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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO. MER-C-_____

GURBIR S. GREWAL, Attorney General of the State of New Jersey, and PAUL R. RODRÍGUEZ, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; XYZ Corporations 1 through 20,

Defendants.

Civil Action

COMPLAINT FOR VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT, N.J.S.A. 56:8-1 ET SEQ., FALSE CLAIMS ACT, N.J.S.A. 2A:32C-1, ET SEQ., AS WELL AS OTHER CLAIMS

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Plaintiffs Gurbir S. Grewal, Attorney General of New Jersey (the "Attorney General"), and Paul R. Rodríguez, Acting Director of the New Jersey Division of Consumer Affairs (the "Director," and together with the Attorney General, "Plaintiffs"), with offices located at 124 Halsey Street, Newark, New Jersey, by way of Complaint state:

I. PRELIMINARY STATEMENT

1. The State of New Jersey is facing a deadly opioid epidemic that is, both nationally and locally, unprecedented in scope and devastating in intensity. Widespread opioid addiction is killing New Jersey residents, removing middle-aged people from their prime workforce years, and compounding the vulnerability and health complications of the elderly.

2. Janssen Pharmaceuticals, Inc. ("Janssen") and its predecessor companies have directly contributed to the opioid crisis by aggressively and deceptively marketing the prescription opioids Nucynta and Nucynta ER and by disseminating misleading and inaccurate statements -- to both patients and prescribers -- regarding the risks and benefits of Janssen products and of opioids generally.

3. Prescription opioids are highly addictive narcotics derived from, and similar to, opium and heroin. As such, they are regulated by the federal government as controlled substances. In addition to these dangerous addictive properties, use of opioids carries a risk of serious adverse side effects, including potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms -- including severe anxiety, nausea, headaches, tremors, delirium, and pain -- if opioids are delayed or discontinued. Depending on the length of use, these symptoms may persist for months, or even years, after complete cessation of use. Moreover, patients who use opioids continuously grow tolerant to the drugs' analgesic effects, requiring progressively higher doses to obtain the

same levels of pain relief, and increasing the risks of painful withdrawal symptoms, addiction, and overdose.

4. Until relatively recently, doctors prescribed opioids only for short-term acute pain, for cancer pain, or for end-of-life pain. Opioids were understood to be too addictive and debilitating to be used long-term, and -- for less severe chronic pain conditions -- it was generally understood that the risks of using opioids dramatically exceeded the benefits.

5. Janssen and other companies that manufacture opioids have sought methodically to enlarge what was an appropriately narrow opioid patient profile. They did so through aggressive and deceptive promotional campaigns designed to expand prescription opioid use into contexts in which opioid treatment had not been traditionally accepted. Beginning in the 1990s, opioid manufacturers set the groundwork for the large-scale adoption of prescription opioids by convincing prescribers and patients that pain was widely and improperly under-treated. Opioid manufacturers exploited a new emphasis on patient-centered pain management to push the message that healthcare providers should prescribe opioids more frequently to combat the prevalence of under-treated pain. Ultimately, opioid manufactures (and the front groups that they funded) sought to change the overall medical perception of opioids so that opioids would be used not just for acute pain and end-of-life care, but routinely for chronic conditions like moderate back, neck, and arthritis pain.

6. This massive marketing scheme -- in which Janssen participated and on which it capitalized -- was profoundly successful, resulting in a measurable shift in the medical and public consensus regarding the use of opioids. Sales of prescription opioids in the U.S. quadrupled from 1999 to 2010. By 2008, 87% of prescription opioids dispensed in the U.S. were for patients dealing with chronic, non-cancer pain; only 13% of prescription opioids were

dispensed to patients dealing with acute pain or cancer pain -- representing an almost complete reversal of long-standing medical practice.

7. With the release of Nucynta in 2008 and Nucynta ER in 2011, Janssen created and implemented a comprehensive marketing plan designed to capitalize on and perpetuate existing deceptions about prescription opioids, including that the benefits of opioids for long-term use for moderate pain conditions significantly outweighed the risks.

8. Janssen also went further, crafting an added layer of deceptive marketing aimed at convincing patients and prescribers that Nucynta and Nucynta ER were safer, milder, and less addictive than competitor opioids, like OxyContin. As part of this scheme, Janssen deceptively promoted Nucynta and Nucynta ER as drugs that were less dangerous than other opioids. Janssen also routinely portrayed Nucynta and Nucynta ER as "unlike traditional opioids" and as having "non-opioid" properties. This doublespeak -- describing Nucynta and Nucynta ER as opioids that are unlike opioids or as opioids with non-opioid properties, and Janssen's related efforts to promote Nucynta and Nucynta ER as milder or less addictive than other Schedule II opioids -- masked the reality that Nucynta and Nucynta ER are not milder and are not less addictive than other Schedule II opioids. To the contrary, Nucynta and Nucynta ER are addictive narcotics that have a high potential for abuse similar to OxyContin, fentanyl, and other Schedule II opioids.

9. In addition to overstating the benefits and understating the risks of Nucynta and Nucynta ER, Janssen engaged in extensive, unbranded marketing that deceptively promoted opioid use in general, and it engaged in a variety of other unconscionable conduct that violated New Jersey law. For example:

(a) Janssen misled patients and prescribers by overstating the benefits of opioid use, particularly with respect to long-term use for moderate, chronic pain, and

exaggerated the risks associated with use of over-the-counter pain relievers such as acetaminophen and ibuprofen;

(b) In its marketing, Janssen intentionally omitted or trivialized the risks associated with opioid use generally, including the risk of addiction, which can cause death;

(c) Janssen created promotional materials that deceptively described opioid use for chronic pain as "rarely addictive";

(d) Janssen routinely promoted the scientifically discredited concept of "pseudoaddiction" (the false notion that patients who demonstrate signs of opioid addiction were simply undertreated -- rather than addicted -- and, therefore, should be provided higher or more frequent doses of opioids); and

(e) Janssen intentionally targeted the elderly with its promotional activity and deceptive statements, even though opioid use in this population carries a heightened risk of overdose, injury, and death.

10. Janssen made these misrepresentations about the benefits and risks of long-term opioid use despite knowing -- as the Centers for Disease Control and Prevention ("CDC") has recently confirmed -- that "there is no good evidence that opioids improve pain or function with long-term use."[1] The CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain ("2016 CDC Guideline" or "Guideline"), which exhaustively reviewed and re-affirmed existing evidence on opioids, further concluded that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder [i.e., opioid addiction]," and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

11. To spread its deceptive marketing messages and to increase its footprint in the opioid industry, Janssen blanketed its home state of New Jersey with sales representatives who were trained to deliver -- and did deliver -- misleading messages about the benefits and risks of

[1] Deborah Dowell et al., "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016," MMWR Recomm. Rep. 2016; 65 (No. RR-1):1–49 (Mar. 18, 2016) (emphasis added).

Nucynta and Nucynta ER. From 2009 to 2015,[2] Janssen's sales force met with New Jersey prescribers and New Jersey pharmacies to promote Nucynta and Nucynta ER at least [redacted] times. Janssen invested substantially in this marketing plan, pouring more than $[redacted] into it from 2009 until it sold the rights to the Nucynta franchise in 2015.

12. As described below in Section F, the opioid epidemic has been catastrophic in New Jersey. In 2016, the last year for which full data are available, there were 1,409 opioid-related overdose deaths in New Jersey. At a rate of sixteen deaths per 100,000 persons, New Jersey's opioid-related death toll is 20% higher than the national average, and it has increased 321% since 1999. Based on a review of preliminary data, the CDC's National Center for Health Statistics predicts that drug overdose deaths will have increased another 21% in New Jersey from 2016 to 2017.

13. The incidence of neonatal abstinence syndrome -- a withdrawal syndrome suffered by infants who have been exposed to opioids in utero -- has also seen a substantial increase in New Jersey, rising 58% from 1999 to 2013.

14. Healthcare costs associated with opioid overprescribing, addiction, misuse and abuse are crushing. The State estimates that its largest Medicaid vendor has paid in excess of $106 million for opioids since 2009. The State has directly paid another $5.6 million under its Workers' Compensation Program since 2009 and over $178 million under its employee and retiree health plans since 2010. In addition to these costs, studies have indicated that healthcare

[2] In April of 2015, Janssen completed the sale of the U.S. rights to the Nucynta franchise of products to Depomed, Inc. ("Depomed"), for approximately $1.05 billion. In late 2017, Depomed announced that it had reached an agreement with Collegium Pharmaceutical, Inc., which allowed Collegium to commercialize the Nucynta franchise of products in exchange for a royalty to be paid to Depomed. In August of 2018, Depomed announced that it had changed its corporate name to Assertio Therapeutics, Inc.

costs for patients with medical diagnoses associated with opioid abuse were up to eight times higher than patients without such diagnoses, and the State has paid millions of dollars to treat addiction, overdose, and other injuries associated with opioid overprescribing and misuse.

15. New Jersey has undertaken substantial efforts to curb overprescribing and limit its effects, including:

(a) establishing, and then mandating use of, a Prescription Monitoring Program by prescribers and pharmacists to help providers determine what other opioids a patient has been prescribed;

(b) making prescription pads more difficult to counterfeit;

(c) publishing best practices for pharmacists for secure handling and dispensing of prescription drugs to reduce diversion;

(d) providing immunity from arrest and prosecution for a use or possession charge when a person seeks medical assistance for an overdose;

(e) presenting the 2016 CDC Guideline to the State's Medicaid vendors and referring prescribers to the Guideline;

(f) setting a new, five-day limit on initial prescriptions of opioids for acute pain;

(g) providing funding and authority for healthcare providers to prescribe -- and first responders to administer -- overdose antidotes; and

(h) requiring insurers to cover 180 days of addiction treatment.

16. New Jersey's Governor also recently announced a multi-pronged, coordinated strategy aimed at combatting New Jersey's opioid crisis. That strategy includes: (a) providing funding for expanded access to prevention, treatment, and recovery programs; (b) providing supportive housing, job training, and social support for individuals and families recovering from opioid addiction; and (c) supporting infrastructure development efforts -- such as development of electronic health records and data technology -- that will allow for greater connectivity among different types of addiction services providers.

17. Yet, much more remains to be done -- and it will be costly. Remediating the opioid crisis requires tremendous financial resources and investment in infrastructure for treatment programs, education, prevention, and effective overdose response. The Attorney General has brought this lawsuit in part because the burden of those costs should be shared by Janssen, a New Jersey-based company that has actively cultivated the demand for opioids generally, and its opioids specifically, and has profited from the indiscriminate and inappropriate sale of these drugs.

18. Janssen's deceptive conduct, which substantially contributed to and perpetuated the opioid crisis, violated (a) the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"); (b) the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq. ("FCA"); and (c) the common-law prohibition against creation of a public nuisance.

19. To redress Janssen's conduct, Plaintiffs seek an order requiring Janssen to cease all unlawful promotion of opioids, correct its misrepresentations, and abate the public nuisance that its deceptive marketing has been a substantial factor in creating. Plaintiffs further seek a judgment requiring Janssen to pay civil penalties and damages; submit to an accounting and disgorge ill-gotten gains; and reimburse fees and costs as permitted by the statutes alleged to have been violated.

II. PARTIES

A. Plaintiffs.

20. The Attorney General is charged with the responsibility of enforcing both the CFA and the FCA. The Acting Director is charged with the responsibility of administering the CFA on behalf of the Attorney General.

21. Under the CFA, the Attorney General may bring an action for injunctive relief, and the Court may order disgorgement, civil penalties, and fees and costs where the Attorney

General has shown that a person has engaged in a practice declared to be unlawful by the CFA. N.J.S.A. 56:8-8, 8-11, 8-13, and 8-19.

22. Under the FCA, the Attorney General may bring a civil action for treble damages, civil penalties, and costs where, as here, a person has caused false or fraudulent claims to be presented to the State or any agent, contractor, or recipient of State funds, or created false records to have a false claim paid. N.J.S.A. 2A:32C-3 to 8.

23. The Attorney General also has parens patriae standing to protect the health and well-being -- both physical and economic -- of its residents and its municipalities. Opioid use and abuse have affected a substantial segment of the population of New Jersey.

B. Defendants.

24. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560-1504. Janssen has operated under prior business names that include Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. (collectively, "Janssen").

25. Janssen is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

26. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including Duragesic, an opioid drug classified in Schedule II of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq., and the opioids Ultracet and Ultram, which are classified in Schedule IV of the CSA. Until 2015, Janssen also manufactured, developed, marketed, and sold in the United States the opioids that are the subject of this lawsuit -- Nucynta and Nucynta ER -- which are classified in Schedule II of the CSA. In April 2015, Janssen completed the sale of the

U.S. rights to the Nucynta franchise of pharmaceutical products to Depomed, a California corporation, for approximately $1.05 billion.

27. XYZ Corporations 1 through 20 are fictitious corporations meant to represent any additional business entities that have been involved in the conduct that gives rise to the Complaint but are unknown to Plaintiffs. As these Defendants are identified, Plaintiffs shall amend the Complaint to include them.

III. JURISDICTION AND VENUE

28. The Court has personal jurisdiction over Janssen because it has regularly transacted business in New Jersey, purposely directed business activities into New Jersey, maintained employees and business locations in New Jersey, and engaged in unlawful practices in New Jersey against New Jersey consumers.

29. Janssen maintains a principal place of business in Titusville, New Jersey.

30. Janssen has generated revenue through sales of its opioid pain medications in New Jersey. Janssen maintained a sales force in New Jersey. [redacted]

31. As alleged herein, Janssen has deceptively and otherwise unlawfully marketed its opioids in New Jersey, through both conduct within New Jersey and other business activities directed into New Jersey. This conduct includes (a) directly conveying promotional messages to New Jersey healthcare providers through sales representatives; and (b) funding, developing, influencing, adopting, disseminating, or making available publications or presentations regarding opioids -- such as information Janssen maintained on publicly available websites, educational

material aimed at medical professionals, and other promotional publications -- to New Jersey healthcare providers and consumers.

32. Venue in this Court is proper, pursuant to R. 4:3-2, because Plaintiffs' claims arose, in part, in Mercer County, and Janssen conducts business there.

