IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CJ-2017-816 Judge Thad Balkman William C. Hetherington Special Discovery Master

TRIAL BRIEF OF DEFENDANTS
JOHNSON & JOHNSON AND JANSSEN PHARMACEUTICALS INC.

REDACTED VERSION

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I. INTRODUCTION

The State's attempt to hold J&J and Janssen liable for the alleged $[redacted] billion cost of addressing its opioid abuse crisis over the next 30 years is both factually and legally unsupportable. Janssen marketed two Schedule II opioid pain medications in Oklahoma during the period involved in this case: a fentanyl-based skin patch called Duragesic and a tapentadol-based tablet called Nucynta. Janssen introduced Duragesic in 1991 and marketed it until 2005, when generic alternatives became available. Scaled-down marketing for Duragesic continued until early 2008, after which the product remained available for prescription but promotional marketing ceased. Janssen introduced Nucynta in an immediate-release/short-acting formulation in late 2009 and an extended-release/long-acting formulation (called Nucynta ER) in mid-2011. Janssen ceased marketing the Nucynta products in April 2015 after selling its rights in the medications to another company.

These Janssen medications bear no responsibility of any kind for Oklahoma's opioid abuse crisis. None occupied more than a miniscule share of opioid pain medication prescriptions written by Oklahoma doctors. Oklahoma Medicaid data, for example, will show that the combined share of Duragesic, Nucynta, and Nucynta ER prescriptions reimbursed by the State between 1996 and 2017 was just [redacted]. In addition, Janssen designed both medications to be difficult to abuse and unattractive to would-be abusers. The evidence will show that Janssen was successful in this regard—post-market surveillance data will show that Duragesic and the Nucynta products ranked consistently among the least abused, misused and diverted of all opioid medications.

The State takes potshots at Janssen's marketing, but those cannot change the fact that Janssen's medications constituted a negligible percentage of opioid pain prescriptions and were not widely abused or diverted. Nor can the State's marketing potshots change the fact that

Janssen's opioid medications came with exhaustive FDA-approved labeling detailing their potential risks, including physical dependence, addiction, and death. The evidence will further show that Janssen's marketing efforts were entirely lawful and proper. Janssen provided extensive and complete risk disclosures and instructions for safe use. It vetted its promotional materials for compliance with FDA requirements and provided extensive compliance training for its sales force. Working with the FDA, it developed comprehensive risk management plans and risk evaluation and mitigation strategies (REMS) for all three products, including FDA-approved educational materials for prescribing physicians and patients as well as multifaceted active surveillance programs to track and assess abuse, misuse, and diversion. In short, Janssen did everything a responsible manufacturer and seller of opioid pain medications should do.

The State's response is hyperbolic rhetoric, untethered to facts. The State accuses Janssen of participating in a "multifaceted campaign to deceive the medical community, policymakers, and the public" about the benefits and risks of opioid pain medications. But no evidence supports that claim. For example, the State accuses Janssen and other pharmaceutical companies of inventing the idea that chronic pain is a significant and costly problem worthy of medical attention. But that has been the consensus of the medical community since at least the 1970s, when the White House urged physicians, researchers, and regulators to develop new pain-relieving options, including opioid-based medicines, to address this growing public-health problem.It remains true today: as recently as last year the CDC estimated that over 50 million Americans suffer from chronic pain, and the U.S. government still considers pain a national health priority, the number one reason people in America go to the doctor.

The State argues that Janssen should not have promoted its opioid pain medications for treatment of chronic pain not attributable to cancer or terminal illness. But the FDA has never

limited the approved indications for Janssen's opioid pain medications to cancer pain; indeed, as recently as 2013 the FDA expressly rejected that distinction. Janssen did no more than promote its medications for their FDA-approved indications. That cannot be a basis for liability. Indeed, the State's own evidence contradicts its assertions. In 2003, for example, after Duragesic had spent 13 years on the market, Oklahoma's Drug Utilization Review Board reviewed Medicaid claims and concluded that Duragesic use fell within acceptable parameters. And more broadly, the State will not offer evidence of even one instance in which any allegedly deceptive statement by Janssen caused an Oklahoma doctor to write an opioid pain prescription that was medically unnecessary or inappropriate.

Likewise, the State cannot credibly claim that any unbranded marketing or educational materials attributable to Janssen caused Oklahoma's opioid abuse crisis. Some of the State's claims with regard to unbranded materials are simply made up. For example, Janssen never promoted opioid use by children. On the contrary, the evidence will show that Janssen established a program to educate children about the dangers of abusing prescription opioids. The handful of educational materials to which the State points—consumer and medical informational websites about pain therapy and a brochure generally discussing pain therapy options for older adults—did not even exist until 2008 or 2009, more than a decade after the State contends the crisis was established. And the materials themselves are balanced, truthful, and innocuous.

The State's remaining evidence that Janssen supposedly engaged in a campaign of deception consists of little more than the observation that Janssen from time to time consulted, supported, or collaborated with pain patient advocacy groups, pain policy groups, professional pain medical societies, and leading experts in the field pain management. These kinds of interactions occur continually in the health care industry and are essential to the advancement of

health care. They are entirely lawful and also protected in many instances by the constitutional guarantees of free speech and right to petition the government. Nothing about them supports a claim that Janssen caused Oklahoma's opioid abuse crisis.

Nor does the State have a viable cause of action based on its newfound claim that Janssen and J&J should somehow be liable because they also owned companies that produced some of the medical-grade raw materials and active pharmaceutical ingredients used in opioid pain medications manufactured and marketed by other pharmaceutical companies who allegedly engaged in deceptive marketing. Resorting to name-calling rather than evidence, the State makes the outrageous and sensationalist claim that ownership of pharmaceutical ingredient suppliers made Janssen and J&J the "kingpins" of the opioid abuse crisis. But again the claim is devoid of substance. The DEA comprehensively regulates every aspect of supplying raw materials and ingredients for opioid medications, setting annual quotas that establish precisely how much of each ingredient may be produced and sold to each end-product manufacturer. Any claim for liability based on such sales would be preempted by the federal regulatory scheme. And likewise, no principle of Oklahoma law would authorize holding ingredient suppliers liable for marketing transgressions allegedly committed by the manufacturer of the finished product.

The State's effort impose this extraordinary unwarranted liability on Janssen and J&J is as unsound legally as it is factually. As detailed below, the State's legal theory would entail a radical expansion of public nuisance law, ignoring one hundred years of Oklahoma precedent confining that tort to cases involving misuse of property and threatening all manner of business within the State. The State's boundless claim would trample the statutory definition of "abatement," as well as the constitutionally guaranteed rights to free speech, to petition the government, and to due process. And the State's claim would gut the requirement of causation—

it simply ignores multiple acknowledged major contributors to the State's opioid abuse epidemic like diversion of lawful prescriptions, unlawful pill mills, and the enormous influx of illegal opioids and other dangerous drugs.

The State's attempt to gloss over the causation requirement by claiming that any alleged contributor is subject to joint and several liability for the State's entire claim is wrong on every level. Contrary to the State's interpretation, 23 O.S. § 15 does not give the State an automatic right to joint and several liability. Imposing joint and several liability is also improper where an injury is divisible, as any harm flowing from the allegations made here against Janssen's marketing would plainly be. At best, any recovery for such harm would be limited by Janssen's market share, which was minuscule. Joint liability is also foreclosed by the State's own role in the opioid abuse crisis: The evidence will show that while Janssen's opioid medications were rarely abused or diverted, the State failed to take easily available steps to prevent abuse and diversion of other opioid medications—even giving widely and notoriously abused medicines like oxycodone and hydrocodone preferential reimbursement treatment because they were cheap. Oklahoma law bars the State from imposing joint and several liability on other parties for harms the State's own actions or inactions have helped cause.

Finally, while the State seeks to impose liability for an astronomical sum, it cannot even show that its $[redacted] billion "plan" will address the opioid crisis. Instead, it will offer only the speculative "hope[s]" of the same two State employees who compiled the $[redacted] billion plan. Those employees cannot testify that that the programs or services under the proposed plan are actually necessary to accomplish the State's goals, and neither has conducted any analysis or study to determine whether the plan, or even its individual elements, will be effective. These failures bar the State's request for such a massive windfall.

After considering the evidence presented at trial, this Court should enter judgment in favor of Janssen and J&J.

II. FACTUAL BACKGROUND

A. Opioid Medications Can Effectively Treat Chronic Pain, a Serious Public Health Problem Affecting All Americans.

Chronic pain touches the lives of every American, either directly or through its staggering costs.[1] Chronic pain affects approximately 50 million U.S. adults, and high-impact chronic pain (i.e., pain that interferes with work or life most days or every day) affects approximately 20 million U.S. adults. The FDA calls chronic pain a "serious and growing public health problem" that "contributes greatly to national rates of morbidity, mortality, and disability."[2] Untreated and undertreated pain can have grave consequences that go beyond physical health: Without proper treatment, patients suffering from chronic pain have higher risks of unemployment, depression, suicide, and other psychological and social harms.[3]

Though chronic pain is widespread, chronic-pain sufferers have limited treatment options, all of which come with their own risks, side effects, and limitations. For example, nonsteroidal anti-inflammatory drugs, such as aspirin and ibuprofen, may not be effective and can increase the risk of gastrointestinal bleeding, myocardial infarction, and stroke. Some of

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[1] *See* Janssen Trial Ex. J1969, *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States, 2016*; Janssen Trial Ex. J926, Ronald T. Libby, Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers, Cato Institute, Policy Analysis No. 545 at 2 (June 16, 2005) at 2 ("The societal costs associated with untreated and undertreated pain are substantial. In addition to the obvious cost of needless suffering, damages include broken marriages, alcoholism and family violence, absenteeism and job loss, depression, and suicide.").
[2] *See* Janssen Trial Ex. J1571, FDA Response to PROP Petition at 1 (Sept. 20, 2013).
[3] *See* Janssen Trial Ex. J1969, *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States, 2016*.

these risks increase with long-term use and for patients over the age of 65, who already experience higher rates of chronic pain.

