THE STATE OF NEW HAMPSHIRE

MERRIMACK, SS SUPERIOR COURT

Docket No. 217-2018-CV-00678

STATE OF NEW HAMPSHIRE

V.

JOHNSON & JOHNSON;

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

JANSSEN PHARMACEUTICALS, INC; and

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICA, INC. n/k/a/ JANSSEN PHARMACUETICALS, INC.

11225 Trenton-Harbourton Road
Titusville, NJ 08560

COMPLAINT

NOW COMES the State of New Hampshire ("State"), by and through the Office of the Attorney General, and complains as follows against the above-captioned Defendants.

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I. PRELIMINARY STATEMENT

1. Until relatively recently, 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.[1]

2. For companies like Janssen and other opioid makers, 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.

3. To make that happen, Janssen 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.

4. Janssen specifically marketed to doctors and patients in New Hampshire 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 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.

5. 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

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

using the drugs. That makes it very difficult 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 made the use of opioids for chronic pain so lethal.

6. Across the country, 91 people die from an opioid-related overdose every day and over 1,000 patients are treated in emergency departments for misusing them. Far more are swept into a cycle of addiction and abuse with which they will struggle their entire lives. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 194,000 people died in the U.S. from overdoses related to prescription opioids— more than the number of Americans who died in the Vietnam War.

7. The outcomes in New Hampshire are equally catastrophic— and getting worse. In 2016, the Deputy Administrator of the DEA called New Hampshire "ground zero" of the opioid epidemic. There were 438 fatal overdoses in the state in 2015, more than double the number in 2012.[2] *Per capita*, New Hampshire is second in the nation in overdose deaths.[3] Rates of substance abuse treatment admissions are up sharply, and based on interviews with addiction treatment providers, demand for help far exceeds their resources. [4]

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[2] See New Hampshire Drug Monitoring Initiative: 2016 Overview Report, Jan. 25, 2017, available at: https://www.dhhs.nh.gov/dcbcs/bdas/documents/dmi-2016-overview.pdf

[3] Benjamin Rachlin, "A Small-Town Police Officer's War on Drugs," *New York Times*, July 12, 2017, *available at*: https://www.nytimes.com/2017/07/12/magazine/a-small-town-police-officers-war-on-drugs.html

[4] Interviews with Peter Kelilher, Mark L, Joshua Nu, and Carol Goodwyn.

8. According to a study conducted by the Dartmouth-Hitchcock Medical Center, in New Hampshire, there were 72 opioid prescriptions for every 100 residents.[5] From October 2014 to September 2015, between 12 and 15.3 million doses of narcotic pain relievers were dispensed in the state each quarter.[6] Janssen's conduct has violated, and continues to violate, the Consumer Protection Act's prohibitions on deceptive acts and practices and unfair competition, RSA 358-A:2, as well as common-law prohibitions against unjust enrichment and creation of a public nuisance.

9. The State seeks an order requiring Janssen to cease its unlawful promotion of opioids, to correct its misrepresentations, and to abate the public nuisance its deceptive marketing has created. The State furthers seek a judgment requiring Janssen to pay civil penalties, restitution, disgorgement, and fees or costs permitted under law.

II. PARTIES

10. Jane E. Young is the Deputy Attorney General. The State of New Hampshire brings this action through the Attorney General's Office Consumer Protection and Antitrust Bureau. Under the Consumer Protection Act, NH RSA 358-A, the Attorney General may bring an action in the name of the State for injunctive relief, restitution, and penalties where, as here, he "has reason to believe that trade or commerce declared unlawful by this chapter has been, is being or is about to be conducted" by any person, including partnerships and corporations. RSA 358-A:4, III; RSA 358-A:1, I.

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[5] Sunpreet Singh, "DHCM study finds overprescription of opioids," *The Dartmouth*, September 23, 2016, available at http://www.thedartmouth.com/article/2016/09/dhmc-study-finds-overprescription-of-opioids

[6] See *New Hampshire Prescription Drug Monitoring Program Annual Report, October 1, 2015 – September 30, 2016, available at*: https://www.oplc.nh.gov/pharmacy/documents/pdmp-annual-report-2016.pdf

11. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents and its municipalities. Opioid use and abuse has affected a substantial segment of the population of New Hampshire.

12. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. 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. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

13. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates

must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

14. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[7]

15. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and New Hampshire, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen also developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

16. Janssen's opioids consist of both long and short-acting opioids (sometimes referred to as extended release or ER opioids and immediate release or IR opioids). Long-acting or extended release opioids like Nucynta ER are, in theory, supposed to provide continuous opioid therapy for 12 hours. In contrast, short-acting opioid formulations last between 4-6 hours. Extended release opioids typically carry higher concentrations of the active pharmaceutical ingredient (the opioid).

III. JURISDICTION AND VENUE

17. The Court has subject matter jurisdiction over this action under RSA 491:7 and RSA 358-A:4.

18. The Court has personal jurisdiction over Defendants because they regularly transact

[7] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, n. 23 ("Payments from Janssen include payments from Johnson & Johnson, Health Care Systems, Inc.")

business in New Hampshire, and the claims asserted herein arise from their business conducted in New Hampshire.

19. Venue in this Court is proper because Defendants are all non-residents. RSA 507:9; RSA 358-A:4, III(a).

20. The Complaint herein sets forth exclusively state law claims against the Defendants. New Hampshire does not plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law. New Hampshire expressly asserts that the only causes of action asserted and the only remedies sought herein are founded upon the statutory, regulatory, common, and decisional laws of New Hampshire.

21. The claims asserted herein by New Hampshire consist of claims on behalf of the State, and the State does not assert any cause of action herein on behalf of any individual or any purported class of individuals.

IV. FACTUAL ALLEGATIONS

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

22. 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.

23. Janssen relied heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, Janssen's sales representatives visited prescribers in New Hampshire. [redacted]

[redacted] This number likely understates the amount of "detailing" by Janssen sales representatives, as it reflects only visits in which a payment was provided and is limited by gaps in the information provided by Janssen to the Attorney General's Office. These visits continued through at least 2016.

24. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report, which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[8] The Report quotes findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty." On 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.

25. To ensure that sales representatives deliver the desired messages to prescribers, Janssen directed and monitored 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 that were reviewed, approved, and supplied by the companies. It ensured marketing consistency nationwide through national and regional sales representative training. Thus, the company's sales force in the State carried out national marketing strategies, delivering centrally scripted messages and materials that

[8] Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.

were consistent across the country.

26. 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. These KOLs received substantial funding and research grants from Janssen and other opioid manufacturers, who often sponsored the CMEs — giving them considerable influence over the messenger, the message, and the distribution of the program. 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." [redacted]

27. 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. For example, from 2012 to 2017, Janssen contributed $465,152 to various third-party groups, including $88,500 to the American Pain Society, and $83,975 to the American Academy of Pain Medicine. [9] 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.