IV. GENERAL ALLEGATIONS COMMON TO ALL COUNTS

A. Overview of the Nucynta Franchise of Drugs.

33. On or around January 22, 2008, Janssen submitted a new drug application to the U.S. Food & Drug Administration ("FDA") seeking approval of its immediate release opioid, Nucynta. The FDA approved Nucynta on or around November 20, 2008, for relief of moderate to severe acute pain in patients eighteen years of age or older. The FDA has subsequently modified Nucynta's approval; it is currently approved for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatment options are inadequate.

34. On or around November 30, 2009, Janssen submitted a new drug application to the FDA seeking approval of the extended release version of Nucynta under the brand name "Nucynta ER." On or around August 25, 2011, the FDA approved Nucynta ER. The FDA initially approved Nucynta ER for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. On or around August 28, 2012, the FDA approved a new indication for Nucynta ER for the treatment of neuropathic pain associated with diabetic peripheral neuropathy ("DPN") in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Nucynta ER is currently approved for the management of: (a) pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate; and (b) neuropathic pain associated with DPN in adults severe enough to require

daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

35. The active molecule in Nucynta and Nucynta ER is tapentadol. The FDA has classified tapentadol as an opioid analgesic, meaning it provides pain-relieving effects by interacting with opioid receptors within the body. The U.S. Drug Enforcement Agency has placed tapentadol in Schedule II of the CSA as a substance that has a high potential for abuse and may lead to severe psychological or physical dependence.

B. Janssen Designed and Carried Out a Marketing Campaign that Overstated the Benefits and Trivialized or Omitted the Risks of its Nucynta Products and of Opioid Use Generally.

36. To create a market for its Nucynta line of products, Janssen devised and implemented a complex, multi-faceted marketing and promotional scheme. Janssen designed that scheme to manipulate patients and prescribers into believing that existing pain treatments were insufficient and that those insufficiencies could be addressed by Nucynta and Nucynta ER, which Janssen misleadingly characterized as having unique, non-opioid properties that allowed those drugs to be milder and less addictive than other Schedule II opioids, while simultaneously being more effective at relieving certain types of pain.

37. As a general matter, opioids relieve pain by attaching to parts of nerve cells in the human body referred to as opioid receptors, of which there are three types: the mu, delta, and kappa receptors. The exact mechanism of action of tapentadol, however, is unknown.

38. Evidence from preclinical studies indicated that tapentadol's efficacy was thought to be due to two separate actions: (a) mu-opioid receptor agonism, meaning that it produces a biochemical response by activating the mu-opioid receptor; and (b) norepinephrine reuptake inhibition, meaning that it impacts neurotransmitters (such as norepinephrine) that communicate between brain cells. The utility of preclinical research is limited. Preclinical studies are

designed only to answer basic safety questions about whether a drug has the potential to cause serious harm. The FDA has explained that preclinical studies are "not a substitute for studies of ways the drug will interact with the human body."[3] Moreover, FDA regulations explicitly restrict advertising that contains claims concerning a drug's mechanism of action that are not scientifically established unless the manufacturer also discloses that the claims are not established and the limitations of the supporting evidence.

39. Even though Nucynta and Nucynta ER's exact mechanism of action is scientifically unknown and the only evidence regarding the mechanism of action was derived from limited, preclinical research, Janssen nevertheless marketed Nucynta and Nucynta ER as having a "dual mechanism of action," i.e., that the drugs acted as both an opioid and a norepinephrine reuptake inhibitor ("NRI"). As described in detail below, Janssen extensively relied on this supposed dual mechanism of action to deceptively portray Nucynta and Nucynta ER as milder opioids that were less addictive than other available Schedule II opioids, such as OxyContin. Janssen also maintained that the dual mechanism of action allowed Nucynta and Nucynta ER to be more effective at treating certain types of pain. In making these representations, Janssen routinely obscured or failed to disclose that Nucynta and Nucynta ER's exact mechanism of action is unknown and that representations regarding the drugs' dual mechanism of action were supported by limited evidence gleaned from preclinical studies.

40. Janssen understood early on that distinguishing Nucynta and Nucynta ER from competitor opioids would be crucial to Janssen's ability to create market share and generate a new profit stream. [redacted]

[3] FDA, "The Drug Development Process, Step 3: Clinical Research," https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.

[redacted] These plans show that, despite that Nucynta and Nucynta ER are addictive Schedule II opioid narcotics, Janssen intentionally developed its marketing strategy around the unsubstantiated and untrue idea that [redacted]

41. To hasten the acceptance of Nucynta and Nucynta ER, Janssen had to devise a way to create an increased demand among patients and prescribers. Janssen's internal business plans and other records reveal that it aggressively sought to create that demand by [redacted]

42. Janssen used a variety of methods to initiate and spread dissatisfaction in the prescription opioids marketplace to create a new and increased demand for its Nucynta products. [redacted]

[redacted]

43. Janssen simultaneously devised a scheme to promote the idea that [redacted]

[redacted]

44. [redacted]

[redacted]

45. Janssen's marketing strategy supported its overarching business strategy, which was [redacted]

[redacted]

46. The conversion of patients from the immediate release version of the drug to the round-the-clock, extended release version was advantageous to Janssen because, [redacted]

47. Thus, even before the ER version of Nucynta had received FDA approval in August of 2011, [redacted]

48. Janssen's internal materials also indicate that the ultimate goal of its marketing plan was [redacted]

49. To distinguish Nucynta and Nucynta ER from competitor drugs and to create a demand among Janssen's target consumer populations, Janssen deployed a broad, multifaceted

marketing campaign aimed at both patients and prescribers. That campaign included dissemination of deceptive information about opioids as a general class of drugs and specific misrepresentations about the attributes and benefits of Nucynta and Nucynta ER.

50. Janssen's campaign utilized both branded and unbranded promotional activities. These included: (a) unbranded promotion through Janssen-sponsored websites, publications, and other channels; (b) unbranded promotion through the sponsorship of research studies, speeches, and other clinical activity designed to advance the idea of an unmet need in the acute and chronic pain treatment market; and (c) branded marketing through paid speakers, direct sales, and printed or electronic promotional material designed to promote Nucynta and Nucynta ER as the treatment of choice for mixed pain.

1. Janssen's Unbranded Websites.

51. Janssen created or sponsored several websites as part of its unbranded marketing campaign. For example, Janssen publishes and has, at all times relevant to the allegations in this Complaint, maintained sole editorial control over the content of the unbranded "Prescribe Responsibly" website, which is currently accessible at www.PrescribeResponsibly.com, and which was last updated in July of 2015. Janssen created Prescribe Responsibly to alleviate prescribers' concerns about risks associated with opioid use, including risks of diversion and misuse. Janssen designed the Prescribe Responsibly website to contain links to tools that purport to assist healthcare professionals in assessing patient pain levels and assessing and managing risks associated with aberrant drug-related behavior -- which Janssen defined as behavior that occurs when a patient "steps outside the boundaries of the agreed upon treatment plan." [redacted]

52. As early as 2011, Janssen had also created and funded the "Let's Talk Pain" website, which was directed at patients rather than prescribers. The website had been located at www.letstalkpain.org, but is now inaccessible. The website was part of the on-line presence of the "Let's Talk Pain Coalition." The Let's Talk Pain Coalition consisted of a collaboration among the American Pain Foundation ("APF"), the Academy of Integrative Pain Management ("AIPM"),[4] the American Society for Pain Management Nursing ("ASPMN"),[5] and Janssen.

53. Janssen funded the efforts of the Let's Talk Pain Coalition. The purpose of the coalition was to encourage patients to identify and discuss dissatisfaction with their acute or chronic pain management with their prescribers. Janssen's internal plans confirm that the [redacted]

54. The Let's Talk Pain Coalition website contained interactive features and other resources targeted at patients and designed to encourage patients to raise concerns about pain management with healthcare professionals. Although the website is no longer publicly

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[4] Prior to 2016, AIPM had operated under the name "American Academy of Pain Management." For the sake of clarity, the organization is referred to herein as AIPM.

[5] AIPM and ASPMN have received substantial funding from opioid manufacturers. According to a recent report from the Ranking Member's Office of the U.S. Senate Homeland Security and Governmental Affairs Committee, AIPM received over $1.2 million from opioid manufactures from 2012 to 2017, including $128,000 from Janssen. Over the same period, ASPMN received over $323,000 from opioid manufactures, including over $55,000 from Janssen. See U.S. Senate Homeland Security & Governmental Affairs Committee, "Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocate Groups" (Feb. 12, 2018), https://www.hsdl.org/?view&did=808171.

accessible, articles that had been published on that website remain accessible through other avenues on the internet.

55. Through the Let's Talk Pain Coalition, Janssen also produced an on-line video series referred to as the "Let's Talk Pain Show" that targeted patients and prescribers and revolved around issues relating to pain management. Videos produced by the Let's Talk Pain Coalition remain available on-line, including through the website www.YouTube.com.

56. The Prescribe Responsibly initiative and the Let's Talk Pain Coalition aimed to cover both sides of the opioid-prescribing relationship by targeting physicians and patients through unbranded marketing that gave the appearance of legitimacy and objectivity, when in fact they were funded by Janssen and involved other entities with a vested interest in increasing the market for long-term opioid use.

2. Janssen's Speakers' Bureau and Peer-to-Peer Programs.

57. Janssen hired, trained, and deployed speakers as part of a speakers' bureau program that Janssen used to promote Nucynta and Nucynta ER. The speakers were primarily practitioners who were paid to present a slide deck written by Janssen that encouraged healthcare providers to prescribe opioids generally and Janssen products specifically. These speakers included New Jersey practitioners.

58. On information and belief, an invitation to join the speakers' bureau was both a reward for writing Nucynta prescriptions -- because speakers were well compensated by Janssen -- and an incentive to continue writing prescriptions. For example, multiple former Janssen representatives identified one West Orange, New Jersey pain specialist as a prominent participant in Janssen's New Jersey speakers' bureau for Nucynta and Nucynta ER. Publicly available data show payments made by Janssen to that physician beginning in 2013. Over the course of that year, that physician wrote approximately [redacted] new prescriptions for Nucynta ER

and [redacted] new prescriptions for Nucynta -- [redacted] total -- and Janssen made nine direct payments to him, totaling over $5,400. Over the course of 2014, the physician increased his prescriptions to approximately [redacted] new prescriptions for Nucynta ER and [redacted] new prescriptions for Nucynta -- [redacted] total -- and Janssen provided the physician with nineteen payments, totaling over $11,000.

59. [redacted]

60. [redacted]

61. [redacted]

62. [redacted] Multiple former Janssen representatives recall attending speaker events in New Jersey promoting Nucynta and Nucynta ER.

3. Janssen's Sales Force.

63. Janssen promoted Nucynta and Nucynta ER through sales representatives (sometimes referred to as "detailers") who called or visited individual New Jersey prescribers. Janssen's sales representatives verbally conveyed messages to prescribers in targeted, one-on-one settings, and showed or distributed to prescribers printed or electronic marketing materials promoting Nucynta and Nucynta ER.

64. Janssen's records indicate that at least [redacted] individual sales representatives have promoted Nucynta or Nucynta ER in New Jersey since 2009. Those representatives detailed at least [redacted] different prescribers in New Jersey from 2009 to 2015. Janssen's representatives called upon these prescribers repeatedly. In New Jersey alone, Janssen's sales representatives made in excess of [redacted] distinct sales visits to promote Nucynta and/or Nucynta ER between 2009 and 2015.

65. Former Janssen detailers stated that they received bonuses based on the number of prescriptions for Nucynta and/or Nucynta ER written by the prescribers they visited, and that average bonus amounts could range from $500 to $5,000 per quarter with the highest-performing representatives making bonuses of over $20,000 per quarter. They reported having goals of up to eight separate prescriber visits and three separate pharmacy visits (for a total of 11) per day. One former detailer described the core job function of Janssen's sales force: "[M]y job is to sell Nucynta . . . my job is to change mindsets."

4. Janssen-Sponsored Front Groups, Publications, and Studies.

66. Janssen distributed, presented, or caused to be published dozens of studies, articles, or presentations that supplemented and lent seemingly independent credibility to its overarching marketing messages. It also funded multiple front groups to maintain and increase focus on pain management among patients and prescribers and to encourage the acceptance and use of opioids in pain treatment.

67. For example, Janssen's internal business plans confirm that a key component of Janssen's promotional strategy for Nucynta and Nucynta ER was [redacted] Janssen knew that sponsorship of these front groups allowed Janssen to wield [redacted]

68. In addition to utilizing front organizations, Janssen also funded, distributed, presented, or caused to be published studies or articles promoting the notion that certain types of chronic, mixed pain are routinely under-treated. [redacted] The conclusion of the study fit nicely with Janssen's larger marketing goal of [redacted]

[redacted]

69. [redacted] The conclusion of the study again comports with Janssen's marketing message [redacted]

70. Janssen also sponsored or distributed studies aimed at allaying prescribers' general fears regarding the presumed risks of opioids. One 2012 study, published in the Journal of Opioid Management, and authored by employees of Janssen Pharmaceutical Research and Development, LLC (a Janssen-affiliated subsidiary of J&J) concluded that the "great majority" of healthcare providers who prescribe opioids "appear to have no opioid shoppers in their practice."[6]

71. [redacted]

72. In all, from the launch of Nucynta in 2009 to the sale of the Nucynta franchise in 2015, Janssen spent over [redacted] dollars nationally to carry out its marketing plan.

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[6] M. Soledad Cepeda et al., "Characteristics of prescribers whose patients shop for opioids," J. Opioid Manag. (2012).

C. Janssen's Marketing Campaign Misrepresented, Trivialized, or Knowingly Omitted the Known Risks of the Nucynta Products and of Opioid Use Generally.

1. Janssen Falsely Claimed that Opioids Carry a Low Risk of Addiction -- and, in Particular, that Nucynta and Nucynta ER Carried a Lower Risk as Compared to Other Opioids.

73. To alleviate the fears of prescribers and patients regarding the potential dangers of opioids, Janssen deceptively minimized the risks of opioid addiction and abuse, both with respect to opioid use generally, and with respect to Nucynta and Nucynta ER. Janssen deceptively portrayed Nucynta and Nucynta ER as "less addictive" than other Schedule II opioids. Janssen also deceptively promoted Nucynta and Nucynta ER as drugs that bridged the gap between non-opioid pain relievers and Schedule II opioids -- providing the misleading impression that these drugs were not in the same class as other highly addictive and dangerous Schedule II narcotics, but were rather more akin to safer, over-the-counter pain medications. Janssen also represented that the addiction risks associated with opioids generally are overestimated and entirely manageable. As described below, Janssen made deceptive statements to both patients and prescribers that the risk of opioid addiction could be controlled, that certain patients were at increased risk for addiction but could be identified through screening tools, and that the vast majority of patients could receive opioids, even for periods of over 90 days, without an increased risk of addiction. Many of these representations are inconsistent with the FDA-approved labeling for Nucynta and Nucynta ER, and all of these representations are contradicted by the 2016 CDC Guideline, which makes clear that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder," and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[7]

[7] 2016 CDC Guideline at 2, 25.

a. Janssen's Sales Force Misrepresented the Risk of Addiction Associated with Nucynta and Nucynta ER.