1. Long before Janssen introduced the drugs at issue in this case, the American medical community recognized the growing problem of untreated chronic pain and confirmed the appropriateness of opioid therapy for properly selected chronic-pain patients.

Some four decades ago, the medical community started paying closer attention to chronic pain and looked to opioids as potential tools to combat it. Opioid analgesics are some of the most effective pain-relieving drugs, but they were not widely used in the United States to treat chronic pain for much of the 20th century. That began to change in the 1970s, as clinicians, medical researchers, and the federal government recognized that untreated chronic pain represented an urgent public-health issue with inadequate treatment options. In 1977, at the request of the White House, a contingent of government researchers and regulators formed the Interagency Committee on New Therapies for Pain and Discomfort in part to assess existing research on chronic pain.[4] The Interagency Committee found that research and treatment options were lacking,[5] and in 1981 it sent a letter to pharmaceutical manufacturers urging them to give "attention to more potent analgesics [and] consider[] other routes of administration."[6]

Recognizing the deficiency in research and treatment options for chronic pain, the medical community embarked on a search for potential solutions—including opioid medications. In the 1980s, independent researchers, including Drs. Russell Portenoy, Kathleen Foley, and Randal France, studied the feasibility of using opioid analgesics to treat patients suffering from

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[4] *See* "The Interagency Committee on New Therapies for Pain and Discomfort: Report to the White House" at I-1 (May 1979).
[5] *Id.*
[6] *See* Janssen Trial Ex. J2722, "Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl)" at 1.

chronic non-cancer pain. Years before Janssen introduced the drugs at issue in this case, these independent researchers concluded that opioids can safely and effectively treat properly selected patients suffering from chronic non-cancer pain. Portenoy and Foley reported "that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[7] And France's "results indicate[d] that narcotic analgesics can be effectively used to provide long-term pain control in combination with a comprehensive pain management program. … There w[ere] no overt long-term side effects[, and the] data show[ed] that addiction does not occur and that narcotic administration can be controlled."[8]

2. Opioid medications can safely and effectively treat chronic non-cancer pain patients when risks are properly managed.

Subsequent research by clinicians and federal regulators has confirmed these early findings. A 2008 study found that the risk of abuse and addiction for patients receiving opioids for chronic non-cancer pain was just 3.27% for patients with a history of abuse and 0.19% for patients without a history of abuse.[9] Later studies reported similar findings.[10] A 2016 review article in the *New England Journal of Medicine*, surveying existing research, concluded that "addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small

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[7] Portenoy, R. and Foley, K., *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, Pain 1986; 25: 171-86.
[8] France, Randal, et al., *Long-Term Use of Narcotic Analgesics in Chronic Pain*, Social Science Medicine 1984; 19(12): 1379-82.
[9] *See* Janssen Trial Ex. J340, David Fishbain, et al., Review Article, "What Percentage of Chronic Nonmalignant Pain Patients Exposed to Chronic Opioid Analgesic Therapy Develop Abuse/Addiction and/or Aberrant Drug-Related Behaviors? A Structured Evidence-Based Review" Pain Medicine, Volume 9, Number 4-2008: pp. 444-59.
[10] Janssen Trial Ex. J657, Noble, M., et al., Long-term opioid management for chronic noncancer pain. Cochrane Database Syst Rev, 2010(1): p. CD006605; Ex. J672, Minozzi, S., L. Amato, and M. Davoli, Development of dependence following treatment with opioid analgesics for pain relief: a systematic review. Addiction, 2013. 108(4): p. 688-98.

percentage of persons who are exposed to opioids—even among those with preexisting vulnerabilities."[11]

The federal government has likewise approved—and consistently advocated for—the use of opioids to treat chronic non-cancer pain. Citing the National Institutes of Health, the FDA stated in 2009 that "studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction." Janssen Trial Ex. J3606, FDA Guide to Safe Use of Pain Medicine (Feb. 9, 2009) at 4. The FDA continues to endorse the use of opioids to treat properly selected patients suffering from chronic pain. As recently as April 9, 2019, the FDA released a statement affirming its commitment to "enabling appropriate access to [opioid analgesics] for patients living with serious pain."[12]

3. The federal government strictly regulates the manufacture and sale of opioid medications.

No prescription opioid drug can be introduced without U.S. government scrutiny and approval. The FDA must approve any prescription medication as "safe and effective" before it can be sold in the United States.[13] To obtain approval, a manufacturer must submit a new drug application ("NDA") containing test results, clinical trial results, and other information.[14] The FDA will not approve an NDA unless it determines "that the drug meets the statutory standards for safety and effectiveness, manufacturing controls, and labeling."[15] Among other things, the

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[11] Janssen Trial Ex. J096, Nora D. Volkow, MD, et al., Opioid Abuse in Chronic Pain—Misconceptions and Mitigations Strategies, New England Journal of Medicine, Vol. 374 (March 31, 2016) at 1253-1263.
[12] *See* Janssen Trial Ex. J2064, Statement by Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs in FDA (Apr. 9, 2019) at 1.
[13] *See* 21 U.S.C. §§ 355(d), 393(b)(2)(B); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011).
[14] *See* 21 U.S.C. § 355(b), (d).
[15] 21 C.F.R. § 314.105(c).

FDA must find that a drug's "benefits . . . outweigh its known and potential risks for the intended population."[16] After approving an NDA, the FDA continues to monitor a drug's safety. It will withdraw its approval if it finds that the drug is unsafe for use or that the labeling is "false or misleading in any particular."[17]

The DEA classifies drugs that use controlled substances like opioids into "schedules" based on their relative abuse potential in accordance with the Controlled Substances Act. These schedules, which govern the manufacturing, possession, and use of the substances, range from illegal street drugs (Schedule I), which have "no currently accepted medical use and a high potential for abuse," to cough and gastrointestinal remedies (Schedule V), which have a low potential for abuse.[18] The opioid analgesics at issue in this case fall into Schedule II,[19] and thus the DEA establishes production quotas for them each year "to meet legitimate medical, scientific, and export needs of United States."[20] The DEA also regulates manufacturers' systems for guarding against the potential diversion of opioid medications, conducting regular inspections of their facilities to ensure compliance.[21]

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[16] FDA.gov, Development & Approval Process (Drugs), *available at* https://www.fda.gov/drugs/development-approval-process-drugs (last accessed May 18, 2019).
[17] 21 U.S.C. § 355(e).
[18] Federal Drug Enforcement Administration, Drug Scheduling, *available at* https://www.dea.gov/drug-scheduling (last accessed May 18, 2019).
[19] *Id.* Ultram and Ultracet have been mentioned in passing by the State and they are not Schedule II drugs; they are Schedule IV and addressed in the brief below in Section II.B.3.
[20] Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019, *available at* https://www.deadiversion.usdoj.gov/fed_regs/quotas/2018/fr1228.htm.
[21] *See* Janssen Trial Ex. J2471, Attachment to email (JAN-MS-0312394), notes taken during DEA's July 30, 2013 inspection at the Kentucky distribution center; Ex. J1696, Email RE DEA's January 27-28, 2015 inspection of the Kentucky distribution center.

B. Janssen Made Good Drugs That Filled Unmet Needs, Discouraged Abuse, and Were Not Widely Abused.

Janssen developed safe and effective, FDA-approved pain medications that met patients' needs. Janssen designed those drugs both to enable safe use and to make them difficult to abuse and undesirable for abusers, and its efforts proved effective: Janssen's drugs were never widely abused. The State has no evidence that any Janssen opioid medication is responsible in any way for the opioid abuse problem here.

1. Duragesic delivers safe and controlled relief from chronic pain.

Heeding calls from the medical community and federal regulators for new opioid medications to address untreated pain, ALZA Corporation and Janssen developed the transdermal patch Duragesic.[22] First approved in 1990 for the safe and effective treatment of chronic pain, Duragesic is currently FDA-approved for "the management of pain in opioid-tolerant patients, severe enough to require around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[23]

Duragesic was a breakthrough medication. It was the first opioid medicine in an extended-release adhesive patch, one that could deliver a safe and controlled dose of pharmaceutical fentanyl for 72 hours without intravenous or subcutaneous administration.[24] By eliminating the need for needles and injections, Duragesic also proved cost-effective, allowing patients to be treated for chronic pain without depending on nursing staff or other caregivers in a hospital setting.[25] The patch's convenient, noninvasive regime gives patients the freedom to

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[22] *See* Janssen Trial Ex. J691, Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl) at 1.
[23] Janssen Trial Ex. J2776, 2018 Duragesic Label at 1.
[24] *See* Janssen Trial Ex. J691, Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl) at 3.
[25] *Id.* at 3-4.

maintain a relatively normal lifestyle and offers in-home caregivers an easy-to-use, painless method of administering opioid analgesia.[26] Its slow, steady dosing reduces the chances of medication errors, provides significantly longer lasting pain relief than oral tablets, and lessens anxiety over the impending return of pain.[27] And for people who have troubling swallowing pills, transdermal delivery is one of the only ways to receive opioid treatment.[28]

Before the FDA approved Duragesic as safe and effective for the treatment of chronic pain, Janssen submitted a 64-volume NDA, including results from clinical trials and detailed information about Duragesic's chemistry and manufacturing process.[29] Seventeen short-term clinical studies included in Duragesic's NDA found the patch "safe and well tolerated when used alone or when supplemented with other narcotics."[30] Similarly, three long-term clinical trials conducted on cancer patients concluded that the patch "is a safe and acceptable analgesic therapy for patients with advanced cancer."[31]

Duragesic was initially indicated for "the management of chronic pain in patients requiring opioid analgesia"; since 1993, it has been indicated for patients requiring continuous opioid treatment and whose pain cannot be managed by alternative means.[32] The FDA has never placed limits on duration or dosage for Duragesic, instead leaving those determinations to

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[26] *Id.*
[27] *See id.* at 4.
[28] *See* Janssen Trial Ex. J2050, Janssen Defendants' Expert Disclosure at 77 (Dr. T. Phillips, D.O.: "In particular, because of its transdermal route of administration, it is helpful for patients who have difficulty swallowing or tolerating orally administered opioid medicines.").
[29] *See* Janssen Trial Exs. J2792-J2783, 1987 Duragesic New Drug Applications.
[30] Janssen Trial Ex. J2652, 1987 Duragesic IND-NDA Safety Summary at 1.1/236.
[31] *Id.* at 1.1/270, 1.1/293.
[32] Janssen Trial Ex. J2762, 1990 Duragesic Label; Ex. J2764, 1993 Duragesic Label; Ex. J2776, 2018 Duragesic label.

doctors' judgment.[33] During the more than three decades Duragesic patches have been on the market, the FDA has never revoked approval, repeatedly concluding that Duragesic is safe and effective for its indications.