[9] Staff Report, Fueling an Epidemic, Report 2, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups.

In many instances, Janssen distributed these publications to prescribers or posted them on their websites.

28. 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.

29. In addition to their marketing to doctors, Janssen also promoted opioids 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. Unlike other direct-to-consumer marketing, Janssen relied on unbranded advertising, knowing that the creation of a new, expansive market for opioids would benefit it.

30. [redacted]

31. Upon information and belief, all of the messages described below were disseminated to New Hampshire prescribers and patients.

1. Minimizing or Mischaracterizing the Risk of Addiction

32. To convince prescribers and patients that opioids are safe, Janssen directly, through its control 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.

33. [redacted] Janssen sales representatives also told one New Hampshire doctor that Nucynta had a lower risk of addiction than other opioids.

34. Upon information and belief, Janssen had no scientific evidence to support these representations that its opioids were less likely to be abused or were safer or less abusable than other opioids. In fact, this claim is directly contradicted by the labels of Duragesic and Janssen, which include warnings that the drugs may be subject to abuse. For example, according to Duragesic's drug label, effective 1990, the opioid, "contains fentanyl, a drug with high potential for abuse." Likewise, the 2011 drug label for Nucynta ER states that the drug "contains tapentadol, a . . . Schedule II controlled substance with an abuse lability similar to other opioid analgesics." [redacted]

[redacted]

35. 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,[10] Janssen encouraged doctors in New Hampshire 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.

36. 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. 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."

37. In addition, Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), as seen below, which

[10] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in New Hampshire in the same manner as elsewhere.

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.

38. 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.

39. 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."[11]

[11] 2016 CDC Guideline at 2.

40. The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 450 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.

41. Janssen currently runs a website, Prescriberesponsibly.com, which, until recently, claimed that concerns about opioid addiction are "overestimated."

42. [redacted]

43. Janssen employees also misled New Hampshire prescribers about the risk of withdrawing from Nucynta. For example, one New Hampshire prescriber was told that Nucynta had fewer withdrawal symptoms than other opioids. [redacted] This comparative claim was not supported by scientific evidence, and gave the misimpression that it would be easier for patients to terminate use of Nucynta, reducing the risk

that they would become addicted to the drug.

44. Janssen's efforts to deny or 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."[12] 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).[13] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[14]

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

45. 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.

46. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009

[12] FDA announces safety labeling changes and postmarket 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.

[13] CDC Guideline at 2.

[14] *Id.* at 21.

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.

47. Janssen, along 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 pseudoaddiction is substantiated by scientific evidence.

48. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[15] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[16]

3. Overstating the Efficacy of Screening Tools

49. Janssen falsely indicated to prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, Janssen advised doctors that they could identify patients likely to become addicted and safely

[15] CDC Guideline at 13.

[16] *Id.* at 25.

prescribe to everyone else.

50. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting long-term opioid therapy for chronic pain. These misrepresentations were especially insidious when Janssen aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. [redacted] Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

51. On information and belief, Janssen conveyed these safe prescribing messages through their in-person sales calls to doctors. Upon information and belief, Janssen discussed screening tools and patient selection with New Hampshire doctors as strategies for keeping patients safe and managing the risk of addiction, abuse, and diversion, and also described screening tools to New Hampshire doctors as useful in helping to identify the "right" patients—meaning patients who can be identified as low risk for addiction. Janssen did not disclose the lack of evidence for the efficacy of these tools.

52. Janssen also promoted screening tools as a means to manage addiction risk in CME programs and scientific conferences, which would have been attended by and were available online to New Hampshire prescribers. Janssen sponsors the website prescriberesponsibly.com, which directly provides screening tools to prescribers for risk assessments. The website includes a "[f]our

question screener" to purportedly help physicians identify possible opioid misuse.[17] The website also states that Janssen is "solely responsible for [the website' s] content."[18] The website is still available to both New Hampshire prescribers and patients.

53. The CDC Guideline confirmed the falsity of Janssen's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[19]

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

54. 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."[20] 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

[17] http://www.prescriberesponsibly.com/risk-assessment-resources (last visited March 2, 2018).

[18] *Id*.

[19] CDC Guideline at 28 (emphasis added).

[20] *Id*. at 10.

≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[21] 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."[22] 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.

55. 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 New Hampshire prescribers.

56. In addition, two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Janssen. Upon information and belief, Janssen exercised considerable influence over their work 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.

[21] *Id.* at 9.

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

57. 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.)

58. 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[23] and many of the other panel members received support from other opioid manufacturers.

59. 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 by contributions that drug companies, including Janssen, made to the sponsoring organizations and committee members.[24]

60. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel

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[23] *See* AAPM/APS, Opioid Treatment Guidelines, *The Journal of Pain*, Vol 10, No 2 (February), 2009, available at https://www.jpain.org/article/S1526-5900(08)00831-6/pdf.

[24] "Painkiller Boom Fueled by Networking," John Fauber, *Milwaukee Wisconsin Journal Sentinel*, February 18, 2012, available at http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

61. 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.

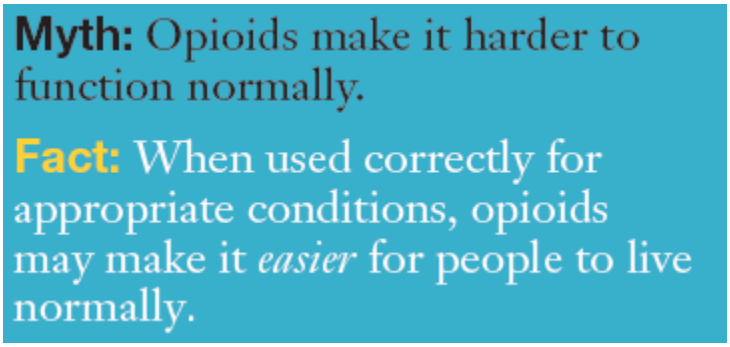
62. The use of third-party, unbranded marketing not only created the false impression that materials requested, reviewed, edited, and distributed by Janssen came from objective and disinterested sources, it allowed Janssen to avoid regulatory scrutiny, as such materials typically are not reviewed by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

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

63. 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 during visits in New Hampshire promoted the ability of opioids to improve patients' function and quality of life.

64. Janssen's materials, distributed or made available in New Hampshire, 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.'"

65. [redacted]

66. [redacted]

[redacted]

67. 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.

68. 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."[25] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[26] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.[27] According to these

[25] 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?