74. The misrepresentations that Janssen's sales force made to prescribers in promoting Nucynta and Nucynta ER began with training on the deceptive marketing messages that were designed to raise Janssen's profits at the expense of disseminating accurate statements about how the drugs work and their serious risk of addiction. [redacted]

75. Janssen's training materials also deceptively minimized the risk of addiction. [redacted]

76. Janssen's sales representatives repeated misleading messages from the training material and made additional misrepresentations to prescribers. For example, one former Janssen sales representative, "Representative A," asserted that "Nucynta was considered a bridge from . . . [a non-prescription anti-inflammatory drug like ibuprofen] to a harder pain medication. So this was considered a milder opioid . . . that was how it was marketed." Representative A went on to explain that "[t]he core message was that . . . Nucynta was less addictive than . . . the Opanas or those opioids, the harder core opioids."

77. Janssen's misrepresentation of Nucynta and Nucynta ER as drugs that bridged the gap between over-the-counter pain medications and "harder" Schedule II opioids like Opana is misleading because it obscures the fact that Nucynta and Nucynta ER are in the same class as all other Schedule II opioids and carry a risk of abuse and addiction similar to the other drugs in that class. Indeed, contrary to the representations of Representative A, the FDA-approved labels for Nucynta and Nucynta ER expressly provide that they contain "a high potential for abuse similar to . . . oxymorphone [e.g., Opana]." And the FDA-approved label for Opana similarly provides that it contains "a high potential for abuse similar to . . . tapentadol [i.e., Nucynta and Nucynta ER]." Nucynta and Nucynta ER are not more closely related to over-the-counter pain medications than other Schedule II opioids; Nucynta and Nucynta ER are not "milder" than other Schedule II opioids; and competitor opioids are not "harder core" than Nucynta and Nucynta ER. Janssen's deceptive promotion of Nucynta and Nucynta ER as bridge drugs that were milder than other Schedule II opioids had the capacity to deceive prescribers who harbored legitimate concerns about the potential for opioid abuse and addiction.

78. Representative A also stated that Nucynta and Nucynta ER were also explicitly promoted as less addictive than other Schedule II opioids. For example, he stated that a specific

sales pitch that he delivered to prescribers in New Jersey was: "So, Doctor, I understand [that addiction is] a concern for you; and basically . . . this is a mild . . . opioid agonist. So . . . there's less addictive properties to it."

79. Other former Janssen sales representatives confirmed that they made similar representations to New Jersey prescribers. One representative, "Representative B," asserted that she would respond to concerns that a prescriber might raise about opioid abuse by stating that "Nucynta is less addictive so it should be [your] go-to choice." Another representative, "Representative C," stated that his response to a healthcare provider's concerns about the addictive properties of Nucynta and Nucynta ER would be: "[D]oc, listen this is not something that is readily abused." Another representative, "Representative D," who made between fifty and seventy-five telephone calls per day to prescribers across the country -- including in New Jersey -- stated that the primary message he delivered in promoting Nucynta and Nucynta ER was "just it was an opioid that was different than what was on the market and had less of an addiction profile . . . . I do remember that they [Janssen] . . . were strongly saying that . . . it had less of an addiction profile than other opioids that were on the market at that point."

80. New Jersey healthcare providers have corroborated that Janssen promoted Nucynta and Nucynta ER as milder and less addictive opioids. For example, one New Jersey physician stated that he was told by Janssen sales representatives that Nucynta was less likely to be addictive because it did not provide the same euphoric effect as other Schedule II opioids. Janssen's sales representatives also told him that Nucynta was less susceptible to illegal diversion because it had little street value due to its lack of a euphoric effect. A separate New Jersey physician stated the main message of Janssen's sales representatives was that Nucynta and Nucynta ER were essentially non-addictive and were not drugs that abusers liked.

81. These misrepresentations regarding Nucynta and Nucynta ER's "mild" nature, lower potential for abuse, and lesser addictive properties are inconsistent with FDA-approved labeling and the drugs' classification as Schedule II controlled substances. FDA labeling explicitly provides that Nucynta and Nucynta ER "expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death," that addiction can occur even when patients use the drugs at recommended doses, and that Nucynta and Nucynta ER have a "high potential for abuse similar to other opioids including fentanyl, hydrocodone [e.g., Vicodin], hydromorphone [e.g., Dilaudid], methadone, morphine, oxycodone [e.g., OxyContin], and oxymorphone [e.g., Opana]." These warnings are nearly identical to the warnings on the OxyContin label, which provides that OxyContin carries a "high potential for abuse similar to other opioids including . . . tapentadol [e.g., Nucynta and Nucynta ER]."

82. Additionally, Janssen's claims regarding opioid addiction are contrary to longstanding scientific evidence, and its failures to disclose the risk of addiction are material given both the magnitude of the risk and the grave consequences of addiction. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction. The labeling for Nucynta and Nucynta ER contain no indication that a lower rate of addiction problems exists among long-term users of those drugs. To the contrary, in requiring a new black-box warning on the labels of all immediate release opioids (like Nucynta) in March 2016 -- and similar to the warning already required for extended

release opioids (like Nucynta ER) -- the FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . . across all prescription opioid products."[8]

83. Similarly, as confirmed by the CDC in its 2016 Guideline, "extensive evidence" exists of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[9]

b. Janssen's Prescribe Responsibly Website Deceptively Misrepresented the Risks of Addiction Associated with Opioid Use.

84. Through its Prescribe Responsibly website, Janssen published multiple articles -- which are still accessible to both prescribers and patients -- that misrepresent, trivialize, or fail to disclose the known risks of opioid products. For example, one article on the Prescribe Responsibly website describes concerns about opioid addiction as "often overestimated," and it represents that addiction occurs in "only a small percentage" of patients who receive chronic opioid therapy:

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[8] Press Release, FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose, and death (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[9] 2016 CDC Guideline at 2, 25.

Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

85. The same article suggests that "with appropriate dosing and titration, [opioids] can be effective and safe medications for the treatment of painful conditions."

86. It is deceptive to describe chronic opioid therapy as "effective and safe" with appropriate dosing and titration while describing the risks of addiction associated with chronic opioid use as "overestimated" and occurring in "only a small percentage" of patients. Those descriptions have the capacity to deceive readers about the realities of chronic opioid therapy: (a) opioids carry a high risk of abuse and addiction; (b) addiction can occur even when opioids are taken at recommended dosages; (c) chronic opioid therapy substantially increases the risk of opioid addiction; and (d) there is no good evidence showing that chronic opioid therapy is effective at improving pain or function.[10] The article further omits that patients on chronic opioid therapy can experience severe withdrawal symptoms, and that withdrawal symptoms are more likely to occur the longer a patient is on continuous opioid therapy.

87. Through its Prescribe Responsibly website, Janssen also falsely instructed New Jersey prescribers and patients that addiction risk screening tools, urine drug screens, and similar strategies allow healthcare providers to identify patients predisposed to addiction, thereby

[10] 2016 CDC Guideline at 2, 20, 25.

purportedly allowing prescribers to manage the risk of opioid addiction in their patient populations.

88. For example, Janssen provides a link to the "Opioid Risk Tool," which is a screening tool created by prominent opioid advocate Dr. Lynn Webster. It is a five-question, one-minute screening tool that relies on patient self-reports. The tool misleadingly purports to allow prescribers to manage the risk that their patients will become addicted to or abuse opioids.

89. Such misrepresentations make healthcare providers more comfortable prescribing opioids to their patients and make patients more comfortable starting on chronic opioid therapy. These misrepresentations provided assurances to healthcare providers that they could safely prescribe opioids in their own practices and that, while addiction was not unavoidable, it was rare and largely the result of failing to screen or manage specific patients who demonstrate very particular risk factors.

90. The 2016 CDC Guideline -- which was based on a review of existing medical evidence -- confirms the lack of scientific substantiation to support Janssen's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. The Guideline notes -- and Janssen knew or should have known -- that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient contracts, urine drug testing, or pill counts "for improving outcomes related to overdose, addiction, abuse, or misuse."[11] As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or

[11] 2016 CDC Guideline at 11.

misuse" and counsels that prescribers "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[12]

c. The "Let's Talk Pain" Coalition Deceptively Misrepresented the Risks of Addiction Associated with Opioid Use.

91. Janssen has also misrepresented or intentionally omitted the risks of addiction associated with opioid use through its production and dissemination of on-line videos, which Janssen created as part of its affiliation with the Let's Talk Pain Coalition. Through that Coalition, Janssen sponsored several videos that were designed to encourage patients to seek treatment for chronic pain. One such video, which is titled "Safe Use of Opioids," and which is currently accessible via www.YouTube.com, overstates the benefits of chronic opioid use and omits discussion of the risks of addiction and abuse associated with opioids.

92. The video consists of an interview between a healthcare professional and patient who is generically described as a "person with pain." The patient purports to have been on a long-acting opioid for a number of years and to be using short-acting opioids for breakthrough pain. In an apparent effort to encourage patients to express dissatisfaction with their current pain treatments, the patient relates that the "burden is upon . . . the person in pain" to ascertain his or her appropriate course of pain treatment.

(a) The patient relates that many people have "preconceived notions [about opioids] that often are not true." She states that she has safely used opioids "over the years," and notes that she had experienced "periods where it just is not working as well as it used to be." The patient explains that, after being on opioid therapy for two years, her body had developed a tolerance; but once her opioid dosage was increased, her pain issues were resolved.

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[12] 2016 CDC Guideline at 28 (emphasis added). These screening tools may, however, serve different purposes: they can assist prescribers in identifying diversion, and they can convey to patients the gravity of the risks associated with opioid use.

(b) The patient makes no mention of the risks of addiction associated with opioid use -- particularly chronic use -- or the increased risks associated with increasing opioid dosages. She mentions only that opioids should be stored in a manner that prevents children from accessing them.

(c) The healthcare professional in the video (an employee of ASPMN) states that appropriate pain management -- i.e., opioid therapy -- can "increase function and quality of life." She also states that undertreatment of pain results in "suffering . . . [that] is inexcusable," "horrendous," and "causes just as many adverse side effects as anything in pain management could and more."

(d) The healthcare professional omits any mention of the risks of addiction associated with opioid use or the increased risks associated with long-term use.

93. The "Safe Use of Opioids" video has the capacity to deceive both patients and prescribers by omitting any discussion of the high risks of addiction and abuse that are associated with opioid use. The video portrays opioids as a class of medications that can be safely and effectively used for years, while materially omitting that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases [the] risk for opioid use disorder."[13]

d. The Janssen Publication "Finding Relief: Pain Management for Older Adults" Deceptively Misrepresented the Risks of Addiction Associated with Opioid Use.

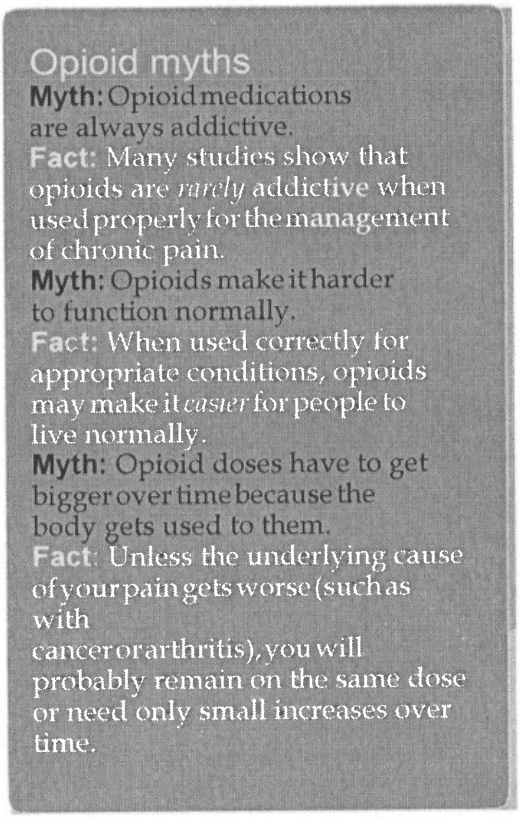
94. Janssen contracted with Conrad Productions and Alan Weiss Productions to produce and distribute a 2009 brochure entitled "Finding Relief: Pain Management for Older Adults," and an accompanying DVD featuring a prominent actress. The Finding Relief brochure and video were targeted to elderly patients and were intended to provide those patients with "what they need to know to get effective pain relief." The video had been accessible on-line, including through the website of the American Academy of Pain Medicine ("AAPM"),[14] and the

[13] 2016 CDC Guideline at 2, 25.

[14] AAPM has also received substantial funding from opioid manufacturers. AAPM received nearly $1.2 million from opioid manufactures from 2012 to 2017, including over

brochure remains available on-line. AAPM also made DVDs of the video and hard copies of the brochure available to its members free of charge.

95. The brochure, a portion of which is excerpted below, deceptively overstates the benefits and understates the risks of opioid treatments for chronic pain. For example, the brochure purports to debunk three "myths" about opioids: (a) that opioids are always addictive -- the brochure deceptively claims they are "rarely addictive"; (b) that opioids make it harder to function normally -- the brochure deceptively claims they may make it "easier for people to live normally"; and (c) that opioid doses increase over time -- the brochure deceptively claims that patients "will probably remain on the same dose or need only small increases over time."



Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

$83,000 from Janssen. See U.S. Senate Homeland Security & Governmental Affairs Committee, "Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocate Groups," (Feb. 12, 2018), https://www.hsdl.org/?view&did=808171.