Duragesic also has unique properties with regard to difficulty of abuse and unattractiveness to abusers. Fentanyl patches are generally more difficult to abuse than pills such as OxyContin and Vicodin: Users cannot, for example, crush or snort patches. And the patch's slow and steady delivery mechanism makes it a less attractive choice for abuse than products with a more rapid onset effect, like injectable pharmaceutical opioids.[34] The Duragesic patch's reservoir formulation, used from 1990 to 2009, infused the fentanyl analgesic in a sticky alcohol gel that made the patch not only difficult to abuse, but also unpredictably risky to abuse and therefore undesirable to abusers. To extract fentanyl from the patch, an abuser would need to separate the fentanyl from the gel, a difficult process in and of itself. In addition, the difficulty of obtaining a predictable dose from such a process would put the abuser at significant risk of consuming a lethal amount of fentanyl—a known danger that further deterred abuse.[35]

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[33] *See, e.g.,* Janssen Trial Ex. J2762, 1990 Duragesic Label at 8 ("[A]s with all opioids, dosage should be individualized."); Ex. J2776 2018 Duragesic Label at 5 ("Initiate the dosing regimen for each patient individually . . . .").

[34] Janssen Trial Ex. J982, 2007 Duragesic Revised Risk Management Plan at 48; *see also* Ex. J2643, Assessment of the Abuse of Transdermal Fentanyl at 5 ("Transdermal fentanyl is less subject to abuse than other potent opioids because of its chemical formulation."); Ex. J862, Assessment of Abuse Potential of Fentanyl Transdermal Systems in the U.S. (Sept. 27, 2004) at 21 ("[I]t appears that rates of abuse of [Duragesic patches] have been relatively low, presumably due to the relative unattractiveness of an intact transdermal system for delivering the drug (the slow onset of effect compared to the rapid onset of preferred forms of fentanyl for abuse), and the relative difficulty of extracting and purifying the fentanyl from the FFS [form, fill and seal] technology as compared to readily accessible fentanyl in abusable forms (e.g., injectable pharmaceutical fentanyl) as well as ready accessibility of other opioids.").

[35] *See* Janssen Trial Ex. J2643, Assessment of the Abuse of Transdermal Fentanyl at 5 (noting that reports showed intravenous injection of the contents of a reservoir patch could be "quickly followed by a massive pulmonary embolism" and that attempts at heating and inhaling the

Surveillance data, discussed below, confirmed that abuse and diversion of the reservoir patches was very low. In 2009, Janssen replaced Duragesic's reservoir formulation with a "matrix" formulation, already used in generic fentanyl patches, which infused the fentanyl analgesic into a hard, mesh-like substance rather a gel.[36] Surveillance data from before and after this reformulation confirms that abuse and diversion of the matrix patches is equally low.

Janssen comprehensively warned of Duragesic's risks, both those generally associated with opioids and those specific to the potent fentanyl analgesic contained in the patch. Janssen developed these warnings in consultation with the FDA and placed them prominently on Duragesic's labels. The labels highlighted Duragesic's potential for abuse, misuse, and diversion, together with the associated risk of fatal overdose.[37] Duragesic's 2005 FDA-approved label highlighted these risks in bolded and boxed language:[38]

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contents of the patch "have resulted in immediate respiratory arrest as have attempts to apply the contents of the patch transmucosally"—i.e., through the mouth's mucous membrane); Ex. J862, Assessment of Abuse Potential of Fentanyl Transdermal Systems in the U.S. (Sept. 27, 2004) at 26; *see also* Ex. J946, Examination of Transdermal Fentanyl Patch Systems Postings on Internet Bulletin Boards (Jun. 7, 2006) at 7 ("It appears that fear of fentanyl dose control, possibly derived in part from the difficulty in extracting known 'safely abusable' doses from Duragesic, is continuing to serve to keep the transdermal systems relatively unattractive as compared to heroin, which continues in the status of the most preferred opioid . . . .").

[36] Janssen Trial Ex. J2717, Review and Conclusion of the RADARS Report Summarizing Abuse and Diversion Data for Transdermal Fentanyl Products in the United States at 1.

[37] *See* Janssen Trial Exs. J2762-J2776, Duragesic Labels since 1990.

[38] Janssen Trial Ex. J2769, Duragesic Label 2005-02 at 1.

DURAGESIC®
(FENTANYL
TRANSDERMAL
SYSTEM) CII

Full Prescribing Information

FOR USE IN OPIOID-TOLERANT PATIENTS ONLY

DURAGESIC® contains a high concentration of a potent Schedule II opioid agonist, fentanyl. Schedule II opioid substances which include fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone have the highest potential for abuse and associated risk of fatal overdose due to respiratory depression. Fentanyl can be abused and is subject to criminal diversion. The high content of fentanyl in the patches (DURAGESIC®) may be a particular target for abuse and diversion.

DURAGESIC® is indicated for management of persistent, moderate to severe chronic pain that:

- **requires continuous, around-the-clock opioid administration for an extended period of time, and**
- **cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids**

DURAGESIC® should ONLY be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to DURAGESIC® 25 mcg/h. Patients who are considered opioid-tolerant are those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid.

The 2018 FDA-approved label likewise warns upfront of risks: [39]

DURAGESIC (fentanyl transdermal system) , CII
Initial U.S. Approval: 1968

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; RISK OF INCREASED FENTANYL ABSORPTION WITH APPLICATION OF EXTERNAL HEAT; and RISKS FROM CONCOMITANT USE OF BENZODIAZEPINES OR OTHER CNS DEPRESSANTS
See full prescribing information for complete boxed warning.

- **DURAGESIC exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing, and monitor regularly for these behaviors or conditions. (5.1)**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. (5.2)**
- **Accidental exposure to DURAGESIC, especially in children, can result in fatal overdose of fentanyl. (5.3)**
- **Prolonged use of DURAGESIC during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.4)**
- **Concomitant use with CYP 3A4 inhibitors (or discontinuation of CYP 3A4 inducers) can result in a fatal overdose of fentanyl. (5.5)**
- **Exposure of the DURAGESIC application site and surrounding area to direct external heat sources has resulted in fatal overdose of fentanyl. Warn patients to avoid exposing the DURAGESIC application site and surrounding area to direct external heat sources. (5.6)**
- **Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.7, 7)**

And, as explained below, Janssen provided additional educational materials to doctors and safety guides to patients, reiterating these warnings and providing instructions for safe use.

[39] Janssen Trial Ex. J2776, 2018 Duragesic label at 1.

After Duragesic came onto the market, Janssen continuously monitored its safety and efficacy. Janssen's pharmacovigilance group tracked and analyzed all reported adverse events whatever the source, including reports from healthcare professionals, clinical trial investigators, literature reports, regulatory agencies, solicited programs, and consumers.[40] Janssen promptly reported all this information, including reports of abuse, misuse, or diversion, to the FDA's Adverse Event Reporting System. The pharmacovigilance group also periodically performed (and provided to FDA) multi-year retrospective analyses of events of interest. For example, a 2006 analysis of the incidence of iatrogenic addiction—*i.e.*, addiction caused by medical treatment—found only 103 reported cases, worldwide, over the fifteen years Duragesic had been on the market, a period that encompassed over 1.6 billion patient-days of exposure to medication.[41] The report concluded the "risk of iatrogenic addiction is very rare."[42] Similarly, a study that evaluated 2004-2005 data from a panel of experts in abuse and diversion as well as from existing data sources, media, and internet monitoring concluded that diversion and abuse of Duragesic "remained well within the range of its historically low 14-year record of diversion and abuse, as established by federal data sources."[43] And a study examining the drug preferences of 797 subjects found that these drug users identified hydrocodone and oxycodone as their "primary drug" far more frequently than other prescription drugs.[44] Only 13 subjects—1.6%—identified

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[40] Janssen Trial Ex. J1041, Duragesic Third Risk Management Plan Progress Report (2008) at 14.
[41] Janssen Trial Ex. J406, Cumulative Review of Iatrogenic Addiction Associated with the Use of Transdermal Duragesic (fentanyl) Patch (Sept. 6, 2006) at 5, 7, 9, 16-17.
[42] *Id.*
[43] *See* Janssen Trial Ex. J1025, DURAGESIC: Progress Report Covering the Period 01 January 2004 to 31 March 2007 at 39.
[44] *Id.* at 39-40.

fentanyl (in any of its forms) as their primary drug.[45] This study also found that fentanyl's rate of diversion was low compared to more commonly prescribed opioids: in the first quarter of 2006, fentanyl was mentioned in only 2.1% of diversion cases, and Duragesic in only 0.9%.[46]

Beginning in the early 2000s, when the media began reporting on abuse, misuse, and diversion of OxyContin, Janssen also commissioned several independent expert assessments of the risks of abuse, misuse, and diversion of Duragesic. These studies uniformly reached the same conclusion: that Duragesic was abused, misused, and diverted at far lower rates than other opioid medications.[47] During this same period, Janssen also undertook to develop a robust post-market surveillance programs to monitor and report Duragesic's rates of abuse, misuse, and diversion in real time. Among other things, Janssen monitored data from the federal Drug Abuse Warning Network ("DAWN"), which collects data on drug-related emergency room visits and deaths as reported by medical examiners and coroners; the American Association of Poison Control Centers, which records calls to the national network of poison control centers; and the National Forensic Laboratory Information System, which collects data on drugs analyzed after seizure by the police.[48]

In 2004 and 2005, the FDA recommended that all opioid manufacturers adopt formal Risk Management Plans ("RMPs") to monitor and assess key risks of opioid products and