[26] *Id.*

[27] Jeffrey A. White, et al., The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

69. 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.[28] 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."[29] 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]."[30] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[31]

3. Omitting or Mischaracterizing Adverse Effects of Opioids

70. In materials Janssen produced, sponsored, or controlled, Janssen omitted known

[28] 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.

[29] CDC Guideline for Prescribing Opioids for Chronic Pain-United States, at 2, 18 (March 18, 2016).

[30] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

[31] *Id.*

risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that 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.

71. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Janssen routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[32] 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).

72. 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.

73. 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 in opioid trials dropped out before the study began because of the "intolerable

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

effects" of opioids.[33]

74. 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%.[34] 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

75. 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.

76. [redacted]

77. 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

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

[34] John N. Mafi et al., Worsening Trends in the Management and Treatment of Back Pain, 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

dosages. Until recently, this guide was still available online.

78. 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. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

79. 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]

80. Janssen was aware of the greater dangers high dose opioids posed. 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

[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.

is directly related to maximum daily dose. [37]

D. Janssen Utilized its Sales Representatives to Detail Doctors because it Knew that these Visits were Effective

81. Janssen's marketing of opioids, along with marketing by other manufacturers, persuaded doctors that opioids were the compassionate—and required—treatment for chronic pain, and that opioids could be taken long-term, and even at high doses, without the risk of addiction, and would allow patients to live fuller lives and function better. The marketing push and messages in which Janssen played a significant role, resulted in recalibration of the risks and benefits of opioids that permitted the widespread use of opioids, with the harms that followed.

82. Janssen's marketing, and especially its detailing 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.[38] The changes 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.[39] An additional study found that doctor meetings with sales

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[37] Bohert, AS, *et al*., *Association Between Opioid Prescribing Patterns and Opioid-related Deaths,* April 6, 2011, available at https://www.ncbi.nlm.nih.gov/pubmed/21467284.\

[38] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

[39] Berdent ER, et al. *Information, marketing and pricing in the US antiulcer drug market,* Amer Econ Rev 1995, 85:101-105.

representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[40] Janssen necessarily expected a return on its multi-million dollar investment in opioid marketing, and carefully calibrated its promotion efforts to serve that end.

E. Janssen Failed to Monitor and Report Suspicious Prescribing of Opioids

81. Janssen has a duty under New Hampshire law to prevent diversion of its opioids and to detect, report, and reject suspicious orders of opioids. These duties apply to ever entity registered to manufacture and ship controlled substances, including Janssen.

82. Pursuant to the New Hampshire Controlled Drug Act ("NHCDA"), willful or repeated violations of any state or federal law, rule or regulation demonstrates conduct sufficient to support disciplinary proceedings against manufacturers of controlled substances. *See* RSA 318:29(II)(g). Federal law requires manufacturers of controlled substances, such as Janssen, to monitor and report suspicious conduct. *See* 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b). In fact, the DEA in 2006 and 2007 sent letters to manufacturers and wholesalers of opioids, including Janssen, reminding them of their legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances," to inform the DEA "of suspicious orders when discovered," and to "maintain effective controls against diversion" of controlled substances. Registrants' "responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."

83. Janssen failed to report suspicious prescribing despite vising offices that were

[40] Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000,283:373-80.

engaged in overprescribing of opioids, and whose health care professionals subsequently lost their licenses to prescribe controlled substances, including opioids, due to overprescribing. For example, Christopher Clough, a Somersworth physician assistant, [redacted]

In 2015, PA Clough was permanently restricted from prescribing controlled substances for several reasons, which included starting patients on high doses of opioids, rapidly titrating the doses to dangerous levels, and failing to assess whether the patients had a sufficient medical need to increase these doses.

84. Janssen sales representatives also visited a New Hampshire doctor who was disciplined by the State Board of Medicine due to his prescribing of opioids. Specifically, Dr. Michael Dipre of Laconia, [redacted] even while his license to prescribe controlled substances had been suspended. Dr. Dipre's ability to prescribe controlled substances was suspended in August 2008 due to inappropriate prescribing and failure to deal with patient's drug-seeking behaviors, and then again in 2012 for overprescribing opioids. The Medical Board found that Dr. Dipre's prescribing practices imposed an imminent danger to life and/or health. [redacted]

85. Janssen did not report either of these prescribers to the Board of Medicine or, upon information and belief, to other law enforcement.

86. Also upon information and belief, based on interviews with former Janssen sales representatives, Janssen did not train its sales representatives to identify signs of suspicious

prescribing or to report to the company or to law enforcement potential diversion of opioids. Janssen also purchased sales data from vendors, such as IMS, which allowed it to track prescribing – and overprescribing—of opioids. Upon information and belief, based on Janssen's marketing strategies in other states, Janssen targeted these high volume prescribers, who were their biggest source of sales, for more frequent sales visits, and would not and did not report these prescribers to federal or state law enforcement, regulatory, or disciplinary authorities.

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

87. Upon information and belief, the vast market for opioids was created and sustained in significant part by Janssen's deceptive marketing in overstating the benefits and understating the risks of opioids, establishing opioids as a safe 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.

88. The Attorney General's Office identified numerous physicians who wrote prescriptions for Janssen's opioids after receiving misrepresentatives from its sales representatives, as documented in their call notes. For example, after visits from Janssen sales representatives who made deceptive statements, as described above:

a. Dr. M. wrote $8,458.20 in prescriptions for Duragesic;

b. Dr. O wrote $5,004.22 in prescriptions for Duragesic;

c. Dr. D. wrote $10,029.96 in prescriptions for Duragesic;

d. Dr. S. wrote $7,706.47 in prescriptions for Duragesic;

e. Dr. F. wrote $5,172.23 in prescriptions for Duragesic; and

f. Dr. H. wrote $207.16 for Nucynta.

These are illustrative examples of the prescriptions written by doctors visited by Janssen sales

representatives covered by Medicaid or private insurers.

89. Further, by failing to report potential diversion or the suspicious prescribing of opioids, Janssen also prevented law enforcement, regulatory, and disciplinary authorities from taking action to prevent the over- and improper use and abuse of opioids in New Hampshire.

90. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.[41] Opioids are now the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.[42]

91. 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."[43]

92. 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.[44] 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

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[41] Marie N. Stagnitti, Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006, Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009), http://meps.ahrq.gov/mepsweb/data_files/publications/st235/stat235.pdf.

[42] *See* CDC Guidelines.

[43] Dr. Volkow, Nora, "America's Addition to Opioids: Heroin and Prescription Drug Abuse," U.S. Department of Health and Human Services, May 14, 2014, available at https://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

[44]CDC, *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.

for legitimate pain."[45]

93. 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."[46] 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."

94. 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.)

