsequently, the FDA approved generic, combination, and extended release (ER) formulations, which included Ultracet.[39]

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[34] *See* Hayhurst, Christina J., M.D., Durieux, Marcel E. M.D., PH.D., Differential Opioid Tolerance and Opioid-induced Hyperalgesia: A Clinical Reality, Anesthesiology 2, 2016, Vol. 124, 483-488. Available at https://anesthesiology.pubs.asahq.org/article.aspx?articleid=2474170.

[35] CDC Guideline at 9 and 22. The 2016 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."

[36] CDC Guideline at 16.

[37] *See* Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA. 2011; 305(13):1315-21(ISSN: 1538-3598), Bohnert,AS; Valenstein,M; Bair,MJ; Ganoczy,D; McCarthy,JF; Ilgen,MA. https://bit.ly/2KqGY32.

[38] Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV, 78 Fed. Reg. 65923, 65924 (proposed Nov. 4, 2013).

[39] 78 Fed. Reg. 65923, 65924; Ultram NDA approved Mar. 3, 1995; Ultracet NDA approved Aug. 15, 2001; Ultram

88. In August of 1994, prior to the original New Drug Application, ("NDA") approval, the FDA held a Drug Abuse Advisory Committee ("DAAC") meeting to review the abuse potential and consider the appropriateness of a scheduling action for tramadol.[40] The DAAC concluded that Ultram could be marketed as an analgesic drug without scheduling under the Controlled Substances Act ("CSA") based upon "extensive pre-clinical, clinical and European epidemiological data."[41] Additionally, it found that "[t]he [1994] approval was contingent on the creation of an independent steering committee (ISC) to proactively monitor abuse/dependence."[42]

89. The ISC was appointed in September 1994; it consisted of eight individuals "with a broad array of experience in the substance abuse field."[43] Janssen publicly disclosed that it provided the funding for the ISC, but would not provide any specifics about the funding.[44] According to Janssen, "[t]he program consisted of systematic collection and scientific evaluation of reports of suspected abuse in high-risk populations surveyed through an extensive key informant network of drug abuse specialists and all spontaneous reports of abuse received through the FDA medwatch system."[45] Janssen stated that "[i]n the event that high rates of abuse were found, [the] ISC was given the authority to immediately recommend to the FDA that Ultram be scheduled."[46] However, despite reports of abuse and diversion, the ISC never recommended control scheduling of Ultram.

90. Janssen's goal was to make sure that Ultram remained unscheduled, and it focused on that fact in its marketing of the drug, despite Janssen's knowledge of its abuse. Janssen trained its sales representatives to emphasize to doctors that Ultram was not a scheduled drug. But, despite

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[40] JAN-MS-01229809 at 4.
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*

Janssen's pursuit of this marketing niche, problems with Ultram and Ultracet that Janssen was or should have been aware of - including its abuse and diversion potential - would prevent it from remaining unscheduled.

91. In 2005, the DEA received four petitions requesting that tramadol be controlled as a scheduled substance under the CSA.[47] A Citizen's Petition from an addiction services center in November of 2005 requested that the Commissioner of the FDA re-evaluate tramadol and designate the drug as a schedule III narcotic.[48] As grounds for the request, the petition stated, among other things, that the center's clinician had first-hand knowledge of cases of tramadol abuse, that there was evidence that tramadol had a "more severe abuse liability than what was previously described," and that the ISC "funded by [Janssen]" misled the public about its abuse liability. The petition also pointed out that there were cases of documented diversion and "illicit distribution" of tramadol, and, according to the National Survey on Drug Use and Health from 2002, "approximately one million persons have consumed Ultram for non-medical use." In addition, the petition noted that tramadol was creating a great risk to public health.