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[45] *Id.* at 40.
[46] *Id.*
[47] Janssen Trial Ex. J752, D-Trans (fentanyl) Summary of Benefits and Risks: Abuse and Diversion (Dec. 17, 2001) at 29 (finding only "scattered and infrequent reports" of Duragesic Abuse); Ex. J862, Assessment of Abuse Potential of Fentanyl Transdermal Systems in the U.S. (Sept. 27, 2004) at 1, 26 ("rates of abuse of [Duragesic] have been relatively low"); Ex. J2643, John J. Coleman, Assessment of the Abuse of Transdermal Fentanyl at 4 (fentanyl patches not "widely sought by drug abusers nor widely diverted or sold by traffickers").
[48] *Id.* at 24, 31, 35, 48.

manage known risks.[49] As a part of its RMP for Duragesic, Janssen adopted the Research Abuse, Diversion, and Addiction-Related Surveillance ("RADARS") system to monitor abuse and diversion.[50] A nonprofit prescription opioid medication surveillance system managed by the Denver Health and Hospital Authority, RADARS collects anonymized healthcare data from multiple proprietary databases to measure misuse, abuse, and diversion of prescription opioids.[51]

That data has consistently showed no new safety concerns related to Duragesic.[52] For example, the June 2012 RMP progress report found that between 2005 and 2011, fentanyl abuse rates were "low relative to other" opioids like hydrocodone and oxycodone.[53] From 2006 to 2011, diversion rates for fentanyl were among the lowest of any opioid. Indeed, the only Schedule II opioid with consistently lower rates was tapentadol—the active ingredient in Janssen's Nucynta pain medication, introduced in 2009.[54] From 2003 to 2011, "intentional exposures"[55] to fentanyl were "low relative to many of the other RADARS System opioids"; since 2006, intentional exposures to Duragesic have been trending downward.[56]

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[49] *See* U.S. Dep't of Health & Human Servs., Food & Drug Admin., Guidance for Industry: Development and Use of Risk Minimization Action Plans (March 2005), available at https://www.fda.gov/media/71268/download.
[50] *See* Janssen Trial Ex. J1041, Duragesic Third Risk Management Plan Progress Report (2008) at 38-39.
[51] *Id.*; *see also* Janssen Trial Ex. J2302 at 2 (Richard C. Dart et al., Diversion and Illicit Sale of Extended Release Tapentadol in the United States, 17 Pain Medicine 1490-1496 (2016)) (describing RADARS).
[52] *See* Janssen Trial Exs. J1041, J1063, J1095, J2451, J2234, J1237, J1284, J1345, J1387, J1434 Duragesic's Third through Twelfth RMP Progress Reports.
[53] Janssen Trial Ex. J1434, Twelfth Duragesic RMP Progress Report at 33.
[54] *Id.* at 36-37.
[55] "[I]ntentional exposure" is used as a "surrogate for abuse and misuse." *Id.* at 44.
[56] *Id.* at 44-46.

2. Nucynta and Nucynta ER address the need for additional safe and effective opioid pain medications.

After the introduction of Duragesic, Janssen continued to develop medications that would provide more options for the safe and effective treatment of pain. Although the risks of opioids were well known and prominently disclosed in FDA-approved labeling,[57] the FDA, state governments, and the medical profession continued to recognize that opioid medications were necessary for the treatment of pain, including chronic pain.[58] For pharmaceutical companies, the challenge was to create a pain medication as effective as an opioid but with fewer side effects and lower rates of abuse. This was Janssen's aim when it set out to develop a new opioid medication in the early 2000s, an undertaking that ultimately led to Nucynta.[59]

After exploring several possible active ingredients for a new opioid medication, Janssen found what it was looking for in tapentadol. Tapentadol was not a conventional poppy-based opioid, but a new chemical entity that differed from other opioids in potentially important ways. First, unlike conventional opioids, tapentadol appeared to act on both opioid and norepinephrine

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[57] *See, e.g.*, Janssen Trial Ex. J2769, Duragesic Label 2005-02 ("Schedule II opioid substances which include fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone have the highest potential for abuse and associated risk of fatal overdose due to respiratory depression.") at 1; Janssen Trial Ex. J2050, Janssen Defendants' Expert Disclosure at 76 (Dr. T. Phillips, D.O.: "Throughout the time period at issue in this case, i.e., since 1996; physicians authorized to prescribe opioids for chronic non-cancer pain have been or should have been aware of the risks of addiction, overdose, abuse, and misuse that opioids carry. This knowledge is commonplace among health care professionals who prescribe opioids.").

[58] *See generally*, Janssen Trial Ex. J615, AAPM Response to Prop Petition to the FDA That Seeks to Limit Pain Medications for Legitimate Noncancer Pain Sufferers; Ex. J1571, FDA Response to Prop Petition at 2 ("Opioids are a class of powerful pain-relieving agents that includes oxycodone, hydrocodone, and morphine, among others. When prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority.").

[59] *See* Janssen Trial Ex. J3765, Nucynta 21st Century Technology Presentation at 3.

receptors, potentially providing a second analgesic pathway not tied to opioid effects.[60] It was hypothesized that this "dual mechanism" of action would enable tapentadol to effectively treat more types of pain—including neuropathic pain, an indication for which FDA approved Nucynta ER in August 2012[61]—and also deliver equivalent analgesia to conventional opioids with less euphoric effect.[62] These hypotheses suggested that tapentadol could be less prone to abuse than other opioids.[63]

Janssen introduced its tapentadol-based pain medication in two formulations.[64] The FDA approved an immediate-release tapentadol tablet, trade-named "Nucynta," in 2008. Janssen began marketing this formulation in 2009 after completion of the DEA scheduling process, which designated tapentadol a Schedule II opioid. Nucynta is a short-acting medication indicated only for acute pain—not for chronic pain.[65] Then, in 2011, the FDA approved and Janssen began marketing an extended-release, long-acting version of Nucynta, called "Nucynta ER." Nucynta ER is approved for the treatment of chronic pain, and, as noted above, in 2012 also received a

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[60] G. Vorsanger (Jan. 17, 2019) Depo. Tr. at 281-82; Janssen Trial Ex. J3765, Nucynta 21st Century Technology Presentation.
[61] Janssen Trial Ex. 2785, "Nucynta ER Label 2012-08" at 1.
[62] B. Moskovitz (Dec. 12, 2018) Depo. Tr. at 320:2-15 ("The molecule itself, Tapentadol has more than one mechanism of action. The one mechanism of action, which is mu opioid agonism, similar to other opioids and a second mechanism of action called norepinephrine reuptake inhibition. In animal models, we had data that suggested it was not as euphoric, it was not as attractive and, therefore, because we were getting similar analgesia but without gaining that analgesia solely through the mu opioid agonism, that there would be a lower propensity for euphoria and associated issues, abuse, misuse, diversion.").
[63] G. Vorsanger (Jan. 17, 2019) Depo. Tr. at 282 ("[W]e thought that it might be likely that there may be less abuse associated with tapentadol compared to some of the stronger opioids, such as oxycodone or morphine."); Janssen Trial Ex. J3765, Nucynta 21st Century Technology Presentation.
[64] Janssen Trial Ex. J2777, 2008 Nucynta Label; Ex. J2138, Nucynta ER Package Insert.
[65] Janssen Trial Ex. J2777, 2008 Nucynta Label.

specific approved indication for the treatment of a form of neuropathic pain (diabetic peripheral neuropathy).[66]

To make it difficult for would-be abusers to defeat Nucynta ER's extended release mechanism by crushing the pills and then snorting or injecting what is intended to be a gradually-released therapeutic dose of medication all at once, Janssen released Nucynta ER with a newly-developed crush-resistant coating.[67] It licensed the proprietary manufacturing technology INTAC, which renders pills resistant to splitting, crushing, and dissolution.[68] Janssen waited until Nucynta ER could be manufactured using this technology before bringing it to market.

Before approving Nucynta ER, the FDA scrutinized the medication to ensure that it was safe and effective for the long-term treatment of chronic pain. Reviewing multiple preapproval studies, the FDA weighed the medication's risks—including those of abuse and overdose—against its benefits.[69] When it approved Nucynta ER for the treatment of chronic pain, the FDA imposed no limit on duration of treatment.[70] As with Duragesic, it left that determination to doctors' discretion. The FDA has continued to monitor Nucynta ER's safety and efficacy since approving it, and has never revoked that approval.[71]

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[66] Janssen Trial Ex. J2138, Nucynta ER Package Insert at 1.
[67] G. Vorsanger (Jan. 17, 2019) Depo. Tr. at 284-85.
[68] *Id.*; Janssen Trial Ex. J586, Evaluation of the tamper-resistant properties of tapentadol extended-release tablets: Results of in vitro laboratory analyses.
[69] Janssen Trial Ex. J2050, Janssen Defendants' Expert Disclosure at 27 (Dr. R. De La Garza, Ph.D.: "The FDA undertakes rigorous review and analysis of date before approving drugs, including Duragesic, Nucynta ER, and Nucynta.").
[70] Janssen Trial Ex. J2138, Nucynta ER Package Insert at 1. Both Nucynta and Nucynta ER have maximum recommended daily doses, specified in their FDA-approved labeling.
[71] *See, e.g.*, Janssen Trial Exs. J2703-J2710, J2712, Nucynta ER Annual Reports; Ex. J1571, FDA Response to Prop Petition.

Nucynta ER—like all Schedule II opioids—carries potential risks of addiction, abuse, misuse, and fatal overdose, but Janssen has aimed to understand and mitigate these risks from the start of the development process. To obtain FDA approval, Janssen conducted clinical studies that assessed Nucynta ER's risks.[72] It continued to conduct risk-assessment studies even after FDA approval.[73] And, as with Duragesic, Janssen developed sophisticated post-market surveillance programs to monitor the abuse, misuse, and diversion of Nucynta ER. At Nucynta ER's launch, Janssen implemented a Safety Surveillance Plan, which incorporated all elements of Duragesic's Risk Management Plan.[74] In 2012, the Safety Surveillance Plan also began to incorporate NAVIPPRO, an additional system that collected information about patients in drug treatment centers and monitored online discussion of illegal drug diversion.[75]

Janssen also created a Risk Evaluation and Mitigation Strategy ("REMS") for Nucynta ER designed to educate doctors and patients on the safe use of the medication and to deter its abuse. The FDA reviewed and approved this REMS in 2011, a year before it approved a REMS for the entire class of extended-release opioids.[76] Nucynta ER was the first new opioid medication to be introduced with a medication-specific REMS in place at initial launch.