95. Most opioid addiction begins with legitimately prescribed opioids. An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had

[45] *Id.*

[46] 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).

been receiving prescriptions from health care providers for chronic pain.[47] Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% to 2% of opioid volume.[48]

96. The sharp increase in opioid use resulting from the marketing of opioids, including Nucynta and Duragesic, has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Hampshire.

97. Young adults (ages 18-25), in particular, are using prescription painkillers non-medically at higher rates in New Hampshire than the rest of the nation.[49]

98. Addiction has consumed the lives of countless New Hampshire residents exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription 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.

99. More than 40% of all opioid overdoses involve a prescription opioid.[50] Drug poisonings now exceed motor vehicle accidents as a cause of death.[51] According to the CDC,

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[47] Simoene, Ronald, "Doctor Shopping Behavior and the Diversion of Prescription Opioids," April 11, 2017, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5398712/.

[48] *Id.*

[49] NH Opioid Fact Sheet, *available at* : https://nhshp.wildapricot.org/resources/Documents/Opioid%20Crisis%20FACTSheet_FINAL.pdf

[50] Centers for Disease Control and Prevention, Prescription Opioid Related Deaths, August 1, 2017, available at https://www.cdc.gov/drugoverdose/data/overdose.html.

[51] Associated Press, "The New American Death: Overdoses and Accidents," *NBC News*, June 10,

between 1999 and 2014, more than 165,000 people died in the United States from prescription-related overdoses. In New Hampshire, drug overdose deaths have spiked from 163 to 438 in 2015, and 91% of those deaths were opioid-related.[52]

100. Overdose deaths represent only the tip of the iceberg. In New Hampshire, opioid- and heroin-related emergency department visits were 2,067 in 2015 and increased 26% in 2016.[53] There was a similar spike in emergency medical technicians' administration of naloxone—the emergency antidote to opioid overdose—with use rising from 1,050 in 2013 to 1,921 in 2015 and to 2,724 in 2015.[54] In 2014, health care costs related to opioid abuse in New Hampshire exceeded $107 million.[55]

101. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men not in the labor force said they took prescription painkillers—compared to just 20% of employed men. Many of those

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2016, available at https://www.nbcnews.com/health/health-news/new-american-death-overdoses-accidents-n589786.

[52] *See* New Hampshire Drug Monitoring Initiative 2016 Overview Report, January 25, 2017, *available at*: https://www.dhhs.nh.gov/dcbcs/bdas/documents/dmi-2016-overview.pdf, and NH Opioid Fact Sheet, *available at* : https://nhshp.wildapricot.org/resources/Documents/Opioid%20Crisis%20FACTSheet_FINAL.pdf.

[53] The Opiate/Opioid Public Health Crisis: Update on the State of New Hampshire's Comprehensive Response, available at: https://www.dhhs.nh.gov/dcbcs/bdas/documents/state-response-opioid-crisis.pdf.

[54] *See* New Hampshire Drug Monitoring Initiative 2016 Overview Report, January 25, 2017, *available at*: https://www.dhhs.nh.gov/dcbcs/bdas/documents/dmi-2016-overview.pdf,

[55] Matrix Global Advisors, Health Care Costs from Opioid Abuse, A State-by-State Analysis (April 2015).

taking painkillers still said they experienced pain daily.[56]

102. The deceptive marketing and overprescribing of opioids also have had a significant detrimental impact on children in New Hampshire. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. In New Hampshire, roughly 1 in 5 teenagers has abused prescription drugs. Five children younger than 10 and 176 teenagers between the ages of 10 and 19 had opioid-related emergency room visits in New Hampshire in 2016.[57]

103. 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 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.

104. In New Hampshire, the number of infants born with NAS rose from just 21 in 2002

[56] Krueger, Alan, "Where have all the workers gone? An inquiry into the decline of the U.S. labor force participation rate," September 7, 2011,The Brookings Institute, available at https://www.brookings.edu/bpea-articles/where-have-all-the-workers-gone-an-inquiry-into-the-decline-of-the-u-s-labor-force-participation-rate/.

[57] Partnership for a Drug Free New Hampshire, "Prescription Drugs: Get the Facts!," available at http://www.drugfreenh.org/families/how-to-keep-kids-safe/prescription-drugs-get-the-facts.

to 182 in 2009.[58] Total births with drug exposure reached 504 in 2015, an increase of 37% from the previous year. In 2015, Memorial Hospital in North Conway reported that the percentage of pregnant women presenting with opioid dependence had skyrocketed, prompting the hospital to institute a coordinated treatment program to reduce NAS and treat the mothers' addiction.[59] A similar program is in place at Dartmouth-Hitchcock Medical Center. Two Manchester hospitals reported that, between them, there were more than 100 babies born with NAS in 2016.[60]

105. The number of children removed from homes with substance abuse problems went from 85 in 2010 to 329 in 2015—a 387% increase.[61] "The opioid crisis is the biggest contributor when looking at what's changed," said one official. There are not only more children requiring assistance, but more children with complex needs who will not have a stable home to which to return. The City of Manchester referred more than 2,500 people to a student assistance program in 2016.[62]

106. Opioids now outpace other sources of addiction in demand for substance abuse treatment. In New Hampshire, the percentage of individuals entering state-funded substance abuse treatment for opioids has sharply risen, while admissions for alcohol, cocaine, marijuana, and

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[58] *See* New Hampshire Drug Monitoring Initiative: 2016 Overview Report, Jan. 25, 2017, available at: https://www.dhhs.nh.gov/dcbcs/bdas/documents/dmi-2016-overview.pdf

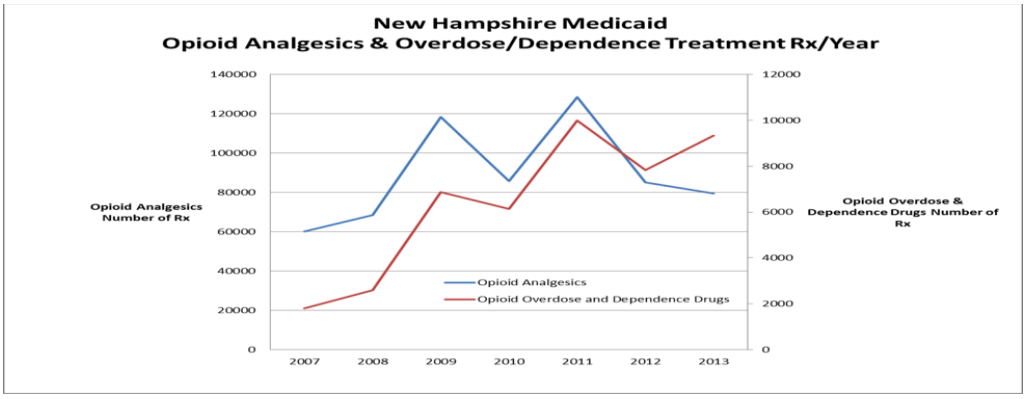
[59] http://www.memorialhospitalnh.org/news-events/news/post/memorial-hospital-announces-plans-for-a-comprehensive-treatment-program-for-opioid-dependent-prenatal-patients

[60] 2016 City of Manchester: Response to the Opioid Crisis, *available at*: https://drive.google.com/file/d/0Bw1u4tuUje88U3k2dHpaUkREZVk/view.