96. The misrepresentations contained in the brochure are deceptive and inaccurate. For example, by portraying opioids as "rarely addictive" -- and omitting any information concerning overdose, withdrawal, or the potential for abuse -- the brochure obscures the fact that opioid use is accompanied by a serious risk of addiction and abuse. The brochure's portrayal of opioids as making it easier for patients to function normally is similarly deceptive because "there is no good evidence that opioids improve pain or function with long-term use."[15]

2. Janssen Misleadingly Promoted Its Nucynta Products as Unlike Traditional Opioids and as Having Non-Opioid Properties that Allowed Them to be Safer, Less Addictive, and More Effective than Other Schedule II Opioids.

97. Despite that Nucynta and Nucynta ER are Schedule II opioids, Janssen promoted those drugs as "unlike traditional opioids" and as having "non-opioid properties." Referring to Nucynta and Nucynta ER as opioids that are unlike opioids, or as opioids that have non-opioid properties, is, itself, highly misleading because it suggests that the drugs are not "real" opioids, like Janssen's competitor's products. Opioids are commonly understood to have two key properties: (a) they prevent the body from feeling pain; and (b) they are highly addictive. Knowing that the chief concern that many prescribers and patients had about opioids was their addictive properties, Janssen must also have known that, by describing Nucynta and Nucynta ER as being "unlike traditional opioids" or as having "non-opioid" properties, prescribers and patients would infer that the drugs were not addictive or were less addictive than "traditional" opioids. But Janssen did not rely solely on these logical, foreseeable inferences. Instead, its marketing went much further, making several explicit misrepresentations.

[15] 2016 CDC Guideline at 20.

98. Janssen's promotion of Nucynta and Nucynta ER as unlike traditional opioids and as having non-opioid properties minimized the dangerous nature of the drugs and had the capacity to mislead prescribers and patients into believing that Nucynta and Nucynta ER were safer, less addictive, and more effective that competitor Schedule II opioids. Moreover, Janssen routinely trivialized or entirely failed to disclose the fact that the purported basis for these misrepresentations -- the supposed dual mechanism of action of Nucynta and Nucynta ER -- was not scientifically established and was grounded on preclinical research of limited utility.

99. [redacted]

100. [redacted]

101. [redacted]

[redacted]

102. [redacted]

[redacted]

103. [redacted]

[redacted]

104. Statements about the level of Nucynta or Nucynta ER's impact on the body's opioid receptors as compared to competitor drugs have the capacity to mislead prescribers into

believing that Nucynta and Nucynta ER carry a lower potential for addiction or abuse than competitor opioids. Moreover, [redacted]

105. [redacted]

106. [redacted]

107. Former Janssen sales representatives who operated in New Jersey also stated that they promoted Nucynta and Nucynta ER as being unlike traditional opioids. For example, Representative C stated that he promoted Nucynta as different than other Schedule II opioids because Nucynta had "a different modality, a different way of treating pain." The message he gave to New Jersey prescribers was that Nucynta acted as both an opioid and a NRI, and that this dual mechanism of action differentiated Nucynta and Nucynta ER. He told prescribers:

"Everybody works [as an opioid] agonist, [but] we work in two modalities and this is why it's better . . . [n]ow doctor is this something you'd be interested in trying[?]"

108. Representative B expressly promoted Nucynta as "less addictive" than other Schedule II opioids, and she remembers "something about it being opioid sparing or some receptor sparing" as the reason for Nucynta's purportedly lower addiction profile.

109. Representative A promoted Nucynta as different from "a traditional opioid," which is "considered more addictive, [and] ha[s] more addictive properties[.]"

110. New Jersey prescribers received this message from Janssen and were misled into believing that the supposed dual mechanism of action caused Nucynta and Nucynta ER to have non-opioid properties, rendering them safer and less addictive than other Schedule II opioids. For example, one East Brunswick physician stated that Janssen sales representatives told him that tapentadol (the active molecule in Nucynta and Nucynta ER) potentiates opioid sparing properties (i.e., that it is possible that tapentadol has little or no impact on the body's opioid receptors), and Janssen sales representatives promoted the Nucynta line of drugs as "safer" than other opioids as a result.

3. Janssen Promoted the Misleading Concept of "Pseudoaddiction" to Allay Prescribers' Fears of Opioid Abuse.

111. Through its unbranded marketing, Janssen promoted the discredited concept of "pseudoaddiction." The term "pseudoaddiction" was originally coined by Drs. David E. Weissman and J. David Haddox, in a 1989 journal article. It is an invented phenomenon that opioid manufacturers used to explain away, and even capitalize on, clear warning signs of addiction. As explained by Weissman and Haddox, pseudoaddiction is observed when a patient manifests signs of addiction -- but that behavior is actually a symptom of undertreated pain that

will resolve once the pain is effectively treated -- i.e., with more frequent or higher doses of opioids.

112. The 2016 CDC Guideline confirms the invalidity of the concept of pseudoaddiction. For example, relying on evidence published in 2007, the CDC explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use."[16] Moreover, a review of the existing clinical evidence indicated that "patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months," and prescribers should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[17] Nowhere does the Guideline recommend that opioid doses be increased if a patient exhibits behaviors commonly associated with abuse or addiction.

113. Janssen's Prescribe Responsibly website contains numerous articles promoting the concept of pseudoaddiction, which the website defines as: "[A] syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."

114. Material that had been published on the Janssen-sponsored Let's Talk Pain Coalition website also promoted the concept of pseudoaddiction. One such article taught patients that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . [t]his includes . . . 'drug-seeking' or 'clock-watching' . . . such behaviors can be resolved with effective pain management."

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[16] 2016 CDC Guideline at 13.

[17] 2016 CDC Guideline at 25.

115. Janssen also funded and contributed to the creation of continuing medical education material that promoted the concept of pseudoaddiction. For example, Janssen jointly funded, along with three other opioid manufactures, a medical education guide published in December of 2009, titled "Opioid Prescribing: Clinical Tools and Risk Management Strategies." The guide was authored by three members of the Board of Directors of AIPM, one of whom served as a paid consultant to Janssen. The guide was made available to members of AIPM at no charge, it was intended to reach primary care physicians and other healthcare professionals, and large portions of the guide remain available on-line. The guide minimizes risks associated with opioid addiction, teaching prescribers, for example, that "fear of addiction and abuse prevents physicians from properly prescribing opioids, particularly for those with a substance abuse history who could benefit from opioids[.]" The guide also promotes the concept of pseudoaddiction, which it defines as "the need to seek additional medications due to the undertreatment of pain." The guide instructs prescribers to treat patients who present symptoms of pseudoaddiction with additional pain treatment (i.e., higher or more frequent dosages of opioids) because "[w]hen pain is treated appropriately, aggressive drug-seeking behavior ceases."

116. In addition to promoting the concept of pseudoaddiction, Janssen also promoted technical distinctions between terms like "dependence," "abuse," "addiction," and "aberrant behavior" in an effort to ally prescribers' concerns about addiction risks. Janssen encouraged prescribers to rely on these technical distinctions to overcome apprehensions about addiction that patients might express. While distinctions among these terms may exist, Janssen engaged in deceptive conduct by using these technical distinctions to obscure or trivialize the very serious risks of opioid addiction, and in promoting technical distinctions among these concepts, Janssen

frequently omitted discussion of the adverse side effects of physical dependence, which can include painful and debilitating withdrawal symptoms.

117. For example, one article appearing on Janssen's Prescribe Responsibly website suggests that "[i]n those cases when a patient expresses concern about addiction," it is important to have a further discussion, because if the concern turns out to fall within the technical definition of "physical dependence," the patient's addiction concerns can be overcome by "reassurance from the healthcare professional." The same article notes that "aberrant behavior," which Janssen defines as patient behavior that is "outside the boundaries of an agreed upon treatment plan," is an "unreliable sign of addiction."

118. A separate article appearing on the Prescribe Responsibly website also distinguishes "aberrant behavior" from addiction. The article states that aberrant behavior might include "intravenous injection of oral formulations," "concurrent use of related illegal drugs," and "aggressively requesting medication or unsanctioned dosage escalations." The article notes that aberrant behaviors, particularly the last two, are "not necessarily an indicator of an opioid addiction," rather, they "may be the result of a patient experiencing unrelieved pain." Put more plainly, Janssen was advising doctors that patients who were harassing and frightening doctors to try and get more opioids and even patients who were shooting up their prescriptions and using heroin -- all of which are behaviors that are physically, mentally, or socially harmful and are understood as among the most compelling manifestations of addiction -- were not necessarily demonstrating signs of addiction, but rather might be showing signs of under-treated pain, which could be addressed through higher or more frequent opioid dosages.

119. The Janssen-sponsored medical education guide, "Opioid Prescribing: Clinical Tools and Risk Management Strategies," similarly encourages prescribers to consider behaviors

commonly associated with addiction merely as signs of tolerance, physical dependence, or general "aberrant behavior." For example, the guide provides that patients who use opioids to "cope with stress [or] relieve anxiety," or even patients who "use opioids to get high, but . . . not in a compulsive way," are not exhibiting signs of addiction, but rather are displaying "other forms of aberrant drug use." The guide further provides that even "behaviors that suggest abuse," such as "unscheduled visits, multiple telephone calls to the clinic, unsanctioned dose escalations, obtaining opioids from more than one source, selling prescription drugs, and forging prescriptions," may not be signs of addiction, but rather "may only reflect . . . having pain that is undertreated." (Emphasis added).

120. Janssen also trained its sales force that a healthcare provider [redacted] Janssen taught its sales representatives to overcome this concern by [redacted]

121. Janssen's promotion of pseudoaddiction and its related attempts to promote technical distinctions among terms like "addiction," "abuse," "tolerance," "dependence," and "aberrant behavior," encourage a course of action that maximizes the potential for high

prescriptions of opioids while minimizing and trivializing the serious risks of addiction associated with chronic opioid therapy.

4. Janssen's Marketing Minimized the Risks of Opioid Withdrawal.

122. Janssen minimized the risks and severity of withdrawal symptoms in its promotion of Nucynta and Nucynta ER.

123. Prescribers of Nucynta and Nucynta ER stated that Janssen sales representatives promoted those drugs as having minimal withdrawal symptoms. For example, Prescriber C stated that Janssen's sales representatives conveyed the message that the Nucynta line of products did not work in the same way as other opioids because they did not attach to the body's mu-opioid receptor. The prescriber was told that patients taking Nucynta products would not experience withdrawal symptoms or addiction.

124. Similarly, one former sales representative, "Representative E," told prescribers that, in dealing with acute pain, once Nucynta relieves the pain, you "take [the patient] off it [and] there's no withdrawal symptoms."

125. [redacted]

D. Janssen Overstated the Benefits of Opioid Use, Exaggerated the Risks of Alternative Pain Treatment, and Failed to Disclose the Lack of Evidence Supporting Long-Term Use.

126. Through its promotional material and detailing activities, Janssen overstated the benefits of both short term and chronic opioid therapy and intentionally omitted the known risks of opioid treatment. Janssen also exaggerated the risks associated with competing pain medications, such as NSAIDs (like Advil or Motrin). This misleading promotional activity was

designed to cause prescribers and patients to choose opioids, such as Nucynta and Nucynta ER, over alternative analgesics.

127. For example, Janssen's brochure "Finding Relief: Pain Management for Older Adults," contains misrepresentations about increased functionality that could result from opioid use. Despite the CDC's confirmation that "no good evidence" exists showing that opioids improve pain or function with long-term use,[18] Janssen nevertheless represented to patients that when "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal' -- get back to work, walk or run, play sports, and participate in other activities." The brochure further provides:

Your recovery will be measured by how well you reach functional goals, such as:

- Sleeping without waking from pain
- Sleeping in your own bed
- Returning to work
- Enjoying recreational activities
- Having sex
- Walking without help
- Climbing stairs

128. Janssen's sales representatives made similar representations about the benefits and increased level of functionality that Nucynta and Nucynta ER would offer. For example, Representative A asserted that "basically what [Janssen] promoted was bringing patients to life .

[18] 2016 CDC Guideline at 20 (emphasis added).

. . talking about a specific patient type that's having trouble getting to work or something like that." Such a patient might be "maxed out" from the "side effects of a[] NSAID . . . internal bleeding, whatever, things like that." That type of patient might be "ready for the next step . . . [t]hey can't get to work . . . they're missing paychecks . . . and [Nucynta] will allow them to get to work."

129. New Jersey prescribers received Janssen's misleading promotional message concerning the ability of opioids to increase function. For example, one New Jersey physician stated that Janssen representatives explicitly promoted Nucynta as being able to improve patient function and quality of life.

130. Janssen also deceptively exaggerated the risks of NSAIDs in promoting opioid use and downplayed negative side effects of opioids. For example, Janssen's brochure "Finding Relief: Pain Management for Older Adults," highlights certain potentially serious "disadvantages" of aspirin, acetaminophen, and NSAIDs, such as "kidney damage," "liver damage," "bleeding in the stomach," and increased "risk of heart attack and stroke." But when describing opioid medications, the brochure does not explicitly identify any "disadvantages." Rather, it states that "opioids have been used for centuries" and that, while they usually produce side effects such as "upset stomach or sleepiness," these "often go away as you get used to the drugs." The brochure notes that constipation can occur with opioid use, but that it can be "prevented or lessened by taking a laxative on a regular basis."

131. Janssen knew these statements about the side effects of opioid use were inaccurate. For example, the brochure entirely omits any discussion of the known risks of addiction associated with chronic opioid use. And Janssen's own internal training material

[redacted]. Janssen's internal training materials provide, for example, [redacted]

132. Articles contained on Janssen's Prescribe Responsibly website also suggest that opioids have fewer or less severe side effects than NSAIDs, and that opioids should be considered as a "first line treatment for many painful conditions." One article provides that opioids offer significant advantages over NSAIDs because opioids "have no true 'ceiling dose' for analgesia and do not cause direct organ damage" like NSAIDs might. The article acknowledges that opioids "do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression," but it notes that "with the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects."

133. Former Janssen sales representatives also promoted Nucynta and Nucynta ER by overstating the disadvantages of NSAIDs. For example, Representative A told prescribers that, if you "keep [patients] on NSAIDs for a while, it could cause some [gastro-intestinal] side effects . . . [s]o, . . . instead of keeping them on that for a long period of time, [Nucynta] could be your next option."

134. New Jersey prescribers received this message. For example, one New Jersey physician stated that Janssen sales representatives told him that Nucynta was safer than NSAIDs because, unlike NSAIDs, Nucynta would not cause ulcers, affect kidney function, or cause stomach problems.