The Nucynta ER REMS incorporated multiple elements designed to reduce the risks associated with the medication. Pharmacies were required to provide a medication guide each

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[72] Janssen Trial Ex. J2702, 2009 Nucynta ER IND-NDA Clinical Summary.
[73] *See* Janssen Trial Exs. J2703-J2710, J2712, Nucynta ER Annual Reports; Ex. J2711, 2014 Nucynta ER NDA PMR Commitments.
[74] Janssen Trial Ex. J449, Binder of Nucynta and Nucynta ER Safety Surveillance Plans marked as Depo. Ex. 37, Tab G (2011 Nucynta ER SSP).
[75] Janssen Trial Ex. J449, Binder of Nucynta and Nucynta ER Safety Surveillance Plans marked as Depo. Ex. 37, Tab I at 78-79, 87, 89 (Dec. 2012 SSP Progress Report).
[76] Janssen Trial Ex. J1369, Nucynta ER Risk Evaluation and Mitigation Strategy (REMS).

time a patient received a Nucynta ER prescription.[77] This guide warned, among other things, of "a chance of abuse or addiction with NUCYNTA™ ER."[78] It also prominently warned of the risk of overdose.[79] In addition, Janssen mailed educational materials to the doctors most likely to prescribe the medication (i.e., pain specialists, physiatrists, and primary care providers) at the time of Nucynta ER's launch.[80] The training materials begin, "WARNING: POTENTIAL FOR ABUSE," and immediately state, "NUCYNTA® ER can be abused in a manner similar to other opioid agonists, legal or illegal. These risks should be considered when prescribing…."[81] Janssen also published the training program online to make it accessible to specialists who would not have received copies by mail.[82] The medication guide and training program were designed "[t]o inform patients and healthcare professionals about the potential for abuse, misuse, overdose, and addiction to NUCYNTA® ER,"[83] using FDA-approved language.

In 2012, both the Nucynta ER REMS and the Duragesic Risk Management Plan were folded into an FDA-mandated classwide REMS for all extended-release opioid pain medications. Like the REMS for Nucynta ER, the classwide REMS required pharmacies to provide medication guides to patients when dispensing extended-release opioid prescriptions. The REMS also required Janssen and other manufacturers to inform prescribers of the risks of extended-release opioids by (i) mailing letters to every physician licensed to prescribe Schedule II and III controlled substances and (ii) providing physicians educational materials that further

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[77] *Id.* at 1.
[78] *Id.* at 12.
[79] *Id.* at 6.
[80] *Id.* at 2-3.
[81] *Id.* at 22.
[82] *Id.* at 3.
[83] *Id.* at 25.

communicated such risks.[84] The classwide REMS also has a surveillance component—it instituted a surveillance program similar to Janssen's Risk Management Program for Duragesic and Safety Surveillance Plan for Nucynta ER to monitor and assess all ER/LA opioid products' risks. The classwide REMS replaced both product-specific surveillance programs.

As with Duragesic, the surveillance programs for Nucynta and Nucynta ER consistently reported very low rates of abuse, misuse, and diversion compared to other opioid medications. One academic study, examining NAVIPPRO reports from substance abuse facilities, concluded that "[t]apentadol abuse was seen infrequently . . . and, on a prescription basis, [the medication] was less likely to be abused than most of the examined Schedule II analgesics."[85] Another academic study, examining internet forum posts, concluded that "recreational abusers . . . appear to be less interested in abusing tapentadol when compared with other, selected prescription analgesics."[86]

3. Ultram and Ultracet, Schedule IV medications, have little potential for abuse or dependency.

The State recently indicated that it intends to present evidence on three Janssen drugs not named in the Petition: Ultram, Ultram ER, and Ultracet.[87] Specifically, the State plans to present

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[84] Janssen Trial Ex. J2644, Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS).
[85] Janssen Trial Ex. J2288, Tapentadol Abuse Potential: A Postmarketing Evaluation Using a Sample of Individuals Evaluated for Substance Abuse by Stephen F. Butler, Emily C. McNaughton, MPH and Ryan A. Black, PhD.
[86] Janssen Trial Ex. J2289, Assessing Abuse Potential of New Analgesic Medications Following Market Release: An Evaluation of Internet Discussion of Tapentadol Abuse, Emily McNaughton et al.; *see also* Ex. J1592, Fourth Nucynta ER Safety Surveillance Plan Progress Report at 80 ("[R]ates of abuse, misuse, and diversion of tapentadol ER ere the lowest of the RADARS opioids."); Ex. J2050, Janssen Defendants' Expert Disclosure at 77 (Dr. T. Phillips, D.O.: "[M]edical literature and clinical experience suggest that Nucynta and Nucynta ER have a lower risk of abuse, misuse, and addiction than some other opioid medicines.").
[87] *See* Hr'g. Tr. (Apr. 11, 2019) at 94:8-17.

evidence about Janssen and J&J's protected petitioning activities related to those medications and about a co-promotion agreement with Purdue that was terminated before any promotion occurred, sparking litigation between Janssen and Purdue.[88]

Ultram, Ultracet, and Ultram ER are FDA-approved Schedule IV medications launched in 1995, 2001, and 2005, respectively. They have the active ingredient tramadol, an analgesic that combines weak opioid analgesic properties with stronger non-opioid analgesic properties. All three formulations are indicated for the management of moderate to moderately severe pain.[89] Schedule IV substances like tramadol receive that classification based on their low potential for abuse or dependency.[90] Studies establish exceedingly low abuse rates for tramadol,[91] which was not scheduled as a controlled substance at all by the federal government until August 2014.[92] The State's own expert, Dr. Daniel Clauw, testified that "in general" he "ha[s] not considered tramadol to be an opioid because . . . most of the effectiveness comes from . . . serotonin norepinephrine reuptake inhibition."[93] To the extent it is an opioid, he opined, "it is such a weak opioid, that it's hard to get into trouble with . . . given how weak the opioidergic effects of the drug are."[94]

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[88] *See* Hr'g. Tr. (May 17, 2019) at 280:8-281:24.
[89] Janssen Trial Ex. J444, Opioids Manufactured, Owned, and/or Developed by Janssen Since 1996 & Tabs 3-5 attached thereto.
[90] *See*, Okla. State. Bd. of Pharm., *What is a controlled (scheduled) drug?* (Dec. 11, 2017), *available at* https://www.ok.gov/pharmacy/Resources/FAQ/Consumers/index.html.
[91] *See, e.g.*, Janssen Trial Ex. J960, "Assessment of the Abuse of Fentanyl Products (Cicero, Inciardi, Munoz)" at 12 ("The rate of tramadol abuse (all formulations) is very low, at approximately .05 cases/100,000.").
[92] *See* DEADiversion.usdoj.gov, Rules - 2014, *available at* https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm (last accessed May 23, 2019).
[93] D. Clauw (May 26, 2019) Depo. Tr. at 59.
[94] *Id.* at 59.

In 2005, the Oklahoma Board of Pharmacy recommended the Legislature consider a bill scheduling tramadol.[95] To schedule a drug is to place it into one of five categories, numbered I through V, depending on the substance's acceptable medical use and potential for abuse or addiction.[96] As the Board considered that draft legislation, Janssen presented data to the Board showing tramadol's low abuse rates and noted its view that "the clinical information did not merit the [Board] scheduling or making a recommendation to schedule" tramadol.[97] Janssen and J&J expressed the same view on similar proposed legislation in 2008.[98] On both occasions, the Board chose not to schedule the medication (which also remained unscheduled under federal law). The next time the issue came up, in 2012, Janssen opted to take a neutral position, and legislation was enacted classifying tramadol as a Schedule IV substance with low potential for abuse and dependency.[99]

4. None of Janssen's products were widely abused in Oklahoma.

Oklahoma has never had a Duragesic or Nucynta problem. When Oklahoma's DURB reviewed utilization rates for several opioid products in July 2003, meeting materials stated that Duragesic utilization "appear[ed] to be within acceptable parameters" and did not recommend any changes or restrictions.[100] The packet shows that the average daily units of Duragesic were 0.378, consistent with only a select group of patients needing to titrate or use multiple 72-hour patches for optimal treatment. The packet also shows that the overwhelming majority of

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[95] State Trial Ex. 1195. E-mail from SGA Update; Subject: State Government Affairs Update - January 2005.
[96] *See* Okla. State Bd. of Pharm., *What is a controlled (scheduled) drug?* (Dec. 11, 2017), *available at* https://www.ok.gov/pharmacy/Resources/FAQ/Consumers/index.html.
[97] B. Colligen (Jan. 31, 2019) Depo. Tr. at 32–33.
[98] *Id.* at 115-117.
[99] *Id*.
[100] Janssen Trial Ex. J812, DUR packet for 7/8/2003 at 75.

Duragesic patients submitted only 1 to 5 claims for Duragesic during the one-year review period, and that Duragesic patients were not among those typically deemed at risk for abuse and addiction: 60% of all patients receiving Duragesic prescriptions were over 65, and half of those patients were over 80. Duragesic's market share among all Medicaid opioid prescriptions from 1996 to 2017 was [redacted]%. Its share of all HealthChoice opioid prescriptions from 2004 to 2017 was only [redacted]%.[101]

Nucynta and Nucynta ER, meanwhile, never got any significant traction in the market. Insurers treated them unfavorably, almost always (and, in the case of Oklahoma's Medicaid program, literally always) requiring prior approval before coverage in an effort to contain costs.[102] Faced with these obstacles, Janssen began to move its promotional resources away from the Nucynta products in January 2013, stopped all promotion of the products by late 2014, and sold them to a third party, Depomed, in April 2015.

All told, Nucynta made up only a tiny fraction of the opioid medications prescribed in Oklahoma. The two Nucynta products accounted for only [redacted]% of all Medicaid prescriptions and [redacted]% of all HealthChoice opioid prescriptions.