[61] Robidoux, Carol, "Foster Care in Crisis: more kids in need due to opioid epidemic, not enough foster families to go around," Manchester Link, May 15, 2017, available at https://manchesterinklink.com/foster-care-crisis-kids-need-due-opioid-epidemic-not-enough-foster-families-go-around/.

[62] 2016 City of Manchester: Response to the Opioid Crisis, *available at*: https://drive.google.com/file/d/0Bw1u4tuUje88U3k2dHpaUkREZVk/view

heroin have either decreased or remained stable.[63] This data echoes the experience of treatment specialists interviewed by the State, who say that prescription opioid abuse is driving increased demand for addiction treatment. From 2007-2013, the last years for which data are available, state Medicaid spending on drugs to counter overdose or addiction increased six-fold. These drugs were prescribed once per 36 opioid prescriptions in 2007 and once every 9 prescriptions in 2013.[64]



107. Janssen's creation through false and misleading advertising of a virtually limitless opioid market has imposed significant burdens on the community at large. Janssen's success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury.

108. Contrary to Janssen's misrepresentations, most of the illicit use stems from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[65]

[63] NH Collective Action Issue Brief #2 – Prescription Pain Medication Misuse.

[64] *Id.*

[65] U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

109. Addiction treatment centers and specialists interviewed by the State likewise indicate that many of their patients—for one Nashua facility, up to 95%—started on legal opioid prescriptions. These observations comport with national studies indicating that opioids are the first drug of abuse by as many as 80% of heroin addicts.[66] These patients are a diverse group, from professionals to the unemployed.

110. Those patients whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[67] One New Hampshire addiction treatment specialist, for example, said her patients were not warned of the risks. She suggested that, to properly prepare patients, "this should be on the bottle – 'could cause homelessness, incarceration, addiction.'"

111. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. According to addiction treatment centers interviewed by the State, while many patients became addicted to prescription opioids, most had crossed over to heroin before they sought treatment. Manchester police seized more than 27,000 grams of heroin in 2015, up from 1,314 in 2014.[68]

112. A recent, even more sinister problem stemming from the prescription opioid

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[66] NPR Staff, With Rise of Painkiller Abuse, A Closer Look At Heroin, NPR (Nov. 2, 2013), available at www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[67] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/ doctors-missing-questions-that-could-prevent-opioid-addiction.

[68] Benjamin Rachlin, "A Small-Town Police Officer's War on Drugs," *New York Times*, July 12, 2017, *available at*: https://www.nytimes.com/2017/07/12/magazine/a-small-town-police-officers-war-on-drugs.html

epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into New Hampshire communities through a booming trafficking network. Patients who traveled from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. According to the DEA, agents previously saw heroin mixed with a little fentanyl; "[n]ow we're seeing fentanyl mixed with a little bit of heroin."[69] Fentanyl-related overdoses now far exceed those involving heroin alone. In 2015 the state medical examiner reported that there were 261 fentanyl-related fatalities[70]. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. And fentanyl abuse is often a game of Russian roulette, with users not knowing what mixture of fentanyl and heroin they are taking.

113. Many patients who abuse or become addicted to opioids will lose their jobs, and some will lose their homes and their families. Some will get treatment, and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falls, traffic accidents, or assaults or from premature heart or neurological disease that hastens their death by 10 or 20 years.

114. Although recovering addicts often are unwilling to discuss their histories, several shared their stories with the State. One, a Nashua lumberyard worker, injured his knee at age 21.

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[69] Shawne K. Wickham, *Fentanyl Killing More People in NH Than Heroin*, N.H. Union Leader (Jan. 30, 2016), http://www.unionleader.com/apps/pbcs.dll/article?AID=/20160131/NEWS12/160139925/-1/mobile&template=mobileart.

[70] Zalkind, Susan, "Heroin Dealers Could Face Murder Charges amid Crisis in New Hampshire," *The Guardian*, February 9, 2016, available at https://www.theguardian.com/us-news/2016/feb/09/new-hampshire-heroin-fentanyl-drug-dealers-murder-charges.

A physician prescribed him the opioid Percocet. Despite a past that included recreational drug use, his doctor did not warn him about the risk of addiction. For years he was on and off various prescription opioids as he repeatedly reinjured his knee. He knew he was addicted when he started getting sick without the drugs. He ultimately turned to the streets for his pills, buying—and stealing, fentanyl, and other opioids. As pills became harder to find, he turned to heroin.[71] At rock bottom, he was homeless, jobless, down to 100 pounds, and could not look himself in the mirror. After more than ten years on opioids, he eventually got clean through a Suboxone program. He wishes he knew more about what he was getting into with the first doctor, including the side effects, withdrawal, and risk of addiction. Having battled addiction to other drugs, he recalled that opioids had the heaviest toll.

115. Another recovered addict, now a treatment counselor in Nashua, injured his back as a teenager playing hockey. At the hospital, he was given morphine and Percocet to take home. He said he thought Percocet was safe because the doctor prescribed it. After successive prescriptions ran out, he started stealing opioid tablets from his grandfather, and later turned to buying them—and heroin—on the street. Despite dreams of playing college hockey, he took drugs instead of studying and never finished his degree. He lost jobs and relationships, overdosed several times, and spent time in detox, ultimately staying clean after time in an in-patient program arranged by his parents. He wishes that at the age of 16 he knew what addiction really meant and the actual potential to become addicted.

116. While the use of opioids has taken an enormous toll on New Hampshire and its residents, Janssen has realized billions of dollars in revenue from use of its opioids for chronic

[71] 94% of patients in treatment for opioid addiction said they chose to use heroin because prescription opioids were more expensive and harder to obtain.

pain as a result of its deceptive, unfair, and unlawful conduct. According to New Hampshire Medicaid data, from 2007 to 2015, 22.45% of all Medicaid brand-name opioid prescriptions dispensed were for Janssen's opioids. Additionally, during this time period, 33.82% of Medicaid spending on brand-name opioids were spent on opioids manufactured by Janssen.

G. Janssen Fraudulently Concealed its Misconduct

117. 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 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.

118. Notwithstanding this knowledge, at all times relevant to this Complaint, Janssen took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent 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. Janssen masked or did not disclose its role in shaping, editing, and approving the content of this information. Upon information and belief, Janssen also failed to identify and report potential

diversion of opioids to government officials, concealing the extent of opioid overprescribing and abuse in the state.