135. Janssen also promoted Nucynta ER as beneficial for use beyond twelve weeks, despite only having studies of the drug's efficacy over a twelve-week maintenance period. [redacted]

[redacted]

136. Janssen failed to disclose the lack of evidence of the benefits of taking Nucynta ER beyond the term of these studies, [redacted] Such a response is misleading in two respects: [redacted]

137. Contrary to Janssen's representations about -- (a) the benefits of opioids in improving functionality and quality of life; (b) the disadvantages of NSAIDs in comparison to opioids; and (c) the efficacy of opioids for long-term use -- the 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[19] The CDC reinforced this conclusion throughout the Guideline, finding that: (a) "[n]o evidence shows

[19] 2016 CDC Guideline at 20 (emphasis added).

a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"; (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy"; and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[20]

138. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[21] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life. Janssen's claims that patients will experience functional improvement, in addition to lacking evidence, also ignore these very serious consequences.

139. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. The FDA has recognized the lack of evidence to support long-term opioid use, stating in 2013 that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[22] Additionally, over the past decade, the FDA has repeatedly warned opioid manufacturers not to make claims regarding functional improvement and ability to perform daily activities because such claims lack substantial scientific evidence.

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[20] 2016 CDC Guideline at 15, 18-19.

[21] 2016 CDC Guideline at 20.

[22] Letter from Janet Woodcock, MD, Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, MD, President, Physicians for Responsible Opioid Prescribing at 10 (Sept. 10, 2013).

140. The available evidence indicates that opioids (a) are not effective to treat chronic pain; (b) are not more advantageous than NSAIDs; and (c) may actually worsen patients' health. As early as 2006, an academic review found that "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids."[23] Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization. Moreover, as reflected in the same study, efficacy trials do not typically include data on opioid addiction.

141. 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."[24] Studies of patients using opioids to treat lower back pain and migraine headaches, for example, consistently have shown that patients experienced deteriorating function over time, as measured by the ability to return to work or physical activity, pain relief, rates of depression, and subjective quality-of-life measures.

142. Similarly, analyses of workers' compensation claims have found that, controlling for other factors: (a) workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work; (b) that receiving an opioid for more than seven days will increase a patient's risk of being on work disability one

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[23] Andrea D. Furlan et al., "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

[24] Andrea Rubenstein, MD, "Are we making pain patients worse?," Sonoma Medicine (Fall 2009).

year later; and (c) that an opioid prescription as the first line treatment for a workplace injury doubled the average length of the claim.

E. Janssen Targeted the Elderly and Opioid-Naïve Patients through Deceptive Marketing for the Purpose of Expanding Market Share and Profits.

143. Part of Janssen's strategy to expand its market share and its revenue has been to target two, overlapping markets: the elderly (a demographic that has seen an explosion in opioid prescribing in recent years); and "opioid-naïve" patients (those who previously had not taken opioids).

144. Janssen's internal business plans make clear that Janssen [redacted]

145. [redacted]

146. [redacted]

147. [redacted]

148. Janssen also sponsored, presented, or distributed studies targeting those who provide care to the elderly. The findings in each of these studies buttressed Janssen's overarching efforts to [redacted] For example, one article -- published in the Journal of the American Geriatric Society and authored by physicians who received funding from Janssen -- concluded that persistent pain in elderly populations is under-assessed and harmful, and recommended that "[a]ll patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy."[25] Another article -- published in the Journal of Pain and Symptom Management and funded by Janssen Scientific Affairs, LLC (a Janssen-affiliated subsidiary of J&J) -- concluded that the presence of pain without appropriate analgesic

[25] Am. Geriatrics Society Panel on Pharmacological Management of Persistent Pain in Older Adults, "Pharmacological Management of Persistent Pain in Older Adults," J. Am. Geriatrics Society 1342 (Aug. 2009).

treatment was prevalent among nursing home residents, and procedures to ensure adherence to guidelines for pain management were warranted.[26]

149. Another article -- published in the Journal of the American Medical Directors Association and funded by Ortho-McNeil Janssen Scientific Affairs, LLC (a Janssen-affiliated subsidiary of J&J) -- concluded that pain is highly prevalent among nursing home residents, and that initiatives to recognize and increase pain treatment would improve well-being among those residents.[27] Janssen's internal public relations plans confirm that [redacted]

150. Janssen trained its sales representatives [redacted]

151. Janssen's sales representatives also convinced prescribers in one-on-one visits that Nucynta and Nucynta ER were particularly appropriate for use with elderly or opioid-naïve patients. [redacted]

[26] Kate L. Lapane, PhD et al., "Pharmacologic Management of Non-Cancer Pain Among Nursing Home Residents," J. of Pain and Symptom Magazine (Jan. 2013).

[27] Kate L. Lapane, PhD et al., "The Association Between Pain Measures of Well-Being Among Nursing Home Residents," J. Am. Med. Dir. Assoc. (May 2012).

[redacted]

152. The typical opioid-naïve patient that Janssen sought to capture was a patient who was not using any opioid products, not even short-acting opioids for episodic pain, and experienced discomfort from relatively common conditions like back and neck pain. This type of patient was likely using over-the-counter products like NSAIDs which were safe and inexpensive. Yet Janssen representatives encouraged prescribers to look for these patients and convert them to Nucynta and Nucynta ER by deceptively overstating the risks of NSAIDs and other products while understating the risks of Nucynta and Nucynta ER.

153. New Jersey prescribers confirm that Janssen representatives promoted the Nucynta and Nucynta ER as particularly well-suited for the opioid-naïve. For example, a New Jersey physician recalled that the main promotional message he received from Janssen was that Nucynta was a good choice for opioid-naïve patients because the lack of euphoria from the drug meant that an opioid-naïve patient was less likely to become addicted.

154. This misrepresentation that the lack of euphoric effect associated with Nucynta and Nucynta ER caused those drugs to be less addictive than other Schedule II opioids is unsupported by scientific evidence and contrary to both the CSA, 21 U.S.C. § 801 et seq., and to the FDA-approved labeling for Nucynta and Nucynta ER. The CSA makes clear that all Schedule II drugs have a high potential for abuse, and the FDA-approved labels for Nucynta and Nucynta ER provide that they have an abuse potential similar to other Schedule II opioids, like OxyContin and fentanyl.

155. Janssen's decision to target elderly and opioid-naïve patients reflects a business strategy that placed too little value on the well-being and safety of consumers. An objective comparison of the risks and benefits of opioid use by either of these populations provides even less justification for initiating opioid therapy than might arguably exist among patients who were already using opioids.

156. Elderly patients taking opioids have an increased vulnerability to adverse side effects such as respiratory depression, which Janssen has acknowledged on its opioids' labels, but not in its marketing. Additionally, one 2010 study found that elderly patients who used opioids had double the risk of fracture when compared to elderly persons who had discontinued opioid use. The risk of fracture has been associated with falls resulting from a variety of opioid-related causes, such as side effects like dizziness, lightheadedness, and nausea.[28]

157. And Janssen's specific focus on opioid-naïve patients is particularly disconcerting in light of the stream of information over the past decade emphasizing, as the CDC summarized in 2016, that "for the vast majority of patients," including the opioid-naïve and elderly, "the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[29] Opioid-naïve patients need never experience the serious consequences of chronic opioid therapy. Yet, through its marketing efforts, Janssen sought to add them to its captive customer base of patients who would continue to require opioids as they became dependent and, perhaps, addicted.

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[28] Kathleen W. Saunders et al., "Relationship of opioid use and dosage levels to fractures in older chronic pain patients," J. Gen. Intern. Med. 25:310-315 (Jan. 2009).

[29] Thomas R. Frieden & Debra Howry, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline," 374 New Eng. J. Med. 1501, 1503 (Apr. 21, 2016) (article announcing 2016 CDC Guideline).

F. Janssen's Promotional Conduct Has Caused Significant Harm to Public Health, Welfare, and Safety in New Jersey.

158. Janssen's promotional conduct foreseeably and substantially contributed to the overprescribing of opioids in New Jersey. The State now faces an epidemic of drug addiction, abuse, overdose, and other injuries, with their attendant societal costs. Additionally, New Jersey, through its State-funded health programs, has been forced to pay hundreds of millions of dollars for opioid prescriptions, attendant treatment, and other costs, even though many of these prescriptions were not medically necessary and would not have been written but for Janssen's fraudulent and deceptive marketing scheme. Consumers, private employers, and insurers have suffered similar financial impacts.

1. Janssen's Deceptive Marketing Has Contributed to the Opioid Epidemic, Resulting in Addiction, Overdose, and Other Injuries to New Jersey Citizens.

159. Janssen's misrepresentations were a substantial factor in, and had the foreseeable effect of, inducing New Jersey healthcare providers to prescribe opioids to patients, and payors to cover opioids, including for the treatment of chronic pain. Through its marketing, Janssen trivialized the risks of opioids, overstated their benefits, and expanded the perception of who was an appropriate patient for opioid use. Janssen engaged in this activity for the express purpose of increasing its opioid prescriptions and revenue, and ultimately exposed thousands of New Jersey residents -- including the elderly and the opioid-naïve -- to dangerously addictive prescription opioids.

160. Janssen's deceptive marketing has contributed to an explosion in the use of opioids in New Jersey. As described in detail below, State spending on opioids -- through claims paid by its Medicaid and Workers' Compensation programs -- have risen dramatically, from

approximately $3.6 million in 2009 to nearly $48 million in 2015, with particularly sharp increases in spending through Medicaid programs occurring in 2011, 2012, and 2014.

161. Janssen devoted enormous resources to its promotional scheme. [redacted] On information and belief, Janssen committed millions of additional dollars to carry out more than [redacted] sales visits to prescribers in New Jersey from just 2009 to 2015.

162. Janssen has devoted such substantial resources to detailing because it knows that this type of marketing works. The effects of sales visits on prescribing behavior are well-documented in the literature.[30] And Janssen's internal marketing plans confirm that [redacted] Moreover, the U.S. Surgeon General and the CDC have independently linked the national opioid crisis to the phenomenon of over-prescribing, and the Surgeon General has specifically found that the crisis "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain."[31]

163. Janssen's aggressive marketing -- including its use of unbranded websites, videos, and articles that deceptively promoted opioids in a general manner -- was designed to reach even those patients and prescribers whom Janssen did not directly target. These marketing efforts

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[30] See, e.g., Art Van Zee, MD, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," 99(2) Am J. Pub. Health 221 (2009).

[31] Letter from U.S. Surgeon General Vivek Murthy (Aug. 2016), https://turnthetiderx.org.

have contributed to opioids becoming entrenched as a routine treatment for chronic pain conditions, despite their serious risks and the absence of evidence that they improve patients' pain and quality of life over the long term. According to the CDC, opioid prescribing in New Jersey rose steadily from a rate of 54.7 prescriptions per 100 persons in 2006 -- the earliest year for which data are available -- to a peak of 61.5 prescriptions per 100 persons in 2011. Unsurprisingly, the National Institute on Drug Abuse has confirmed that greater rates of opioid prescribing have led to "widespread diversion and misuse" of prescription opioids. Between 21 and 29 percent of patients prescribed opioids for chronic pain misuse them, and approximately 4 to 6 percent of those individuals ultimately transition to heroin.[32]

164. In New Jersey, while the State's years-long efforts to curb overprescribing have recently borne some fruit, prescribing rates -- as measured in morphine milligram equivalent ("MME") -- stubbornly remained constant or even increased in a majority of counties through 2016. The problem of overprescribing is particularly acute in seven New Jersey counties -- Atlantic, Burlington, Cape May, Camden, Cumberland, and Gloucester -- all of which had prescribing rates of between 74 and 92 opioid prescriptions per 100 persons in 2016, compared to a national average of 66.5 prescriptions per 100 persons.

165. The consequences of over-prescribing can be deadly. According to the CDC, opioid overdoses resulted in 42,000 deaths nationwide in 2016, the last year for which data are available, and 40% of all opioid overdose deaths involve a prescription opioid. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2016 than 1999.

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[32] National Institutes of Health, National Institute on Drug Abuse, "Opioid Overdose Crisis," https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

According to the most recent data from the National Institute on Drug Abuse, New Jersey has continued to be particularly hard hit by the opioid epidemic. In 2016, there were 1,409 opioid-related overdose deaths in New Jersey, which, at a rate of 16 deaths per 100,000 persons, is a death toll that is 20% higher than the national average.

166. According to national 2009 data analyzed by the National Institute on Drug Abuse, overdose deaths represent only the tip of the iceberg. For every overdose death that year, there were nine abuse treatment admissions, thirty emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users of opioids. In New Jersey, opioid-related emergency department visits doubled between 2005 and 2014 and rose another 13% in 2015. Law enforcement officers and emergency medical technicians administered naloxone -- the emergency antidote to opioid overdoses -- more than 14,300 times in New Jersey in 2017 alone, a 177% increase since its use was approved in the State in 2014. According to a 2015 report by a national economic consulting firm, New Jersey's annual healthcare costs related to opioid abuse were estimated to exceed $683 million.

167. Rising opioid use, abuse, and addiction have had negative social and economic consequences far beyond overdoses and hospital visits. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with the use of prescription opioids.[33] The data indicate that labor force participation is lower and has fallen more in areas with a high rate of opioid prescriptions. These conclusions hold even when accounting for demographic, geographic, and other variables.

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[33] Alan B. Krueger, "Where Have All the Workers Gone?," Princeton University and National Bureau of Economic Research (Oct. 4, 2016).

168. The deceptive marketing and consequent overprescribing of opioids also have had a significant detrimental impact on young people in New Jersey. The overprescribing of opioids for chronic pain has given children access to opioids, nearly all of which were prescribed for adults in their household. In New Jersey, roughly one in four teenagers has abused prescription drugs, according to 2012 data.

169. Even infants have not been spared the impact of widespread opioid use and 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," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born and 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 neurological 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.

170. According to an analysis by NJ.com, 6.4 out of every 1,000 babies in New Jersey were born with NAS in 2014 -- more than double the 2008 figure. The problem is particularly acute in Atlantic, Cape May, and Cumberland counties, where, in 2014, more than one out of every fifty babies was born addicted to opioids.

171. Opioid addiction now outpaces other forms of addiction in demand for substance abuse treatment, and treatment providers are struggling to keep up. In 2016, prescription opioid and heroin abuse accounted for half of the substance abuse treatment admissions (including

admissions for alcohol abuse) in New Jersey -- more than 38,300 -- and accounted for the overwhelming majority of drug abuse admissions. Yet, the demand for treatment far outstrips the supply. The New Jersey Department of Human Services estimates that approximately 37,500 New Jersey residents needed and wanted substance abuse treatment in 2016, but did not receive it.