5. J&J is not a kingpin; Noramco and Tasmanian Alkaloids operated under the strict scrutiny of federal and international regulators.

Faced with Duragesic and Nucynta's low abuse rates and minuscule market shares, the State has invented a new line of attack on Janssen and J&J found nowhere in its Petition. Citing J&J's prior ownership of Tasmanian Alkaloids, a company that farms and processes medical-

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[101] *See* Janssen Trial Ex. J327, Further Explanation of Certain Disclosed Expert Opinion Testimony of Laurentius Marais, Ph.D.; Ex. J2121, Documents Related to Oklahoma HealthChoice Prescriptions and Medical Claims; Ex. J2122, Documents Related to Oklahoma Medicaid Prescriptions.

[102] *See* J. Cohen Further Explanation of Certain Disclosed Opinion Testimony, at 3-5.

grade poppy products for incorporation into active pharmaceutical ingredients, and Janssen's prior ownership of Noramco, a company that manufactures active pharmaceutical ingredients for use by manufacturers of FDA-approved opioid pain medications, the State now asserts a sensationalist claim that J&J is the "kingpin behind this Public Health Emergency."[103] The evidence at trial will rebut this newfound claim. International and federal regulators strictly and pervasively regulate the markets in which Noramco and Tasmanian Alkaloids operate, allowing the manufacture and sale of their products only to the extent regulatory authorities deem necessary for medical and research needs. Noramco and Tasmanian Alkaloids operated independently from Janssen and J&J—receiving no input from either on their business plans, and providing no input on Janssen's marketing or sales of its Duragesic or Nucynta products. Likewise, Noramco and Tasmanian Alkaloids had no role or involvement in the marketing, distribution, or sales any other manufacturer's finished opioid medications.

From 1979 to 2016, Noramco was a Janssen subsidiary that sold medical-grade APIs to manufacturers of FDA-approved pharmaceutical products.[104] Over roughly the same period, Tasmanian Alkaloids was a J&J subsidiary that farmed and processed medical-grade "poppy straw" used to make some of Noramco's APIs.[105] Noramco produced APIs for both narcotic and non-narcotic pharmaceuticals, as well as chemicals for non-narcotic materials such as topimarate (used for epilepsy medications) and sutures.[106] Among the Schedule II opioid APIs that Noramco

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[103] *See* State's Motion for De-Designation (Feb. 26, 2019) at 4-5.
[104] Janssen Trial Ex. J1673, 2014 DEA Notice of Registration, Bulk Manufacturer of Controlled Substances Application, Noramco, Inc.; W. Grubb (Dec. 4, 2018) Depo. Tr. at 23-24.
[105] *Id.* at 24-25.
[106] *See* M. Martin (Feb. 20, 2019) Depo. Tr. at 11-12; Janssen Trial Ex. J3521, Noramco Sales Spreadsheets.

manufactured were codeine, morphine, oxycodone, oxymorphone, and noroxymorphone.[107] Noramco did not have a monopoly in this business. Multiple other companies—including Mallinckrodt, Johnson Matthey, Siegfried, and Cambrex—supplied opioid APIs to pharmaceutical manufacturers in the U.S.[108] Noramco's market share varied by year and type of API, and it was not always the market leader for certain APIs.[109] Between 2013 and 2015, for instance, Noramco supplied less than 50% of the market for five of the nine opioid APIs it produced.[110]

These businesses are far from "drug kingpins." International and federal regulators substantially dictated Noramco and Tasmanian Alkaloids' business at every stage of their supply chain—from cultivating raw materials to selling opioid API to pharmaceutical manufacturers.[111] The Controlled Substances Act establishes a quota system designed to ensure that Schedule II controlled substances are manufactured and sold in the United States only to the extent needed for medical and research purposes. Each year, the DEA dictates the aggregate quantity of each Schedule II API that may be produced,[112] then divides that quota amongst API manufacturers to establish the amount each may produce.[113] The DEA also sets procurement quotas establishing the amount of each Schedule II API that each particular pharmaceutical manufacturer may obtain

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[107] Janssen Trial Ex. J1673, 2014 DEA Notice of Registration.
[108] Janssen Trial Ex. J3451, Noramco's major competitors.
[109] W. Grubb (Dec. 4, 2018) Depo. Tr. at 86, 212.
[110] Janssen Trial Ex. J3453, Noramco market share calculation 2013-15.
[111] The CSA mandates that the DEA ensure the "necessary" supply of controlled substances that have a "useful and legitimate medical purpose … to maintain the health and general welfare of the American people" while combatting "improper use." 21 U.S.C. § 801(1)-(2).
[112] 21 U.S.C. § 826(a); 21 C.F.R. § 1303.11.
[113] *See* W. Grubb (Dec. 4, 2018) Dep. Tr. at 252 (DEA regulates narcotic raw material importation consistent with UN treaties).

to make medications that year.[114] Thus, every gram of API was produced and sold pursuant to the DEA's express regulatory determination authorizing the API in question be produced and sold in the specified quantities to the specified pharmaceutical manufacturers. Similarly, the International Narcotics Control Board, established pursuant to a UN treaty, enforces limits on the cultivation of opium poppies in Australia, thereby restricting the amount of narcotic raw material Tasmanian Alkaloids may produce each year.[115] At each stage of the supply chain, therefore, Noramco and Tasmanian Alkaloids acted in compliance with an extensive regulatory scheme limiting the supply and demand for its products to what the federal government deemed necessary to meet medical and research needs.[116]

Finally, notwithstanding its wild speculation, the State has no evidence that Janssen or J&J ever influenced Noramco's or Tasmanian Alkaloids's operations. Contrary to the State's wild conspiracy theory, Noramco and Tasmanian Alkaloids operated entirely independently of Janssen's pharmaceutical business. Noramco and Janssen interacted minimally. Indeed, current Noramco Vice President of Global Business Development Innovation William Grubb testified that interactions between Janssen and Noramco were "few and far between,"[117] and that Noramco was "an independent company" that "worked very autonomously" from Janssen.[118] Noramco developed its "own business plans" and determined its "own product selection criteria"

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[114] 21 C.F.R. § 1303.12.
[115] International Narcotics Control Board, "Narcotic Drugs," International Narcotics Control Board, available at https://www.incb.org/incb/en/narcotic-drugs/index.html (last accessed May 20, 2019) ("The 1961 [UN] Convention establishes strict controls on the cultivation of opium poppy"); Janssen Trial Ex. J239, Keith Bradsher, *The New York Times*, "Shake-Up on Opium Island" (July 19, 2014) at 3-4 (the "entire process is tightly monitored by a United Nations-authorized board, which tracks production and requires strict security").
[116] *See* W. Grubb (Dec. 4, 2018) Dep. Tr. at 282, 284.
[117] *Id.* at 74-75.
[118] *Id.* at 274.

with little to no input from Janssen or J&J.[119] Tasmanian Alkaloids was similarly autonomous.[120] Most importantly, neither Noramco nor Tasmanian Alkaloids had any involvement whatsoever in the marketing or sales of any finished opioid medications—not Janssen's Duragesic or Nucynta products, and not any other pharmaceutical manufacturer's opioid medications.[121]

C. Janssen Marketed Its Opioid Products Appropriately and with FDA Approval, and It Engaged in Constitutionally Protected Lobbying and Trade-Group Activity.

The State claims that, beginning in the mid-1990s, Janssen engaged in deceptive marketing that transformed doctors' and patients' views of opioid medications. In substance, the State asserts that, except for patients who have cancer or terminal illnesses, extended-release opioid medications are almost *never* appropriate for patients who suffer from chronic pain,[122] and that Janssen's FDA-approved promotion of opioids for that purpose was therefore wrongful. The State also cherry-picks statements from Janssen's marketing to argue that Janssen understated the risks and overstated the benefits of opioid medications. Again, the evidence will not support these claims. Janssen was legally entitled to promote its medications for their FDA-approved indications, and viewed in their entirety, its promotional materials were in no way misleading.

Among other things, all the State's arguments about Janssen's alleged wrongdoing fail because they do not account for the ample scientific evidence backing Janssen's representations;

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[119] *Id.* at 274-75.
[120] B. Fitzsimons (June 1, 2018) Dep. Tr. at 224 (denying that Tasmanian Alkaloids was part of an integrated company structure with J&J and Janssen).
[121] *See* W. Grubb (Dec. 4, 2018) Dep. Tr. at 284-285 (confirming that Noramco has "no involvement in the marketing or promotion … of the products" it sells and that Noramco does not "market finished dosage form").
[122] *See* State's Resp. to J&J and Janssen's Mot. Summ. J. at 14 ("There was no new evidence that [opioids] were effective at treating every-day pain, nor was there any evidence that opioids were suddenly less addictive … The only thing that changed was the way the drugs were marketed."); A. Kolodny (Mar. 7, 2019) Depo. Tr. at 253-55; A. Kolodny (Mar. 8, 2019) Depo. Tr. at 362-64.

because they rely on statements made in many cases long after the State itself claims its opioid abuse crisis was caused; and because the State has no evidence that Janssen ever made even one alleged misrepresentation that ever caused an improper prescribing decision that led to harm. And the State's claims flatly contradict the views of the FDA, which has long maintained that opioids are an appropriate treatment for chronic non-cancer pain and has rejected many of the same fringe theories the State's experts will advance here.

The State challenges statements that appeared in Janssen's FDA-approved product labels and branded marketing materials—that is, marketing materials specific to Duragesic and other Janssen opioid medications. The State also challenges statements in unbranded educational materials, which sought to raise awareness about pain conditions and treatment options generally (opioid and non-opioid). It also challenges lobbying and trade-group activities, and it challenges statements made by key opinion leaders ("KOLs"). All of Janssen's challenged statements were and are truthful and appropriate. Moreover, all of its lobbying and trade-group activities were and are constitutionally protected.