119. Janssen thus successfully concealed from the medical community, patients, and the State of New Hampshire facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Janssen's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

V. CAUSES OF ACTION

COUNT I

CONSUMER FRAUD—DECEPTIVE AND UNFAIR ACTS AND PRACTICES

Violations of the Consumer Protection Act, RSA 358-A

120. The State realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

121. The Consumer Protection Act makes it unlawful for a business to engage in "any unfair or deceptive act or practice in the conduct of any trade or commerce within this state." RSA 358-A:2.

122. Janssen's conduct as described in the Complaint was intended and likely did deceive prescribers, consumers, and payors and occurred in the course of Janssen's marketing activities in New Hampshire in violation of RSA 358-A:2.

123. At all times relevant to this Complaint, Janssen, directly, through its control of third parties, and/or by aiding and abetting third parties, violated the RSA 358-A:2 by making or causing to be made, and by disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions, to New Hampshire prescribers and consumers to promote the sale and use of opioids to treat chronic pain. These unfair, false, deceptive, and misleading statements included, but were not limited to:

a. Mischaracterizing the risk of opioid addiction and abuse;

b. Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

c. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

d. Mischaracterizing the difficulty of discontinuing opioid therapy, including by mischaracterizing the prevalence and severity of withdrawal symptoms;

e. Claiming or implying that increased doses of opioids pose no significant additional risk;

f. Misleadingly depicting the safety profile of opioids prescribed by minimizing their risks and adverse effects while emphasizing or exaggerating the risks of competing products, including NSAIDs; and

g. Claiming or implying that opioids would improve patients' function and quality of life.

124. Janssen knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were unfair, false, deceptive, and misleading and therefore likely to deceive the public. In addition, Janssen knew or should have known that its marketing and promotional efforts created an unfair, false, deceptive, and misleading impression of the risks, benefits, and superiority of opioids generally and its opioids in particular.

125. Janssen failed to disclose or misrepresented clinically significant risks of Nucynta, Nucynta ER, and Duragesic, and opioid therapy to New Hampshire consumers and their doctors. At all times relevant to this Complaint, Janssen directly, as well as through its control of third parties, and/or by aiding and abetting third parties, violated RSA 358-A:2 by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they are unconscionable, offend public policy, and are immoral, unethical, oppressive, or unscrupulous.

126. Janssen unfair acts or practices include, but are not limited to:

a. Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

b. Engaging in untrue, false, unsubstantiated, and misleading marketing;

c. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing; and

d. Deliberately using the funding and/or control of third parties to avoid regulatory scrutiny of its marketing and to mislead consumers into believing that claims being made by KOLs and front groups were those of objective, independent professionals untainted by financial interest in the success of Janssen's drugs or the use of opioids to treat chronic pain.

127. These acts or practices were unfair in that they immorally and unethically deprived prescribers of the information they needed to appropriately prescribe—or not prescribe—these dangerous drugs. Patients who use opioids can quickly become dependent or addicted, such that neither the patient nor the prescriber could avoid injury by simply stopping or choosing an alternate treatment. Janssen also immorally and unethically withheld information from authorities that they could have used to reduce opioid abuse and diversion in New Hampshire.

128. These acts or practices were unfair in that they have resulted in a substantial injury to New Hampshire consumers that is not outweighed by any countervailing benefits to consumers or competition. Janssen's marketing has caused New Hampshire consumers to suffer opioid addiction, abuse, overdose, death, and associated economic loss, and there is no countervailing benefit of such unsubstantiated and unbalanced marketing.

129. Janssen's conduct as described in the Complaint violated RSA 358-A:2 because Janssen, by minimizing and misstating the risks of opioids and overstating their benefits, has represented that its opioids have characteristics and benefits they do not have in the course of Janssen's marketing activities within New Hampshire. In particular, Janssen engaged in untrue,

false, unsubstantiated and misleading marketing, deliberately used funding and/or control of third parties and KOLs to avoid regulatory scrutiny of its marketing to mislead consumers, and targeted a vulnerable population—the elderly—for the promotion of opioids to treat chronic pain despite the known, heightened risks of opioid use to that population.

130. In addition, by representing that its opioids are less addictive or harder to abuse, Janssen has caused a likelihood of confusion or misunderstanding as to the approval of its opioids, which are not approved as less addictive than other opioids or abuse-deterrent. Further, by misrepresenting its opioids as safer and less likely to be abused or less addictive and by overstating the risks of competing treatments, like NSAIDs, Janssen disparaged the goods, services, or business of another by false or misleading representation of fact.

131. Janssen's conduct, as described in this Complaint, meets and exceeds a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce.

132. By reason of Janssen's conduct, New Hampshire consumers have suffered substantial injury as described above.

133. As a direct result of the foregoing deceptive and unfair acts and practices, Janssen obtained income, profits and other benefits that it would not otherwise have obtained.

134. Pursuant to RSA 358-A:4, III, the State requests an order permanently enjoining Janssen from engaging in these deceptive and unfair acts and practices.

135. Pursuant to RSA 358-A:4, III(a), the State requests an order directing restitution of money to consumers, the State, and other payors spent on Janssen opioids as a result of these deceptive and unfair acts and practices.

136. Pursuant to RSA 358-A:4, III(b), the State requests an order assessing a civil

penalty of $10,000 against Janssen for each violation of the Consumer Protection Act.

137. Pursuant to RSA 358-A:6, IV, the State requests and order awarding to the State all legal costs and expenses.

COUNT II

CONSUMER FRAUD—UNFAIR COMPETITION

Violations of the Consumer Protection Act, RSA 358-A

138. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

139. The Consumer Protection Act makes it unlawful for a business to engage in "any unfair method of competition . . . in the conduct of any trade or commerce within this state." RSA 358-A:2. The Act specifies that one such unfair method of competition is "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have." Specifically, Janssen violated RSA 358-A:2 by claiming that its opioids were safer and less likely to be abused than other opioids and alternative treatments like NSAIDs.

140. Janssen's conduct as described in the Complaint violated RSA 358-A:2 because Janssen, by minimizing and misstating the risks of opioids and overstating their benefits, has represented, that its opioids have characteristics and benefits they do not have in the course of Janssen's marketing activities within New Hampshire. In particular, Janssen has stated or implied that:

a. Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

b. Engaging in untrue, false, unsubstantiated, and misleading marketing; and

c. Deliberately using the funding and/or control of third parties to avoid regulatory scrutiny of its marketing and to mislead consumers into believing that claims being made by KOLs and front groups were those of objective, independent professionals untainted by financial interest in the success of Janssen's drugs or the use opioids to treat chronic pain.