172. Janssen's false and misleading promotion of opioids for routine pain treatment has also contributed to expanding the market for opioids to new patients, fueling a new wave of addiction, abuse, and injury. Researchers have estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

173. Various studies report that as many as 80% of heroin addicts used prescription opioids before crossing over to heroin. In New Jersey, too, many of those who have overdosed started out on opioids with a prescription to treat chronic pain. Although prescribed opioids are prized among drug abusers because they are legal and predictable (i.e., the dose is clearly specified), recent years have seen a surge in prescription opioid abusers shifting to heroin because it is cheaper and easier to obtain than prescription opioids.

174. An even more sinister problem stemming from the prescription opioid epidemic involves fentanyl -- a powerful opioid carefully prescribed for cancer pain or in hospital settings. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. Drug dealers are mixing fentanyl into heroin because it can be cheaply produced and creates an intense high, and patients who moved from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. In 2015, 72% of heroin seized by law enforcement authorities in New Jersey was adulterated with fentanyl.

175. In addition to presenting heightened risks to persons addicted to opioids, the rise in the criminal market for opioids has burdened the State with increased law enforcement costs.

176. In all, the CDC estimates the national economic burden of the opioid crisis at approximately $78.5 billion annually, with over one-third of that amount due to increased healthcare and substance abuse treatment costs, and approximately one-quarter of that amount borne by the public sector in healthcare, substance abuse treatment, and criminal justice costs.

2. Janssen's Deceptive Marketing Has Burdened the State of New Jersey with Direct Financial Costs.

177. The State has been damaged through the payment of false claims for chronic opioid therapy under: (a) the State's Medicaid programs; (b) the State's employee and retiree health plans; and (c) the State's Workers' Compensation Program. The State has also been damaged by the payment of additional claims for drugs and medical services to treat conditions and injuries caused by chronic opioid use. These include treatments for neo-natal abstinence syndrome, addiction, and drug overdose.

a. The State's Spending on Opioids under Comprehensive Healthcare Plans.

178. Commensurate with Janssen's heavy promotion of opioids and the resultant, massive upswing in prescribing of opioids nationally and in New Jersey, State spending on opioids -- through claims paid by its Medicaid and Workers' Compensation programs -- has risen dramatically between 2009 and 2014, with particularly sharp increases, year-over-year, in 2011, 2012, and 2014.

(1) New Jersey Medicaid

179. The State provides comprehensive healthcare benefits, including prescription drug coverage, to low- and moderate-income residents through the New Jersey Medicaid Program. Approximately 1.94 million New Jersey residents are enrolled in New Jersey Medicaid; the State

funds prescription drug benefits for approximately 1.6 million of these enrollees. New Jersey Medicaid is currently administered through five managed care organizations -- Horizon NJ Health, United HealthCare Community Plan, Amerigroup New Jersey, Inc., Wellcare, and Aetna Better Health of New Jersey (collectively "the Medicaid Contractors" or "MCOs") -- which are paid a capitated rate, per beneficiary on a monthly basis, to provide the services covered under the State's Medicaid Plan.

180. Under the State's contract with the Medicaid Contractors, the Contractors are required to provide healthcare services and products to program beneficiaries "in accordance with medical necessity." "Medically necessary services" are those that:

> can be safely provided, . . . consistent with the diagnosis of the condition and appropriate to the specific medical needs of the enrollee and . . . generally recognized by the medical scientific community as effective . . . . Medically necessary services provided must be based on peer-reviewed publications, expert pediatric, psychiatric, and medical opinion, and medical/pediatric community acceptance.

181. These services include opioids prescribed by providers as well as office visits for pain management (including toxicology screens) and treatments related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction.

182. The Medicaid Contractors enlist healthcare providers ("Medicaid Providers") -- including doctors and pharmacies -- to provide services to New Jersey Medicaid beneficiaries. Among other things, these Medicaid Providers agree to comply with all State and federal Medicaid requirements under a Provider Agreement that is "subject to the applicable material terms and conditions of the contract between the Contractor and the State and shall also be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon the Contractor."

183. Opioids are only dispensed based on a licensed medical practitioner's prescription, which a practitioner must not write without first examining and diagnosing a patient. A Medicaid Provider submits a standardized form -- the CMS 1500 form -- to the Medicaid Contractor seeking reimbursement for such an office visit. By submitting a CMS 1500 form, the signatory certifies "that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction." Pharmacies participating in Medicaid submit their requests for reimbursement of prescriptions electronically, using the NCPDP v.D.0 format.

184. The Medicaid Contractor verifies the validity of each claim and confirms compliance with program requirements. It submits a record of each payment -- called an Encounter Report -- to the State. The Encounter Report reflects the nature of the service provided and the Contractor's certification that the service was covered by the State Medicaid Plan and therefore medically necessary. The Encounter Reports are used to calculate and adjust, on a semi-annual basis, the capitated rates that the State pays its Medicaid Contractors. Where utilization rates or costs rise, the State's capitated rates rise, too.

185. The New Jersey Department of Human Services, Division of Medical Assistance & Health Services also administers fee-for-service benefits for certain New Jersey Medicaid patients who are ineligible for those benefits through an MCO.

(2) The State Employee Health Plans

186. The State provides comprehensive healthcare benefits, including prescription drug coverage, to its current and retired employees and their dependents through two programs: the State Health Benefits Program and the School Employees' Health Benefits Program (collectively, the "Employee Health Plans"). Approximately 830,000 persons are enrolled in

these plans. The Employee Health Plans are self-funded, meaning that the State bears the charges for all services and products used by beneficiaries.

187. The medical benefits provided to State employees are administered by two private companies: Horizon and Aetna. Employees are offered an array of plans, which are structured as preferred provider organizations ("PPOs") and health maintenance organizations ("HMOs"). The plans vary in terms of flexibility and cost (i.e., employee contributions, deductibles, and co-payments), but coverage under all plans is restricted to medically necessary care, which is defined by Horizon as a service or supply that it is "safe and effective for its intended use," that is the "most appropriate level of service or supply considering the potential benefits and harm to the patient," and that is "known to be effective in improving health outcomes," including through "scientific evidence" demonstrating efficacy. Aetna uses a substantially similar definition, covering as medically necessary treatments that are "clinically appropriate," supported by "generally accepted standards of medical or dental practice," supported by "credible scientific evidence," and cost-effective when compared to alternatives likely to produce the same result.

188. Such care includes not only opioids prescribed by providers, but office visits for pain management (including toxicology screens) and treatments related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction.

189. The providers participating in the Employee Health Plans use the CMS 1500 form when seeking payment for office visits, thereby certifying that the services provided were "medically indicated and necessary" to the health of the beneficiary. The claims are reviewed by the administrators, paid, and then forwarded to the State for reimbursement.

190. State employees' prescription drug benefits were administered by Express Scripts between 2010 and 2017, and by Optum Rx thereafter and through the present. These State

Pharmacy Benefits Managers ("PBMs") cover all medically necessary and appropriate prescription drugs for plan participants. The terms of coverage include prescription drugs that meet FDA approved indications, that are safe and effective for their intended use, that are most appropriate considering potential benefits and harms to the patient, and that are known to be effective in improving health outcomes. That a practitioner prescribes a certain drug is not alone sufficient to make the prescription "medically necessary and appropriate."

191. Pharmacists providing services for the Employee Health Plans use the NCPDP v.D.0 format to submit claims for prescription drugs to the PBM. The PBM pays the pharmacies for all prescriptions that comply with plan guidelines. The claims are then submitted to the State for reimbursement.

(3) The false claims against these State-funded comprehensive health benefits plans

192. Most long-term use of opioids to treat chronic pain is not medically necessary as defined by the State's comprehensive health benefits plans. As described above in Section D, the long-term benefit of such use is not supported by substantial scientific evidence and is generally not the most appropriate treatment for moderate, chronic pain considering potential benefits and harms. Yet Janssen engaged in a marketing campaign designed to encourage prescribers to use opioids as the first line of treatment for chronic pain. In doing so, Janssen induced prescribers and pharmacies to submit claims to its health plans that were false by:

(a) causing prescribers to write prescriptions for chronic opioid therapy supported by Janssen's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs; and

(b) causing prescribers to certify that these prescriptions were "medically necessary" when, in fact, the prescriptions were not supported by substantial scientific evidence showing that the risks associated with the drugs were outweighed by benefits, that the drugs were safe and effective for long-term, chronic use, or that long-term, chronic use would not render the patient dependent on continued and increased use of the drugs.

193. For the majority of patients experiencing moderate chronic pain, long-term opioid use should not have been prescribed because it was neither necessary nor appropriate. As such, long-term opioid prescriptions would not have been eligible for reimbursement. The State would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage. For example, the State paid the following Employee Health claims:

(a) New Jersey Employee Health Patient A was diagnosed with lumbosacral and cervical root lesions (nerve root disorder) and joint pain in multiple sites. Patient A received 87 Nucynta prescriptions and 24 Nucynta ER prescriptions -- totaling a 2,473 day supply -- between September of 2010 and July of 2017, at a cost of $50,378.25 in claims paid by the State's managed care contractor and subsequently presented to the State. These prescriptions were written by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(b) New Jersey Employee Health Patient B was diagnosed with lumbosacral root lesions (nerve root disorder), lumbago (lower back pain), and joint pain in multiple sites. Patient B received 73 total prescriptions for Nucynta or Nucynta ER -- totaling a 1,736 day supply -- between March of 2010 and December of 2017, at a cost of $35,124.21 in claims paid by the State's managed care contractor and subsequently presented to the State. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(c) New Jersey Employee Health Patient C was diagnosed with myalgia and myositis (muscle pain and inflammation) and sacroiliitis (pelvic joint inflammation). Patient C received 125 total prescriptions for Nucynta or Nucynta ER -- totaling a 2,799 day supply -- between February of 2014 and December of 2017 at a cost of $48,311.88 in claims paid by the State's managed care contractor and subsequently presented to the State. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(d) New Jersey Employee Health Patient D was diagnosed with cervicalgia (pain in the upper back and neck region) and a neck sprain. Patient D received 133 total prescriptions for Nucynta or Nucynta ER -- totaling a 2,660 day supply -- between October of 2011 and September of 2017 at a cost of $67,376.61 in claims paid by the State's managed care contractor and subsequently presented to the State.

These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(e) New Jersey Employee Health Patient E was diagnosed with lumbago (lower back pain) and lumbosacral spondylosis (deterioration of the lower spine). Patient E received 76 total prescriptions for Nucynta or Nucynta ER -- totaling a 1,900 day supply -- between August of 2011 and September of 2017 at a cost of $44,012.96 in claims paid by the State's managed care contractor and subsequently presented to the State. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted]

(f) New Jersey Employee Health Patient F was diagnosed with myalgia and myositis (muscle pain and inflammation) and psoriatic arthropathy (joint disease related to psoriasis). Patient F received 64 total prescriptions for Nucynta or Nucynta ER -- totaling a 1,535 day supply -- between March of 2010 and December of 2017 at a cost of $35,277.99 in claims paid by the State's managed care contractor and subsequently presented to the State. Patient F was over 60 years-old in March of 2010, and Patient F spent $1,153.67 in out-of-pocket costs for these prescriptions. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(g) New Jersey Employee Health Patient G was diagnosed with rheumatoid arthritis. Patient G received 35 Nucynta prescriptions -- totaling a 1,030 day supply -- between December of 2014 and August of 2017 at a cost of $17,429.91 in claims paid by the State's managed care contractor and subsequently presented to the State. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

(h) New Jersey Employee Health Patient H was diagnosed with myalgia and myositis (muscle pain and inflammation). Patient H received 36 total prescriptions for Nucynta or Nucynta ER -- totaling a 1,020 day supply -- between April of 2012 and September of 2016 at a cost of $12,910.48 in claims paid by the State's managed care contractor and subsequently presented to the State. Patient H was over 60 years-old in April 2012, and Patient H spent $413.84 in out-of-pocket costs for the Nucynta prescriptions. These prescriptions were written primarily by a practitioner who was detailed by Janssen [redacted] times from [redacted].

194. Based on a preliminary review, the State spent more than $178 million for over 307,000 claims for opioid prescriptions submitted to the Employee Health Plans from 2010 to 2017. This includes approximately $12.5 million for over 41,000 claims for Nucynta or Nucynta

ER. Moreover, in many instances, Nucynta or Nucynta ER appear to have been used frequently as one component of a patient's larger opioid regimen. For example, a preliminary analysis of New Jersey Medicaid paid claims data indicates that over 90% of beneficiaries who received a 90-day or more supply of opioids that included at least one claim for Nucynta or Nucynta ER subsequently transitioned to a separate Schedule II opioid after having received the Nucynta or Nucynta ER prescription. The State estimates that a substantial percentage of these claims -- as well as similar claims filed under the State Employee Health Plans -- were not medically necessary and were thus false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

195. Based upon a preliminary review, the State's largest Medicaid MCO spent more than $106 million for over 2.8 million claims for opioid prescriptions submitted during the period January 2009 through June 2017. This includes approximately $546,000 for the Nucynta line of products. The State estimates that hundreds of thousands of opioid claims were submitted during the same time-period to the State's other Medicaid MCOs, and that a substantial percentage of these claims were medically unnecessary and were thus false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

196. As a result of Janssen's deceptive marketing, New Jersey patients who used opioids long-term to treat chronic pain required additional services and supplies -- in the form of office visits, toxicology screens, hospitalization for overdoses and infections, rehabilitation and

addiction-related therapy, and other treatments -- necessitated by the adverse effects of opioids. The State incurred additional costs in providing these services and supplies.

b. The State's Spending Under the Workers' Compensation Program.

197. When a State employee is injured on the job, he or she may file a claim for workers' compensation; if the injury is deemed work-related, the State is responsible for paying its share of the employee's medical costs and lost wages. The State pays these claims through a self-funded program that is managed by Horizon Casualty Services ("HCS").

198. The State's Workers' Compensation Program has three overarching goals: to ensure prompt medical treatment for workers injured on the job; to maximize the likelihood that those workers can return to work; and to compensate workers for injuries that cannot be cured and for wages lost during periods of disability.