1. Janssen's Accurate, Science-Based Branded Marketing Activities Followed FDA Rules.

Janssen used branded marketing to educate doctors about risks, benefits, and appropriate patients for its opioid products. For example, Janssen's branded marketing for Duragesic often focused on the potential benefits of the transdermal delivery system, which provided patients with up to 72 hours of steady-state pain relief. Branded marketing for Nucynta and Nucynta ER highlighted the unique dual mechanism of the drugs' active ingredient, tapentadol. And branded marketing for all three medications were subject to FDA "fair balance" regulations, which required the materials to prominently list the products' risks—including their risks of abuse,

misuse, diversion, and death.[123] Janssen's branded marketing was directed to trained medical professionals.

Janssen's branded marketing efforts could not have caused a public health crisis because they promoted only Janssen's medications—products that represent a negligible share of opioid medications prescribed in Oklahoma and were not significantly abuse, misused, or diverted, as discussed above. Further, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") oversaw all of Janssen's branded promotional activities; Janssen submitted all branded marketing materials to the FDA prior to disseminating them publicly.[124] DDMAC reviews advertising and promotional labeling for prescription medications to ensure that they are supported by substantial evidence and do not include false or misleading information as defined by federal regulations. Janssen submitted promotional pieces to DDMAC at the time of first use.[125]

Janssen received one warning letter from DDMAC in connection with its marketing for an opioid product. In 2004, Janssen received a warning letter regarding a file card (a promotional aid used by sales representatives) for Duragesic. In the letter, DDMAC took issue with the sufficiency of certain data cited in the file card to support claims made in the card vis-à-vis the FDA's evidentiary standard for claims made in regulated promotional materials. Janssen responded by citing additional scientific support for both the use of the cited data and the claims themselves, but agreed to remove the card from circulation.[126] Janssen also sent a correction

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[123] *See* 21 C.F.R. § 202.1.
[124] In 2011, DDMAC was renamed the Office of Prescription Drug Promotion.
[125] 21 C.F.R. § 314.81.
[126] Janssen Trial Ex. J3681, Response to Sept. 7, 2004 Letter (Sept. 17, 2004) JAN-MS-00291332.

letter to healthcare providers.[127] DDMAC took no further action and pursued no enforcement action against Janssen.

a. **Sales Representatives**

Janssen's branded marketing for Duragesic and Nucynta included sales representatives calling on physicians. All Janssen sales representatives received thorough training. Before contacting any prescriber, a sales representative had to complete a training program that lasted months and included in-home study, group training, and testing. This initial training covered, among other things, background information on pain and pain management, package inserts and other product information, relevant scientific studies, and healthcare compliance. After their initial training, sales representatives would communicate with doctors under a trainer's supervision until demonstrating their ability to present medically accurate information, and to do so in compliance with Janssen policies and applicable law.

Janssen's training of sales representatives did not end with these initial sessions. It incorporated training into regularly scheduled district, regional, and national meetings to reinforce compliance requirements and provide scientific and market updates. Janssen also provided issue-specific trainings as needed, such as updates concerning product label revisions. After many of these trainings, Janssen required sales representatives to pass a subject-matter test before they could continue calling on healthcare providers.

Janssen's sales representatives often detailed pain specialists, orthopedic surgeons, and rheumatologists—doctors who had clinical experience with opioid medications and who treated the types of patients who could benefit from Duragesic or Nucynta. The State points to some of these doctors' high prescribing volumes to suggest that Janssen's visits to their offices were

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[127] Janssen Trial Ex. J866, Johnson & Johnson Letter Response JAN-MS-00291335.

somehow improper. But it is unsurprising that doctors working to manage patients' pain—that is, the prescribers for whom Janssen's detailing was relevant—prescribed high volumes of scheduled medications for the purpose of pain management. And any switching of patients from hydrocodone or oxycodone to Janssen's less-abused medications stood to *decrease* overall abuse.

The State also claims that certain common detailing practices somehow amount to evidence of misconduct. For example, sales representatives sometimes brought food when visiting an office mid-day, because the lunch hour is often the only time that doctors with busy practices are available. And they sometimes gave snacks, pens, and other trinkets to doctors and their staff. According to the State, these nominal gifts caused doctors to prescribe improperly. But the notion that handfuls of Duragesic pens and lunch items caused the opioid abuse crisis defies common sense.

b. **Promotional Speaker Bureaus**

Janssen also used promotional speaker programs to provide information on Duragesic and Nucynta. Promotional speaker programs are company-sponsored presentations, usually held over dinner, where respected practitioners present materials that have been reviewed and approved by Janssen's Promotional Review Committee ("PRC")—an internal review and compliance committee independent from the marketing department—to a small audience of healthcare providers. These programs help educate practitioners about medical products and therapeutic innovations with which they are not familiar. They give practitioners the opportunity to learn about a new drug or an updated drug label from a respected peer who has experience with the medicine and speaks the same language, providing context and depth that a sales representative cannot.

The FDA authorizes and regulates promotional speakers programs, and Janssen has strict policies governing them. Janssen requires—as does the FDA—that presentations include

relevant safety information, including warnings, precautions, and adverse reactions.[128] Doctors who served as speakers for Janssen completed in-depth training on compliance requirements as well as the specific materials they would be presenting.[129]

The State has identified not one false or misleading statement in any of Janssen's speaker programs. Nonetheless, the State suggests that the Court hold that speaker programs—common throughout the pharmaceutical industry and by no means unique to opioids—are inherently improper because speakers are paid for their time and attendees are provided a free meal. But regulations permit drug companies to compensate speakers and provide free meals to program attendees so long as these payments and meals are reported.[130] Contrary to the State's oft-repeated but never-substantiated claim, Janssen did not use speaker fees or dinner invitations to reward high prescribers. Rather, Janssen paid speakers fair market value. And the company invited practitioners based on their location, their interests, and whether the sales representative organizing the event thought a particular provider would find the presentation beneficial.

2. Janssen's Unbranded Educational Materials Did Not Cause Oklahoma's Opioid Abuse Crisis.

Between 2008 and 2010, Janssen created or sponsored certain educational materials that addressed the broad subject of pain management, including the use of prescription opioids where appropriate. The State claims that these programs "helped cause a public nuisance in the State of Oklahoma" because they promoted "aggressive opioid prescribing," "encouraged prescribing that was not needed," "obscured and downplayed the addictiveness of opioids," and "target[ed]

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[128] *See, e.g.,* Janssen Trial Ex. J1486, Nucynta and Nucynta ER Speaker Training at 11, 16.
[129] *See, e.g., id.*; Ex. J3452, [Powerpoint] Nucynta ER Tapentadol Extended Release Tablets New Perspectives in the Management of Moderate to Sever Chronic Pain.
[130] *See* Centers for Medicare and Medicaid Services, *Natures of Payment*, (Sept. 24, 2014), https://www.cms.gov/OpenPayments/About/Natures-of-Payment.html.

vulnerable populations, such as children, veterans and the elderly."[131] But these materials could not have caused Oklahoma's opioid abuse crisis because the materials *did not even exist* until, at the earliest, 2008—when prescribing was already approaching its peak and well after the State claims the opioid abuse crisis in Oklahoma began (1996). Nor could anything about these materials be deemed to have caused an opioid abuse crisis, timing aside.

The State has pointed to only a handful of Janssen unbranded publications in support of this implausible claim: Let's Talk Pain (a website launched in 2008), Neo Pathways (a website launched in 2008), Finding Relief (a booklet and DVD released in 2009), and Prescribe Responsibly (a website launched in 2010). These materials were designed to educate about pain management, including the risks, benefits, and effective use of opioid and non-opioid products for chronic pain, and answered calls from practitioners and patients for more information on opioids and pain-relief treatment. [132]

By definition, these "unbranded" programs did not promote—or even reference—Janssen's opioid medications. Not to mention, Janssen always fully disclosed its role in creating or contributing to these unbranded materials. For example, every page on

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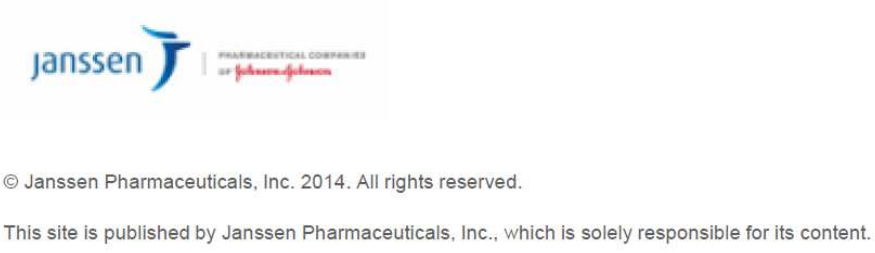
[131] Mot. to Dismiss Hr'g Tr. (Dec. 5, 2017) at 112; State's Resp. to Janssen's MIL No. 5 (May 3, 2019) at 8-9.

[132] For example, Janssen helped launch the Let's Talk Pain website in 2008 following a survey of 500 pain patients and 275 pain physicians that revealed a communication gap between patients and physicians about pain (inability to be open and honest about pain, lack of time to adequately discuss pain, and miscommunication regarding severity of pain). Janssen Trial Ex. J3905, Let's Talk Pain Survey Messages. Similarly, Janssen launched the Prescribe Responsibly website in 2010 following a survey revealing that physicians "largely agreed that a Web site on responsible opioid management would be of interest." Janssen Trial Ex. J1129, Email from L. Hoffman concerning Prescribe Responsibly survey results.

www.prescriberesponsibly.com, including the homepage, contained the following logo and disclaimer:[133]



And, contrary to the State's assertions, Janssen worked to ensure that its materials included only truthful and medically accurate statements.[134] Unbranded materials published by Janssen were thoroughly vetted by the PRC.[135] The PRC included members from several Janssen business units, including Medical Affairs, Medical Communications, Legal, Regulatory, and Health Care Compliance.[136]

The State's accusations about Janssen's unbranded educational materials are baseless:

Prescribe Responsibly. Prescribe Responsibly, a website launched in 2010, provided dozens of articles, pain-assessment tools, and risk-assessment resources to educate doctors about responsibly prescribing opioids for acute and chronic pain. In various articles, it recommended that doctors assess patients for risk factors before prescribing opioids, encouraged the use of "opioid agreements" for patient compliance, and provided a variety of tools to help doctors manage opioid risks with their patients, including the FDA-approved REMS.[137]

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[133] Janssen Trial Ex. J3662, Prescribe Responsibly Website Printout at 2, 3, 5.
[134] K. Deem-Eshelman (Jan. 25, 2019) Depo. Tr. at 264.
[135] *See* Janssen Trial Ex. J1227, Let's Talk Pain Medication Safety Series Filming Schedule (second Let's Talk Pain video season concept submitted for PRC review); Ex. J3124, PRC Approval Forms for Finding Relief Brochure and associated DVD (PRC approval of Finding Relief).
[136] *Id.*
[137] Janssen Trial Ex. J3508, Prescribe Responsibly Website at 6; Ex. J3662, Prescribe Responsibly Website Printout at 14, 16, 18; Ex. J2137, Opioid Risk Tool.