141. At the time it made or disseminated these statements, Janssen knew or recklessly disregarded that there was no scientific evidence to support the statements or that available science contradicted the statements.

142. By reason of Janssen's conduct, New Hampshire consumers have suffered substantial injury, including but not limited to pain and suffering from inappropriate dosing, opioid addiction, injury, overdose, death, and economic loss.

143. By reason of Janssen's conduct, New Hampshire's cities, towns, and counties have suffered substantial injury, including but not limited to costs associated with administering first responder services and support care for the families of individuals suffering drug overdoses.

144. As a direct result of the foregoing deceptive acts and practices, Janssen obtained income, profits, and other benefits that it would not otherwise have obtained.

145. Pursuant to RSA 358-A:4, III(a), the State requests an order permanently enjoining Janssen from engaging in unfair methods of competition as described herein.

146. Pursuant to RSA 358-A:4, III(a), the State requests an order directing restitution of money Janssen acquired by virtue of the unfair methods of competition described herein.

147. Pursuant to RSA 358-A:4, III(b), the State requests an order assessing a civil penalty of $10,000 against Janssen for each violation of the Consumer Protection Act.

148. Pursuant to RSA 358-A:6, IV, the State requests and order awarding to the State all legal costs and expenses.

COUNT III

FALSE CLAIMS

Violations of the Medicaid Fraud and False Claims Act, RSA 167:61-b

149. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

150. RSA 167:61-b is violated when any person:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the [New Hampshire] department [of Health and Human Services], a false or fraudulent claim for payment or approval.
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
> (c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid. . . .
>
> N.H. Rev. Stat. Ann. § 167:61-b(I).

151. RSA 167:61-b(V)(a) defines a claim as:

> any request or demand, whether under a contract or otherwise, for money or property that is made to an officer, employee, agent, or other representative of the department or to a contractor, grantee, or other person, if the department provides any portion of the money or property that is requested or demanded, or if the department will reimburse the contractor, grantee, or other recipient for any portion of the money or property that is requested or demanded.

152. Defendants' practices, as described in the Complaint, violated RSA 167:61-b. Defendants, through their deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement to get a false or fraudulent claim for payment approved by the State.

153. Defendants knew that the doctors, pharmacists, other health care providers, and/or agents of the State Medicaid program to whom they deceptively marketed prescription opioids had treated and would continue to treat New Hampshire Medicaid patients.

154. Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting

the State's Medicaid program to pay for opioids for long-term treatment of chronic pain. In addition, Defendants knew, deliberately ignored, or recklessly disregarded, that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

155. Defendants knew their false statements were material to healthcare providers' decision to prescribe opioids to New Hampshire Medicaid patients. Indeed, Defendants intended such statement to be material to encourage additional opioid prescriptions.

156. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the State's Medicaid program for payment. The State only covers the cost of prescription drugs that are medically necessary. Specifically, New Hampshire's rules governing the Medicaid program define "medically necessary" services as:

> health care services that a licensed health care provider, exercising prudent clinical judgment, would provide, in accordance with generally accepted standards of medical practice, to a recipient for the purpose of evaluating, diagnosing, preventing, or treating an acute or chronic illness, injury, disease, or its symptoms, and that are:
>
> > (1) Clinically appropriate in terms of type, frequency of use, extent, site, and duration, and consistent with the established diagnosis or treatment of the recipient's illness, injury, disease, or its symptoms;
> >
> > (2) Not primarily for the convenience of the recipient or the recipient's family, caregiver, or health care provider;
> >
> > (3) No more costly than other items or services which would produce equivalent diagnostic, therapeutic, or treatment results as related to the recipient's illness, injury, disease, or its symptoms; and
> >
> > (4) Not experimental, investigative, cosmetic, or duplicative in nature.

PART He-W 530.01(e). In addition, under He-W 570.09, practitioners or pharmacists must certify specific brand drugs as "brand necessary" or "brand medically necessary." Doctors, pharmacists,

other health care provides, and/or agents of the State Medicaid program expressly or impliedly certified to the State that opioids were medically necessary to treat chronic pain because they were influenced by the false and misleading statements disseminated by Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians or other health care providers and/or authorized by the State Medicaid program and submitted to the State were for uses that were misbranded and/or not otherwise approved by the FDA.

157. Defendants knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of their actions, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud.

158. Defendants' misrepresentations and omissions were material because if the State had known of the false statements disseminated by Defendants and their third-party allies that doctors, pharmacists, and other health care providers or agents of the State Medicaid program, health plan, and workers' compensation program were relying on to certify and/or determine that opioids were medically necessary, the State could have undertaken efforts to avoid its payment of false claims and to rein in the harm from the inappropriate prescribing of opioids.

159. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the State.

160. By virtue of the above-described acts, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts, to induce the State to approve and pay such false and fraudulent claims.

161. But for Defendants' false statements, the false claims at issue would not have been submitted for payment and would not have been paid by the State's Medicaid program.

162. To the extent that such prescribing is considered consistent with generally accepted standards of medical practice, clinically appropriate and/or consistent with established treatment, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

163. The State, unaware of the falsity of the records, statements and claims made, used, or presented or caused to be made, used or presented by Defendants, paid claims that would not be paid but for Defendants' illegal business practices.

164. By reason of Defendants' unlawful acts, the State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. The State's damages from false claims submitted, or caused to be submitted, by each Defendant exceed $5,000 in value. From 2011-2015, the State's Medicaid program spent $3.5 million to pay for some 7,886 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

165. Because Defendants' unbranded marketing caused doctors to prescribe and the State to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims as well.

166. Pursuant to RSA 167:61-b(I), the State requests an order compelling Defendants to pay three times the amount of damages sustained by the State for each violation of RSA 167:61-b.

167. Pursuant to RSA 167:61-b(I), the State requests an order assessing a civil penalty of not less than $5,000 and not more than $10,000 against Defendants for each violation of RSA 167:61-b.

168. Pursuant to RSA 167:61-b(II)(b), the State requests an order compelling Defendants to pay the State's costs and attorneys' fees arising from this action

COUNT IV

PUBLIC NUISANCE

169. Janssen, through the actions described in the Complaint, has created—or was a substantial factor in creating— a public nuisance by unreasonably interfering with a right common to the general public that harms the health, safety, peace, comfort, or convenience of the general community.

170. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Janssen's illegal and deceptive marketing of opioids for the treatment of chronic pain.

171. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Hampshire families and communities; (d) lost employee productivity; (e) the creation and maintenance of a secondary, criminal market for opioids; (g) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (h) increased health care costs for individuals, families, and the State.