92. On September 16, 2010, the United States Department of Health and Human Services ("HHS") sent the DEA a written scientific and medical evaluation and scheduling recommendation entitled "Basis for the Recommendation to Schedule Tramadol in Schedule IV of the Controlled Substances Act,"("Recommendation") which described several reasons as to why tramadol should be a scheduled drug.[49] The Recommendation stated that according to DAWN[50] data, in 2007 there were 8,039 emergency department visits related to the non-medical

[47] 78 Fed. Reg. 65923, 65924.
[48] Pine Grove Citizens Petition.
[49] JAN-MS-02964142
[50] DAWN is the Drug Abuse Warning Network, which collects data from hospitals regarding substance abuse related hospital emergency department visits.

use of tramadol. In 2008, this number increased to 11,850 visits.[51] HHS also noted that between 2000 and 2008, law enforcement agencies across the country seized over one thousand drugs during criminal investigations, including tramadol, which demonstrated that it was likely being diverted.[52] Additionally, HHS found that between 1997 and 2002, DAWN reported 395 deaths that involved the use of Ultram.[53] HHS concluded that tramadol should be classified as a Schedule IV drug. In November 2014, the DEA officially classified tramadol as a Schedule IV drug.[54]

93. Janssen did not publicly object to this classification because it knew of Ultram's abuse and diversion potential and, as such, had no data to support Ultram remaining unscheduled. Thus, despite having evidence of abuse and diversion of tramadol, Ultram, and Ultracet, and lacking evidence that these drugs were less likely to be abused than other, scheduled opioids, Janssen nonetheless marketed its tramadol products as preferable to or to be tried before other opioids, clearly, and deceptively, implying that Ultram and Ultracet were safer alternatives.

E. Defendants Violated Laws Requiring Them to Monitor and Report Diversion of Opioids

94. West Virginia's Uniform Controlled Substances Act ("WVUCSA") and the legislative rules promulgated pursuant to the Act, 15 C.S.R. 2, require Janssen 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. § 15-2-5.1.1.

95. Janssen's 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

[51] JAN-MS-02964142
[52] Id.
[53] Id.
[54] 78 Fed. Reg. 65923.

information concerning prescription fills in the form of "chargeback" data.

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

97. Janssen's obligations to provide effective controls and procedures to guard against diversion would necessarily include procedures to report diversion or suspicious orders suggesting diversion. However, Defendants' failed to comply with these obligations. Janssen's suspicious order monitoring system ("SOM") uses an algorithm and definition that has been unchanged since 2005.[55] The system flags orders exceeding 300% of the customer's 12 month per-week or order average, and thus omits from consideration customers without a prior order history or real-time frequencies or patterns. It could not detect, therefore, (i) multiple customer orders during a given month; (ii) orders which consisted of gradual quantity increases of a controlled substance over time; or (iii) a new customer's orders for controlled substances which initially commence with larger than normal quantities and remain at a constant. Moreover, its rigid and high 300% threshold was insufficient to identify suspicious orders.

98. Despite the many deficiencies in its SOM program, Janssen did not conduct an internal or external review of its SOM program until around December 2017. At that time, both its internal workshop and its outside consultant's report acknowledged the existence of these deficiencies and recommended significant modifications to its SOM program.

99. The review confirmed that Janssen not only failed to implement a sufficient SOM system, it failed to report the orders that were actually flagged by its system. Specifically, in January 2018, Janssen's outside consultant concluded: "It appears that the JOM SOM has not

[55] JAN-MS-03741170-176; JAN-MS-03741177-200; JAN-MS-03741201-205; JAN-MS-03124101-110.

reported an order for controlled substances as suspicious during its time in operation."[56]

100. In addition, upon information and belief, Janssen targeted prescribers in West Virginia and elsewhere whom it had reason to know were engaged in diversion, contributing to the oversupply of non-medical opioids in the State and nationally.

101. Janssen therefore failed to comply with their obligations to maintain a system to prevent diversion and identify suspicious orders, and to report the suspicious orders they could identify, both of which contributed to the illegal secondary opioid market in West Virginia and nationwide.

F. Janssen Fueled and Profited from a Public Health Epidemic That Has Significantly Harmed West Virginia and Devastated Thousands of Its Citizens

102. Upon information and belief, the vast market for opioids was created and sustained in part by Janssen's deceptive marketing in establishing opioids as a first-line treatment for chronic pain. Janssen's deceptive marketing caused patients to believe they would not become addicted, addicted patients to seek out more drugs, and health care providers to make and refill opioid prescriptions that maintain dependence and addiction.