(1) Medical and prescription drug benefits under the Workers' Compensation Program

199. HCS's provider agreement limits covered, or reimbursable, services and supplies to those that are: (a) causally linked to the worker's injury or condition; (b) medically necessary; and (c) reasonable. Consistent with the goals of the program, services and supplies are also intended to yield "maximum medical improvement," which is achieved when "[t]he patient has reached maximal benefit from a curative treatment plan, or further medical treatment will not provide any improvement in the patient's current condition."

200. The State's Workers' Compensation Program covers all costs associated with treatment for workplace injuries and conditions. This coverage includes opioids, when prescribed by a healthcare provider as medically necessary, and also includes treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment.

201. Janssen's promotional conduct caused prescribers and pharmacies to submit, and the State to pay claims to the State's Workers' Compensation Program that were false by:

(a) causing prescribers to write prescriptions for chronic opioid therapy supported by Janssen's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs; and

(b) causing prescribers to certify that these prescriptions and associated services were medically necessary, likely to improve functional capacity, or otherwise reasonably required, when, in fact, the prescriptions were not supported by substantial scientific evidence showing that the risks associated with the drugs were outweighed by benefits, that the drugs were safe and effective for long-term, chronic use, or that long-term, chronic use would not render the patient dependent on continued and increased use of the drugs.

202. In many instances, the long-term use of opioids to treat moderate, chronic pain is not medically necessary, reasonably required or appropriate because: (a) the risks do not materially exceed the benefits; and (b) such use is not supported by substantial scientific evidence demonstrating that they improve physiological function or are otherwise safe and effective. In fact, the long-term use of opioids to treat chronic pain is antithetical to the purposes of the State's Workers' Compensation Program: long-term use of opioids can cause hyperalgesia (increased sensitivity to pain) and cognitive impairment without improving physiological function.

203. In addition to these prescription costs, the State has paid for medical care and prescriptions necessitated by long-term opioid use and abuse including addiction treatment.

(2) Lost wages and disability

204. A growing body of research shows that long-term opioid use to treat chronic pain is associated with slower returns to work. On information and belief, the State has paid claims for lost wages attributable, in whole or in part, to opioid-related disability.

(3) The false claims against the State's Workers' Compensation fund

205. The following is a representative sample of claims submitted to the State's Workers' Compensation Program:

(a) New Jersey Workers' Compensation Patient A was diagnosed with a sprain of the lumbar region and a sprain of the sacrum. Patient A received 1 Nucynta prescription and 67 Nucynta ER prescriptions -- totaling a 1,830 day supply -- between September of 2011 and June of 2017. The State has paid $38,155.81 for Patient A's medical care. These prescriptions were written by a practitioner who received [redacted] visits from Janssen from [redacted]

(b) New Jersey Workers' Compensation Patient B was diagnosed with a neck sprain and hip contusion and received 3 Nucynta prescriptions and 57 Nucynta ER prescriptions -- totaling a 1,729 day supply -- between October of 2011 and October of 2016. The State has paid $27,838.37 for Patient B's medical care. These prescriptions were written by a practitioner who received [redacted] visits from Janssen detailers [redacted]

(c) New Jersey Workers' Compensation Patient C was diagnosed with a shoulder/arm contusion and a knee contusion and received 40 Nucynta prescriptions -- totaling a 1,585 day supply -- between October of 2009 and December of 2016. The State has paid $2,020.87 for Patient C's medical care. These prescriptions were written by a practitioner who received [redacted] visits from Janssen detailers from [redacted]

206. The State paid these prescription claims believing that they were medically necessary and therefore covered by the State's Workers' Compensation Program. Long-term opioid use is generally neither necessary nor the most appropriate treatment for moderate, chronic pain. Thus, these claims -- and their attendant and consequential costs -- were ineligible for payment.

207. Based on a preliminary review, the State spent more than $5.6 million for over 11,900 claims for opioid prescriptions submitted to the State's Workers' Compensation Program during the period January 2009 to August 2017. This includes approximately $257,000 for approximately 926 total claims for Nucynta or Nucynta ER. The State estimates that a

substantial percentage of these claims were not medically necessary and were thus false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medication and physical therapy.

3. Misrepresentations Regarding Medical Necessity Were Material to the State's Decision to Pay These Claims.

208. That the State would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Janssen's marketing scheme. As described above, Janssen intentionally designed its marketing scheme [redacted].

209. Janssen's marketing scheme was designed to achieve the basic goal of inducing as many prescriptions as possible for its Nucynta line of products. Janssen spent millions of dollars to carry out that scheme. A foreseeable -- and largely inevitable -- consequence of that scheme was that government payors, such as the State, would ultimately pay for long-term prescriptions of opioids to treat chronic pain despite the absence of substantial scientific evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

210. Janssen's misrepresentations caused the State to pay claims for opioids for chronic pain and, subsequently, to bear consequential costs in treating overdose, addiction, and

other side effects of opioid use. But for Janssen's fraudulent and deceptive marketing campaign, the State would not have been presented with, or paid, many of the claims it paid for opioids to treat moderate, chronic pain.

211. Janssen's misrepresentations and omissions related to the State's requirement that medical treatments be medically necessary -- a condition of coverage for any medical treatment under the State's comprehensive health plans and Workers' Compensation Program. But for Janssen's fraudulent and deceptive marketing, prescribers would have more accurately understood the risks and benefits of long-term opioid use and would not have prescribed opioids as medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to opioids, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters; those misrepresentations went to the core of a prescriber's decision-making.

212. Since becoming aware of the growing use and abuse of opioids in New Jersey, the State has taken numerous steps to address the problem by educating prescribers and consumers about the risks and benefits of opioids, restricting prescribing, reducing the number of opioid pills in circulation, and increasing the coverage and availability of treatment for opioid overdose and addiction. The State's efforts include:

(a) establishing, and then mandating use of, a Prescription Monitoring Program by prescribers and pharmacists to help providers determine what other opioids a patient has been prescribed;

(b) making prescription pads more difficult to counterfeit;

(c) publishing best practices for pharmacists for secure handling and dispensing of prescription drugs to reduce diversion;

(d) providing immunity from arrest and prosecution for a use or possession charge when a person seeks medical assistance for overdose;

(e) presenting the 2016 CDC Guideline to the State's Medicaid vendors and referring prescribers to the Guideline;

(f) setting a new, five-day limit on initial prescriptions of opioids for acute pain;

(g) providing funding and authority for healthcare providers to prescribe, and first responders to administer, overdose antidotes; and

(h) requiring insurers to cover 180 days of addiction treatment.

213. The State also has taken concrete steps to limit the prescribing of long-term opioid use for chronic pain. The New Jersey Legislature passed legislation in February 2017 that requires practitioners to take certain affirmative steps before issuing an initial opioid prescription to treat chronic pain. The practitioner is required to prescribe the lowest effective dose and to disclose and discuss:

- risks of addiction and overdose even when the drug is taken precisely as prescribed;
- alternative therapies; and
- the reasons why the prescription is necessary.

Before issuing a third re-fill prescription, practitioners are required to enter into a "pain management agreement" with patients which, among other things:

- documents a pain management plan;
- identifies other non-opioid medication and modes of treatment that are part of the pain treatment program; and
- specifies measures that will be used to confirm proper prescription use, like toxicology screening and pill-counting.

Where opioid use is continuous and long-term, the practitioners must:

- assess the patient before issuing each renewal prescription;
- document the course of treatment, the patient's progress, and new information about the etiology of the pain every three months;
- assess whether the patient is experiencing problems associated with physical and psychological dependence and document the assessment;

- make periodic efforts to taper the dosage or otherwise reduce or discontinue opioid use; and
- refer the patient to a pain management or addiction specialist for independent evaluation or treatment.

214. The State Board of Medical Examiners' implementing regulations took effect in March 2017 and were consistent with the standards set forth in the 2016 CDC Guideline.

215. The State has also taken steps to limit its own coverage of long-term opioid use for chronic pain. The State presented the 2016 CDC Guideline to Medicaid vendors in April 2016. The State has also ratified coverage restrictions proposed by Express Scripts, applicable to the Employee Health Plans, for the purpose of monitoring and creating safer opioid utilization. Similarly, Optum Rx employs an opioid risk management program that is aligned with the 2016 CDC Guideline and designed to minimize opioid misuse and addiction.

4. Janssen's Deceptive Marketing Has Caused Financial Injury to New Jersey Consumers.

216. Consumers, private employers, and insurers are paying costs similar to, but far greater than, the State for opioid prescriptions. These costs are paid out-of-pocket by individuals who are uninsured or who are insured through plans that require pharmacy co-payments; by employers that provide health insurance or self-fund healthcare coverage for their employees; and by insurance companies that provide managed care and traditional point-of-service plans to individuals, corporations, and political subdivisions. According to a 2015 report by a national economic consulting firm, New Jersey's annual healthcare costs related to opioid use and abuse were estimated to exceed $683 million in 2007, and -- because the opioid crisis has worsened substantially since then -- the report estimates that those numbers present a conservative estimate of costs incurred in more recent years.

217. Because the State requires private employers and political subdivisions to provide workers' compensation to employees injured in the course of work, private employers and political subdivisions are incurring costs through their workers' compensation programs, too. According to a 2011 study by the National Council on Compensation Insurance ("NCCI"), approximately 38% of pharmacy costs in workers' compensation cases are for opioids and opioid combinations, amounting to approximately $1.4 billion in that year nationally. New Jersey's pro rata share of that amount is about $42 million.

G. Janssen Knew that Its Marketing of Opioids Was False and Misleading, and the Company Fraudulently Concealed Its Misconduct.

218. 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 twenty 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, both the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of Janssen's misrepresentations.

219. 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, and also to conceal or minimize questions or concerns raised by prescribers about addiction. Janssen disguised its own 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 Janssen's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Janssen masked its role in shaping, editing, and approving the content of this information. And, as described above, Janssen's sales force made numerous misrepresentations to prescribers in the privacy of one-on-one visits that were misleading and inconsistent with the labeling of Nucynta and Nucynta ER.

220. Janssen thus successfully concealed -- from the medical community, patients, and the State -- facts sufficient to arouse suspicion of the claims now asserted. 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 ONE
VIOLATIONS OF THE CONSUMER FRAUD ACT, (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

221. Plaintiffs reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

222. The CFA makes it unlawful for a business to engage in "deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with intent that others may rely upon such concealment, suppression or omission" in connection with the sale or advertisement of merchandise, including pharmaceutical products. N.J.S.A. 56:8-2.

223. The CFA defines "advertisement" as:

> . . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to

> induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . . .
>
> [N.J.S.A. 56:8-1(a).]

224. The CFA defines "merchandise" as including "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

225. The CFA defines "sale" as "any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute." N.J.S.A. 56:8-1(e).

226. The CFA defines "person" as "any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trustent thereof." N.J.S.A. 56:8-1(d).

227. Janssen is a "person" as defined by the CFA, and Janssen has advertised, offered for sale, and sold "merchandise" as defined by the CFA.

228. The CFA makes it unlawful for a business to engage in any unconscionable commercial practice in connection with the sale or advertisement of pharmaceutical products. N.J.S.A. 56:8-2.

229. Pharmaceutical manufacturers, like Janssen, cannot engage in practices in their marketing, promotion, sale, and distribution of prescription drugs that are in violation of the CFA.

230. Janssen violated N.J.S.A. 56:8-2 by engaging in the following unconscionable commercial practices and acts of deception:

(a) Engaging in deceptive, fraudulent, false, and misleading marketing that was unsupported by substantial scientific evidence in violation of 21 C.F.R. § 202.1(e);

(b) Engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(c) Promoting the purported advantages of opioids over other pain relief products, including but not limited to, the risks and/or benefits of opioids in comparison to NSAIDs, without substantial scientific evidence to support those claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(d) Promoting opioid use for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances;

(e) 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;

(f) Targeting opioid-naïve patients and patients using immediate release opioids for conversion to Janssen's extended release opioid products;

(g) Using unbranded marketing, front groups, key opinion leaders, and peer-to-peer speakers to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed;

(h) Making and disseminating false or misleading statements about the use of opioids to treat chronic pain;

(i) Promoting the misleading concept of pseudoaddiction and concealing the risk of opioid addiction by emphasizing technical distinctions between addiction and dependence;

(j) Deceptively claiming or implying that chronic opioid use would improve patients' function and quality of life; and

(k) Deceptively claiming or implying that opioid addiction can be avoided or successfully managed through the use of screening and other tools.

231. These acts or practices may be deemed unconscionable and unfair in that they violate notions of good faith, honesty in fact and observance of fair dealing; they have the capacity to mislead both prescribers and patients; and they offend public policy reflected in: (a) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R.

§ 202.1(e); (b) the CFA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace; and (c) State legislation and standards of practice related to controlled substances -- including but not limited to the prescribing and dispensing standards set forth in N.J.A.C. 13:35-7.6 -- that seeks to minimize the risk of addiction to and abuse of controlled substances.

232. These acts or practices were unconscionable because they 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 and addicted, such that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

233. Each unconscionable commercial practice and act of deception by Janssen constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

COUNT TWO
VIOLATIONS OF THE CONSUMER FRAUD ACT
(MISREPRESENTATIONS AND OMISSIONS OF MATERIAL FACTS)

234. Plaintiffs reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

235. At all times relevant to this Complaint, Janssen violated N.J.S.A. 56:8-2 by making misrepresentations, including, but not limited to, the following:

(a) Misrepresenting the risk of opioid addiction and abuse, including by stating that Nucynta and Nucynta ER were less addictive, had fewer or no withdrawal symptoms, had non-opioid properties, were milder than other opioids, were unlike traditional opioids, or were less likely to be abused than other opioids;

(b) Failing to correct prior misrepresentations and omissions about the risks and benefits of opioids; and

(c) Misrepresenting the mechanism of action of Nucynta and Nucynta ER to imply that those drugs were more effective, less addictive, and safer than other opioids.

236. At all times relevant to this Complaint, Janssen violated N.J.S.A. 56:8-2 by knowingly concealing, suppressing, or omitting material facts with the intent that others rely upon those concealments, suppressions, or omissions, including, but not limited to, the following:

(a) Omitting or concealing material facts regarding the lack of evidence demonstrating the benefits of opioids for treatment of chronic pain;

(b) Omitting or concealing material facts regarding the risks associated with chronic opioid therapy, including the risks of addiction and abuse;

(c) Omitting or concealing material facts regarding the risks of chronic use of Nucynta and Nucynta ER; and

(d) Omitting or concealing material facts regarding the mechanism of action of Nucynta and Nucynta ER to imply that those drugs were more effective, less addictive, and safer than other opioids.