172. At all times relevant to the Complaint, Janssen's deceptive marketing substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Janssen engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting its opioids duration of efficacy and by failing to disclose the lack of

evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

173. At all times relevant to the Complaint, Janssen exercised control over the instrumentalities constituting the nuisance—*i.e.*, its marketing as conveyed through sales representatives, other speakers, and publications. As alleged herein, Janssen created, or was a substantial factor in creating, the nuisance through multiple vehicles, including (a) making in-person sales calls; (b) recruiting physician speakers; (c) disseminating advertisements and publications; (d) sponsoring and creating flawed and biased scientific research and prescribing guidelines; and (e) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids. To the extent Janssen worked through third parties, it adopted their statements as its own by disseminating their publications, and/or exercised control over them by financing, reviewing, editing, and approving their materials.

174. Janssen's actions were, at the very least, a substantial factor creating the public nuisance by deceiving prescribers and patients about the risks and benefits of opioids and distorting the medical standard of care for treating chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in New Hampshire would have been averted or would be much less severe.

175. The public nuisance was foreseeable to Janssen, which knew or should have known of the harm it would cause. As alleged herein, Janssen engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Janssen knew that there was no evidence showing a long-term benefit of opioids on pain and function, and

that opioids carried serious risks of addiction, injury overdose, and death. A reasonable person in Janssen's position would foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Janssen's conduct—that was Janssen's goal—but also that widespread problems of opioid addiction and abuse would result. In fact, Janssen was on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

176. This public nuisance can be abated through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

177. The State therefore requests an order providing for abatement of the nuisance that Janssen created or was a substantial factor in creating, and enjoining Janssen from further conduct contributing to the nuisance.

COUNT V

UNJUST ENRICHMENT

178. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

179. Janssen has unjustly retained a benefit to the State detriment, and the Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

180. As alleged herein, the State has reimbursed opioid prescriptions covered by its employee health and workers' compensation plans. By deceptively and illegally promoting opioids to treat chronic pain, Janssen has caused health care providers to write, and the State to reimburse, prescriptions for opioids that otherwise would not have been written and reimbursed.

181. Further, as alleged herein, Janssen made fraudulent misrepresentations, directly and indirectly, to prescribers, patients, and the State of New Hampshire, which resulted in the State paying for Janssen's opioids, and for the consequences of those opioids in abuse, addiction, and

overdose. Thus, the State's spending on opioids is the result of Janssen's fraudulent marketing of its drugs.

182. Janssen has reaped revenues and profits from the State's payments, enriching itself at the State's expense, even as the State continues to cope with a crisis of opioid addiction, overdose, injury, and death that Janssen helped create. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

183. Accordingly, under principles of equity, Defendants should be disgorged of money retained by reason of their deceptive and illegal acts that in equity and good conscience belong to the State and its citizens.

COUNT VI

FRAUDULENT OR NEGLIGENT MISREPRESENTATION

184. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

185. As alleged in the Complaint, Janssen engaged in false representation and concealment of material facts about the use of opioids to treat chronic pain.

186. Janssen knew, deliberately ignored, or recklessly disregarded , that:

a. its statements about the use of opioids to treat chronic pain were false or misleading;

b. statements about opioids that it caused to be made or disseminated were false or misleading;

c. its statements made to promote the use of opioids to treat chronic pain omitted or concealed material facts; and

d. it failed to correct prior misrepresentations and omissions about the risks and benefits of opioids.

187. The statements Janssen made, or caused to be made about the use of opioids to treat chronic pain, were not supported by or were contrary to the scientific evidence, as confirmed by

the CDC and FDA based on that evidence.

188. Further, Janssen's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading.

189. Janssen's intended that healthcare providers and patients would rely on its misrepresentations and deceptive marketing regarding the use of opioids to treat chronic pain, the characteristics of Janssen's branded opioids, and Janssen's efforts to cooperate with law enforcement and assist in avoiding addiction, abuse, and overdose.

190. Janssen had a duty to the State and its citizens to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs.

191. Janssen had a duty to the State and its citizens not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain.

192. Janssen had a duty, as one who volunteered information to others not having equal knowledge, with the intention that they would act upon it, to exercise reasonable care to verify the truth of their statements before making them.

193. Janssen had a duty to report suspicious prescribers and to prevent diversion of its drugs

194. Janssen so negligently, carelessly, and recklessly advertised, marketed, promoted, and sold its opioid drugs and the use of opioids to treat chronic pain, and so negligently, carelessly, and recklessly misrepresented the risks and benefits of using opioids to treat chronic pain that they breached their duties and directly and proximately caused New Hampshire consumers to suffer opioid addiction, abuse, overdose, death and associated economic damage, resulting in the damages alleged in this Complaint.

195. Janssen knew, or should have known, that prescribers and patients would rely on

its misrepresentations and deceptive statements, and would be misled by its material omissions. Further, Janssen knew, or should have known, that its failure to report suspicious prescribing has resulted in continued illicit and over-prescribing and –supply of opioids.

196. Janssen knew, or should have known, that as an inevitable consequence of the conduct described herein, New Hampshire citizens would suffer opioid addiction, overdose, death, and associated economic loss, and the State would suffer economic loss.

197. In light of the facts alleged herein, Defendants breached their duty to use due care in the advertising, marketing, promotion, and sale of opioids.

198. In addition, Defendants' false representations and concealments were reasonably calculated to deceive the State and health care providers who treated patients whose care was paid for or reimbursed by the State.

199. Prescribers and the State relied to their determinant on Janssen's misrepresentations and concealment of material fact.

200. But for Defendants' misrepresentation and concealment of material facts, the State would not have incurred damages in paying for medically unnecessary prescriptions and in addressing the public health crisis that Defendants' actions have created.

201. As a direct and proximate result of Defendants' acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Complaint.

202. Defendants' conduct, as alleged herein, was wanton, malicious, and/or oppressive.

VI. PRAYER FOR RELIEF

203. WHEREFORE, the State prays for an order:

a. awarding judgment in its favor and against defendants on each cause of

action asserted in the Complaint;

b. permanently enjoining Janssen from engaging in the deceptive acts and practices and unfair methods of competition described in the Complaint;

c. directing disgorgement of money Janssen wrongfully and unjustly acquired by virtue of the conduct described in the Complaint;

d. awarding restitution and damages, including enhanced compensatory damages, as appropriate, for the costs incurred by the State, cities, counties, and consumers in paying for the prescribing of opioids and their direct costs in abuse, addiction, abuse, overdose, injury, and death;

e. assessing civil penalties of $10,000 for each violation of the Consumer Protection Act and up to $10,000 for each violation of the False Claims Act

f. requiring Janssen to abate the public nuisance its conduct has created;

g. requiring Janssen to pay the costs of the suit, including attorneys' fees; and

h. awarding such other, further, and different relief as this Court may deem just.

DATED: October 18, 2018.

THE STATE OF NEW HAMPSHIRE

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