103. Janssen's marketing, and especially its detailing[57] to doctors, has been effective. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[58] The changes

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[56] JAN-MS-05444748-763 at 761.

[57] *See* https://searchhealthit.techtarget.com/definition/detailing. "Detailing" is a one-on-one marketing approach used by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often. *See* https://searchhealthit.techtarget.com/definition/detailing.

[58] *See* Larkin I, Ang D, Steinhart J, et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, *JAMA*. 2017;317(17):1785–1795. doi:10.1001/jama.2017.4039

in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies. Janssen necessarily expected a return on its multi-million dollar investment in opioid marketing, and carefully calibrated its promotion efforts to serve that end.

104. Upon information and belief, Janssen marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive.

105. Unlike other direct- t o - consumer marketing, Janssen relied on unbranded advertising, knowing that the creation of a new, expansive market for opioids would benefit it. Janssen also targeted particularly vulnerable, but usually well-insured, groups of patients, such as the elderly.

106. Defendants also failed to provide effective controls to guard against diversion and failed to identify and report suspicious orders of which they were aware, further fueling West Virginia's opioid crisis.

107. Overall sales of prescription opioids in West Virginia skyrocketed. In 2006, the opioid prescribing rate in West Virginia was 129.9 for every 100 people. In 2011, it increased to 139.6 prescriptions for every 100 people. In Boone County in 2006, the prescribing rate was 176.56 per 100 people and rose to 205.1 per 100 people by 2011.[59]

[59] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

108. In 2017, West Virginia ranked highest in deaths due to drug overdose at 57.8 per 100,000 people. Between 2016 and 2017, the incidence rate of overdose increased in West Virginia by 11.2 percent.[60]

109. In 2017, 70,237 drug overdose deaths occurred in the United States. Opioids are currently the main driver of drug overdose deaths. Opioids were involved in 47,600 overdose deaths in 2017 (67.8% of all drug overdose deaths).[61]

110. The Substance Abuse and Mental Health Services Administration ("SAMHSA") has stated that the number of individuals enrolled in substance use treatment in West Virginia has varied between 10,711 in 2011, 9,596 in 2012, 10,057 in 2013 and 10,099 in 2015.[62]

111. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that aggressive marketing by pharmaceutical companies is likely to have contributed to the severity of the current prescription drug abuse problem.[63]

112. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing.[64] He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[65]

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[60] https://www.cdc.gov/drugoverdose/data/statedeaths.html
[61] Id.
[62] Behavioral Health Barometer West Virginia, Vol. 4, Substance Abuse and Mental Health Services Admin. 13, (hereinafter Behavioral Health Barometer West Virginia).
[63] *See* https://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.
[64] Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.
[65] Id.

113. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[66] In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

114. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with extended-release opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (Emphasis added).

115. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Janssen's deceptive marketing scheme is a cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout West Virginia.

116. Addiction has consumed the lives of countless West Virginians exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription

[66] Theodore J. Cicero, et al., Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription—even pulling their own teeth.

117. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin when they can no longer get access to or afford the pills. It was foreseeable that users who become addicted to a particular prescription opioid, such as Nucynta and Nucynta ER, would migrate to another drug (including heroin) if those drugs become less expensive or more readily available. In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street.

118. Nationally, roughly 80% of heroin users previously used prescription opioids. From 2010 to 2017, heroin related overdose deaths increased by more than five (5) times. Social service agencies report being overwhelmed by the number of overdose and addiction cases in West Virginia. In the city of Huntington (population 49,000), for instance, authorities responded to 26 heroin overdose cases in one four-hour span last year.[67]

119. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

120. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2017 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 43% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men not in the labor force

[67] *See* https://www.washingtonpost.com/news/wonk/wp/2016/08/17/the-latest-overdose-outbreak-shows-just-how-dangerous-the-heroin-epidemic-has-gotten/?noredirect=on.

said they took prescription painkillers—compared to just 20% of employed men. Many of those taking painkillers still said they experienced pain daily.[68]