237. Janssen's statements about the use of opioids were not supported by or were contrary to substantial scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence. Janssen's material omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading because they were incomplete. Finally, at the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, Janssen knowingly failed to include material facts about the risks and benefits of opioid use, particularly with respect to long-term use, and Janssen intended that the recipients of its marketing messages would rely upon those omissions.

238. Each misrepresentation and knowing omission by Janssen constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

COUNT THREE
VIOLATIONS OF THE CONSUMER FRAUD ACT
(CAUSING INJURY TO SENIOR CITIZENS)

239. Plaintiffs reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

240. The CFA, N.J.S.A. 56:8-14.3, provides for additional penalties for pecuniary injury to a senior citizen or a person with a disability:

> In addition to any other penalty authorized by law, a person who violates the provisions of [the CFA] shall be subject to additional penalties as follows:
>
> (1) A penalty of not more than $10,000 if the violation caused the victim of the violation pecuniary injury and the person knew or should have known that the victim is a senior citizen . . .; or
>
> (2) A penalty of not more than $30,000 if the violation was part of a scheme, plan, or course of conduct directed at senior citizens . . . in connection with sales or advertisements.

241. At all relevant times, Janssen promoted its opioid products for use by "senior citizens" within the definition of the CFA, N.J.S.A. 56:8-14.2.

242. At all relevant times, Janssen has caused pecuniary injury to senior citizens within the definition of the CFA, N.J.S.A. 56:8-14.2.

243. Janssen targeted senior citizens as part of its strategy to continue expanding its market share in the sale of opioids, and, as such, its revenue. Janssen's conduct was part of a promotional scheme explicitly directed at senior citizens. Janssen knew that its conduct was directed at senior citizens, and its conduct caused senior citizens to suffer pecuniary injury.

244. Among other things, Janssen's conduct included:

(a) Targeting prescribers who participate in the long-term care market;

(b) Affirmatively educating prescribers about Medicare Part D coverage for opioids in an effort to induce opioid prescriptions to senior citizens;

(c) Targeting seniors through the creation and dissemination of misleading publications that overstate the benefits and trivialize the risks of opioid use; and

(d) Targeting prescribers and caregivers in the long-term care and nursing home markets with misleading publications designed to propagate dissatisfaction with existing pain management and to promote opioid use among seniors.

245. Each instance in which Janssen engaged in deceptive practices in the marketing and sale of opioids and caused pecuniary injuries to senior citizens entitles Plaintiffs to recovery of additional penalties as provided by N.J.S.A. 56:8-14.3.

COUNT FOUR
VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT

246. Plaintiffs reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

247. A person is liable under the FCA, N.J.S.A. 2A:32C-3, when that person:

(1) knowingly presents or causes to be presented to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval; [or]

(2) 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 State.

248. The FCA defines a "claim" as "a request or demand, under a contract or otherwise, for money, property, or services that is made to any employee, officer, or agent of the State, or to any contractor, grantee, or other recipient if the State provides any portion of the money, property, or services requested or demanded, or if the State will reimburse the contractor, grantee, or other recipient for any portion of the money, property, or services requested or demanded." N.J.S.A. 2A:32C-2.

249. Janssen's practices, as described in the Complaint, violated N.J.S.A. 2A:32C-3. Janssen, through its 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 false statements to get false or fraudulent claims paid or approved by the State.

250. Janssen 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, misleading, or unsupported by substantial scientific evidence, and were made for the purpose of inducing the State, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. In addition, Janssen knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

251. Janssen's scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to the State's Medicaid, Employee Health, and Workers' Compensation plans for payment. Doctors, pharmacists, other healthcare providers, and/or other agents of the health plans and Workers' Compensation Program expressly or impliedly certified to the State that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Janssen through the marketing campaign described above in Sections B through G. To the extent that such prescribing was considered customary or consistent with generally accepted medical standards, those standards were influenced and ultimately corrupted by Janssen's deceptive marketing as well.

252. Janssen knew or should have known that, as a natural consequence of its 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 Janssen's fraud. The misrepresentations Janssen made and caused to be made were material to the State's decisions to pay the costs of long-term opioid use because they falsely suggested that such treatment was medically necessary.

253. The State has paid millions of dollars for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed -- or covered and reimbursed -- by State insurance plans but for Janssen's deceptive, fraudulent, and unlawful marketing practices.

254. The State has paid and will continue to pay consequential healthcare costs necessitated by Janssen's deceptive, fraudulent, and unlawful marketing practices: drugs for persons dependent upon and addicted to opioids and treatment costs for those dealing with addiction, overdose, and other adverse effects.

COUNT FIVE
PUBLIC NUISANCE
(INTEFERENCE WITH PUBLIC SAFETY, PEACE, COMFORT, AND CONVENIENCE THROUGH THE CREATION, EXPANSION, AND MAINTENANCE OF AN UNNECESSARY AND DANGEROUS MARKET FOR CONTROLLED SUBSTANCES)

255. Plaintiffs reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

256. Janssen's marketing and promotional activity has created -- or was a substantial factor in creating -- an unreasonable interference with rights common to the general public. Through the actions described in this Complaint, Janssen has significantly and adversely interfered with the public health, the public safety, the public peace, the public comfort, and the public convenience.

257. The Attorney General, as the modern representative of the sovereign, is empowered to vindicate those public rights. The Attorney General's sovereign interest in protecting the public safety and welfare is distinct from the private interest an individual may have in redressing a personal injury. Through this public nuisance claim, the Attorney General seeks to abate the nuisance resulting from Janssen's marketing and promotional activity; the Attorney General does not seek recovery for any individual harms caused by Nucynta or Nucynta ER or any other opioid product -- including harm resulting from any physical damage to property; personal physical illness, injury or death; pain and suffering, mental anguish or emotional harm; or loss of consortium or services.

258. Janssen's illegal and deceptive marketing of opioids for the treatment of chronic pain has interfered with the rights of the community at large by: (a) causing widespread dissemination of false and misleading information regarding the risks and benefits of opioids, including the use of opioids to treat chronic pain; (b) causing 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. In doing so, Janssen created and fueled an expanded, dangerous, and unnecessary market for prescription opioids that has placed millions of opioid pills unnecessarily and ill-advisedly into circulation in New Jersey and created and fueled a secondary, criminal market for opioids.

259. Janssen engaged in marketing and promotional conduct that was proscribed by the Consumer Fraud Act, as described in this Complaint. Janssen's marketing scheme recklessly endeavored to enlarge and supply a market in New Jersey for opioids -- drugs that the Legislature has explicitly identified as "controlled dangerous substances" subject to restricted access and monitoring because of their high potential for misuse, abuse, and diversion. Janssen's

conduct has resulted in a long-lasting and significant interference with the interests of the community at large.

260. At all times relevant to the Complaint, Janssen exercised control over the instrumentalities constituting the nuisance -- its marketing as conveyed through sales representatives, its paid speakers, and its branded and unbranded publications, which it created and/or disseminated. As alleged herein, Janssen created, or was a substantial factor in creating, the nuisance through multiple vehicles, including: (a) making [redacted] of in-person sales visits to New Jersey prescribers; (b) disseminating false or misleading advertisements and publications; (c) sponsoring, creating, and/or disseminating flawed and biased scientific research; and (d) sponsoring, creating, and/or disseminating false and misleading messages about opioids. To the extent Janssen collaborated with or worked through third parties, it adopted those third-party statements as its own by disseminating third-party publications, and/or exercising control over them by financing, reviewing, editing, or approving their materials.

261. Janssen's actions were a substantial factor in creating the public nuisance; without Janssen's actions, accepted medical standards and consumer views regarding the propriety of chronic opioid use would not have become so distorted, and the market for opioids would not have grown explosively.

262. The public nuisance was foreseeable to Janssen. Janssen knew that the Legislature has classified opioids as controlled dangerous substances under N.J.S.A. 24:21-6, and that their manufacture, distribution, and sale are strictly regulated by the State. Despite these known dangers, Janssen expressly set out to create a vastly expanded market for opioid use. Janssen could foresee that widespread problems would result from the expansion of the opioid market -- problems that have, in fact, materialized. Janssen was on notice and aware that its

marketing and promotional activities and its creation, expansion, and fueling of the market for opioids -- particularly for chronic use -- would cause a significant and unreasonable interference with public rights, as described in this Complaint.

263. This public nuisance can be abated -- in part -- through healthcare provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, proper disposal of unused opioids, implementation and maintenance of tools -- like the New Jersey Prescription Monitoring Program -- that can be used to halt the circulation and diversion of opioids that have flooded into New Jersey, expansion and maintenance of a public services infrastructure aimed at addressing the opioid epidemic, and other means.

COUNT SIX
PUBLIC NUISANCE
(INTERFERENCE WITH PUBLIC HEALTH, SAFETY, COMFORT AND CONVENIENCE BY CAUSING OVERPRESCRIBING AND OVERUSE)

264. Plaintiffs reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

265. Janssen, through the actions described in this Complaint, has created -- or was a substantial factor in creating -- an unreasonable interference with rights common to the general public. Through the actions described in this Complaint, Janssen has significantly and adversely interfered with the public health, the public safety, the public peace, the public comfort, and the public convenience.

266. 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.

267. The Attorney General, as the modern representative of the sovereign, is empowered to vindicate those public rights. The Attorney General's sovereign interest in protecting the public safety, health, and welfare is distinct from the private interest an individual may have in redressing a personal injury. Through this claim, the Attorney General seeks to abate Janssen's interference with rights common to the general public; the Attorney General does not seek recovery for any individual harms caused by Nucynta or Nucynta ER or any other opioid product -- including harm resulting from any physical damage to property; personal physical illness, injury or death; pain and suffering, mental anguish or emotional harm; or loss of consortium or services.

268. Janssen's illegal and deceptive marketing of opioids for the treatment of chronic pain has interfered with public rights, resulting in, among other things: (a) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (b) increased healthcare costs for individuals, families, employers, and the State; (c) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; and (d) the collective burdens placed on public services and goods, including healthcare systems, emergency services, law enforcement, and social services.

269. At all times relevant to the Complaint, Janssen's marketing substantially and unreasonably interfered in the enjoyment of these public rights by the State and its citizens. Janssen engaged in a pattern of conduct that: (a) overstated the benefits of chronic opioid therapy, including 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 opioid use.

270. Janssen's conduct was proscribed by statute -- including the Consumer Fraud Act, as described in this Complaint -- and has resulted in a long-lasting and significant interference

with the interests of the community at large, including by creating and maintaining a shift in the willingness of healthcare providers to prescribe -- and patients to take -- opioids for chronic pain, resulting in a dramatic increase in opioid prescribing, abuse, addiction, and other injuries described above.

271. At all times relevant to the Complaint, Janssen exercised control over the instrumentalities constituting the nuisance -- its marketing as conveyed through sales representatives, its paid speakers, and its branded and unbranded publications, which it created and/or disseminated. As alleged herein, Janssen created, or was a substantial factor in creating, the nuisance through multiple vehicles, including: (a) making [redacted] of in-person sales visits to New Jersey prescribers; (b) disseminating false or misleading advertisements and publications; (c) sponsoring, creating, and/or disseminating flawed and biased scientific research; and (d) sponsoring, creating, and/or disseminating false and misleading messages about opioids. To the extent Janssen collaborated with or worked through third parties, it adopted those third-party statements as its own by disseminating third-party publications, and/or exercising control over them by financing, reviewing, editing, or approving their materials.

272. Janssen's actions were a substantial factor in 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 Janssen's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in New Jersey would have been less severe.

273. The public nuisance was foreseeable to Janssen. As alleged herein, Janssen engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids, including for the treatment of 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. Janssen foresaw -- and, indeed, expressly set out to create -- a vastly expanded market for opioid use, including for the treatment of chronic pain. Janssen could also foresee that widespread problems of opioid addiction and abuse would result from the expansion of the opioid market -- problems that have, in fact, materialized. Janssen was on notice and aware of signs that the broader use of opioids was causing exactly the kinds of injuries described in this Complaint.

274. This public nuisance can be abated -- in part -- through the creation, expansion, and maintenance of public health and social services initiatives and programs aimed at halting and preventing the negative effects of the opioid crisis.

VI. PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Janssen:

(a) Finding that the acts and practices of Janssen constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;

(b) Permanently enjoining Janssen, its officers, directors, agents, employees and all other persons acting on its behalf and/or under its control from engaging in, continuing to engage in or doing any acts and practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including but not limited to, the acts and practices alleged in this Complaint, as authorized by the CFA, N.J.S.A. 56:8-8;

(c) Directing Janssen to disgorge all profits unlawfully acquired or retained, as authorized by the CFA, N.J.S.A. 56:8-8;

(d) Directing Janssen to pay the maximum statutory civil penalties for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13 and 56:8-14.3, and the FCA in accordance with N.J.S.A. 2A:32C-3;

(e) Directing Janssen to pay costs and fees including attorneys' fees for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A 56:8-11 and N.J.S.A 56:8-19, and the FCA, N.J.S.A. 2A:32C-8;

(f) Awarding judgment in favor of Plaintiffs and against Janssen on the Public Nuisance Count;

(g) Directing Janssen to abate the public nuisance its conduct has created, including paying costs associated with abatement and reimbursing expenses already incurred in abating the nuisance; and

(h) Granting such other relief as the interests of justice may require.

Dated: November 8, 2018
Newark, New Jersey

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ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

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(202) 408-4600

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of any other action pending in any other court of this State, other than Camden County v. Purdue Pharma L.P., et al., Dckt. No. 18cv11983 (D.N.J. filed July 23, 2018) and Cape May County v. Purdue Pharma L.P., et al., Dckt. No. L-000261-18 (Cape May County filed July 3, 2018). I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated.

Dated: November 8, 2018
Newark, New Jersey

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia A. Schiripo
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RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents submitted in the future in accordance with R. 1:38-7(b).

Dated: November 8, 2018
Newark, New Jersey

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ATTORNEY GENERAL OF NEW JERSEY
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By: Patricia A. Schiripo
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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Patricia A. Schiripo is hereby designated as trial counsel for the Plaintiffs in this action.

Dated: November 8, 2018
Newark, New Jersey

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