121. The abuse of opioids, including Nucynta and Nucynta ER, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP.

122. In 2015, statistics from the Centers for Disease Control and Prevention, as well as the West Virginia Department of Health, showed that the Appalachian state has the highest rates of HBV and HCV cases in the United States. In 2012, West Virginia's hepatitis C rate was reported at 3.1 cases per 100,000 people, compared with 0.7 cases per 100,000 nationally. Reports show about two-thirds of people with hepatitis in West Virginia identify themselves as drug users.[69]

123. Children have not been spared by the opioid crisis. Between 2006 and 2016, children entering the West Virginia foster care system due to parental addiction rose 124%. About 70% of referrals to Child Protective Services in 2017 had a substance abuse component according to the statistics from the Centralized Intake Unit of the West Virginia Bureau for Children and Families. The state court Child Abuse and Neglect (CAN) database indicates that about 80% of referrals from family court and circuit court judges have a substance abuse factor. As of July 2019, there were 6,940 children placed in foster care.[70]

124. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from Neonatal Abstinence Syndrome ("NAS"). These infants painfully withdraw from

[68] *See* https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf.
[69] *See* https://www.hepmag.com/article/west-virginia-hepatitis-27088-916981843.
[70] *See* https://dhhr.wv.gov/bcf/Reports/Documents/2019%20August%20Legislative%20Foster%20Care%20Placement%20Report.pdf.

the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

125. NAS has become a great source of concern in West Virginia. West Virginia's rate of NAS is five times the national average.[71] In 2017, the overall incidence rate of NAS was 50.6 cases per 1,000 live births for West Virginia residents. The incidence rate of NAS in 2000 was only 0.5 cases per 1,000.[72]

126. While the use of opioids has taken an enormous toll on the state of West Virginia and its residents, Janssen has realized billions of dollars in revenue from use of its opioids for chronic pain as a result of its deceptive, unfair, and unlawful conduct.

G. Janssen Deceptively Concealed its Misconduct

127. Janssen made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Janssen 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

[71] *See* Proposed Opioid Response Plan for the State of West Virginia, Jan. 10, 2018, p. 20, https://bit.ly/2Oyu48a..
[72] *See* https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm#T1_down.

death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these misrepresentations.

128. Notwithstanding this knowledge, at all times relevant to this Complaint, Janssen took steps to avoid detection of and to conceal its deceptive marketing and unlawful conduct. Janssen disguised its role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of its false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Upon information and belief, Janssen masked or did not disclose its role in shaping, editing, and approving the content of this information.

129. Defendants' 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.

130. Defendants thus successfully concealed from the medical community, patients, and the State of West Virginia facts sufficient to arouse suspicion of the claims that West Virginia now asserts.

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

131. 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. Many tens of thousands of West Virginians are currently addicted to opioids.

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

133. The opioid crisis has also impacted some of West Virginia's most vulnerable demographics, such as the elderly. The AARP reports that elderly Americans have faced a 500% increase in hospitalization rates related to opioids over the last twenty years. In 2015, "physicians prescribed opioid painkillers to almost one-third of all Medicare patients, or nearly 12 million people. In the same year, 2.7 million Americans over age 50 took painkillers in amounts—or for reasons—beyond what their physicians prescribed." Hospitalization rates due to opioid abuse has quintupled for those 65 and older in the past two decades.[73]

134. 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 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.

135. 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

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

medical treatment, rehabilitation costs, hospital stays, emergency room visits, emergency personnel costs, law enforcement costs, substance abuse prevention costs, costs for displaced children, naloxone costs, medical examiner expenses, self-funded state insurance costs, and lost tax revenues, among others.

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

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

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

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

139. 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.

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

141. 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.

142. 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.

143. 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.

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

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

COUNT II
Common Law Public Nuisance

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

147. 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.

148. 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.

149. 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.

150. 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, helped to create an overabundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

151. 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.

152. 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.

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

154. 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.

155. 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.

156. The Defendants intended health care providers to prescribe opioids for long-term use, including those produced and sold by the Defendants, 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.

157. 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.

158. 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.

159. 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.

160. 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. Janssen's conduct interfered in the enjoyment of these public rights.

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

Prayer for Relief

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

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

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

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

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

e. Pre- and post-judgment interest;

f. Costs and reasonable attorneys' fees; and,

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

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

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

STATE OF WEST VIRGINIA ex rel.
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