From the hundred-plus pages of educational materials on this website, the State has pointed to just a few statements—including a definition of the term "pseudoaddiction" from the medical literature and a statement, also supported by cited medical literature, that "true addiction occurs only in a small percentage of patients."[138] Janssen's experts will testify at trial that each of these statements challenged by the State is medically accurate and not misleading to any healthcare professional.

What's more, all but one of these statements are contained in a single article: "Use of Opioid Analgesics in Pain Management" by independent pain-management expert, Dr. Keith Candiotti.[139] Read as a whole, the article provides prescribers with information on the risks, benefits, and limitations of opioid therapy based on a review of medical literature. Among other things, the article includes citations to 19 medical journal articles, informs physicians that the use of opioids for treatment of neuropathic pain "remains somewhat controversial," notes that concerns about opioid addiction are "not without some merit," and leaves physicians with this bottom-line conclusion: "[T]here still remains much to be learned [about opioids], and ongoing research will no doubt help clarify some of these questions."

If this article amounts to anything other than an informative literature review, it reflects the opinions of a single healthcare professional—which Candiotti's peer healthcare professionals would fully understand when viewing this article. And to resolve any possible confusion, the

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[138] Janssen's experts, including Dr. B. Moskovitz, Dr. T. Philips, and Dr. R. De La Garza, will testify at trial that each of these select challenged statements are medically accurate and not misleading to any healthcare professional. *See generally* Janssen Trial Ex. J2050, Janssen Defendants' Expert Disclosure.

[139] State Trial Ex. 949, Use of Opioid Analgesics in Pain Management.

article includes a disclaimer reminding healthcare professionals of their duty to exercise their own "independent medical judgment" and noting that Candiotti was compensated by Janssen.[140]

Finding Relief. An educational booklet and DVD released in 2009, *Finding Relief* was sponsored by Janssen and created in collaboration with the American Academy of Pain Medicine and the American Geriatrics Society. The booklet was designed to educate older adults about their options for pain management and how to talk to their doctors about finding the right pain treatment option.[141] The State takes issue with a single quote taken from the 34-page booklet, and even then removes vital context in an attempt to turn an accurate statement into a misleading one. By the State's telling, the booklet claims that "opioids are rarely addictive"—but omits important qualifiers that appeared in the original text. The booklet in fact states, "Many studies show that opioids are rarely addictive when used properly for the management of chronic pain."[142] Janssen's experts, including Dr. Richard De La Garza, will confirm the truth of this statement at trial. Indeed, the FDA made virtually the same statement in its own 2009 publication.[143] And the suggestion that this statement from 2009 caused an increase in opioids prescriptions the State contends began in 1996 is absurd.

Other statements in the booklet counterbalance the statement in any event, warning patients about opioid risks and that opioids require informed discussions with a doctor: "If you are taking an opioid medication for pain, you must be careful," "Don't take your medication more often—or in larger dose—than prescribed," "Be aware of how you react to your

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[140] *Id.* at JAN-MS-03090610, 613.
[141] Janssen Trial Ex. J206, Finding Relief Pain Management in Older Adults at 5.
[142] *Id.* at 17.
[143] Janssen Trial Ex. J3606, FDA Guide to Safe Use of Pain Medicine (Feb. 9, 2009) ("Studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction").

medication," and "Your doctor's goal should always be to balance the benefits of a drug with the side effects the drug might cause."[144] And *Finding Relief* presents prescription opioid medications as just one of many pain-management tools. The 34-page booklet covers opioids on just *one* page but devotes *twelve* pages to other pain-management drugs and techniques, including aspirin, acetaminophen, NSAIDS, topical anesthetics, injection therapies, physical therapy, counseling and emotional support, acupuncture, hypnosis, meditation, massage, exercise, weight loss, and good posture.[145]

Let's Talk Pain. Let's Talk Pain, a website launched in 2008, was developed by Janssen, the American Pain Foundation, the American Academy of Pain Management, and the American Society for Pain Management Nursing. The site was designed to "encourage individuals with pain and their healthcare professionals to improve how they communicate with each other about pain and its treatment."[146]

The State points to the website's citation to a medical definition of the term "pseudoaddiction," its mention of the "under-treatment" of pain, and a statement that "[u]nless you have a past or current history of substance abuse, the chance of addiction is very low when these medications are prescribed by a doctor and taken as directed."

But the State itself concedes that Janssen did not invent the concept of "pseudoaddiction"—the term was coined in a 1988 medical article by Dr. J. David Haddox,[147]

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[144] *Id*. at 19.
[145] *Id*. at 14-16, 18, 20-27.
[146] Janssen Trial Ex. J3646, Let's Talk Pain Website Printout at 2.
[147] Janssen Trial Ex. J428, Opioid pseudoaddiction – an iatrogenic syndrome, David Weissman and David Haddox.

and the concept was recognized in medical literature even earlier, in the early 1970s.[148] The concept is also reflected in FDA-approved labels for prescription opioids, including Duragesic, Nucynta ER, and Nucynta, and has been since 2009.[149] At trial, Janssen's experts will establish that the other statements are also true, including the realities associated with the under-treatment of pain and the low addiction rate for opioids that are appropriately prescribed and taken as prescribed. These online statements posted in 2008 plainly did not cause the opioid abuse crisis.

Let's Talk Pain also includes significant content about the risks of opioids and stresses the importance of patients' communications with doctors about opioids. For example, the website states, "If you suffer from pain, it's natural to want to know the truth about opioid therapy. It's even more important that you talk to your healthcare professional about whether or not these pain treatment options are right for you." [150] It also tells readers to "[a]sk your provider what you should watch for when taking opioids" and notes that prescribers should undertake a "careful assessment of potential risks for addictive disease, abuse, and diversion."[151] Finally, Let's Talk Pain, like *Finding Relief*, covered not just opioids but also a variety of non-opioid

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[148] Janssen Trial Ex. J3762, R. Marks & E. Sachar, Annals of Internal Medicine, Undertreatment of Medical Inpatients with Narcotic Analgesics.

[149] *Compare* Janssen Trial Ex. J3646, Let's Talk Pain website at 10 ("A related term is *pseudoaddiction*, which refers to patient behaviors that may occur when pain is under-treated. This includes an increased focus on obtaining medications ('drug seeking' or 'clock watching') and even illicit drug use or deception."), *with* Janssen Ex. J2778 Nucynta Label 2009-03 at 13 ("'Drug seeking' behavior is very common in addicts, and drug abusers ... ***Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.***" (emphasis added)).

[150] Janssen Trial Ex. J3646, Let's Talk Pain website at 67.

[151] *Id.* at 68.

pain treatments—medical devices, NSAIDs, acetaminophen, topical analgesics, adjuvant analgesics, and herbal alternatives to pain medications.[152]

Neo Pathways. Neo Pathways was an unbranded program launched in 2008 consisting of a website, a sales-force program, and a speakers-bureau program. The program aimed to educate doctors about a "multipathway" approach to treating pain—the idea that drugs could treat pain by targeting more than just one receptor in the brain, as Nucynta ultimately did. The State challenges two concepts the program presented: the "under-treatment" of pain and that untreated acute pain can turn into chronic pain.[153] But, as with all of its unbranded programs, Janssen collected a wealth of medical support for these concepts, which the PRC reviewed before launch.[154] And again, it is beyond implausible that a 2008 promotional program discussing such general concepts could cause an opioid abuse crisis.

All of Janssen's unbranded programs presented balanced discussions about the risks and benefits of opioid medications, and they all post-date by more than a decade the opioid abuse crisis the State says began in 1996.[155]

3. Janssen Did Not Market Opioids to Children.

Janssen *never* promoted opioids to children; the State has no evidence to support its baseless and irresponsible assertions to the contrary. In fact, Janssen has a long record of working to *prevent* drug abuse by children.

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[152] Janssen Trial Ex. J1227, Let's Talk Pain Medication Safety Series Filming Schedule; Ex. J364 Let's Talk Pain Web Site Manuscript 12-Month Review at JAN-MS-00006888-90; Ex. J3646, Let's Talk Pain website at 70-71, 74-78; Exs. J3071-3074, 3080 Let's Talk Pain Videos.
[153] K. Deem-Eshleman (Feb. 25, 2019) Dep. Tr. at 1233-37.
[154] Janssen Trial Ex. J3702, Slide Presentation, "Neo Pathways - What Every Physician Should Know About Pain"; Ex. J1057, NeoPathwaysInPain Submission.
[155] The State consistently cites *Responsible Opioid Prescribing*'s promotion of pseudoaddiction as an example of misleading marketing, but Janssen did not fund, much less author, *Responsible Opioid Prescribing*.

The State bases its outrageous accusation first on a statement in a 2011 presentation used *internally* within the Imagine the Possibilities Pain Coalition ("IPPC"), a pain coalition brought together by Janssen. This statement references the IPCC's consideration of a public-relations campaign aimed at teaching children how to communicate their pain to trusted adults. This was not a proposal to market opioids to children. And, in any event, the IPPC never implemented the proposal anywhere, let alone in Oklahoma. The IPPC shut down in 2012.

The State has also zeroed in on Growing Pains, a website created by the American Chronic Pain Association ("ACPA") to help youth understand, cope with, and communicate about their chronic pain. The ACPA independently developed the website and exercised complete control over its contents, which make *not a single mention of opioids*. Rather, the site focuses on self-esteem and mental well-being in children suffering from chronic pain. It stated, for instance, "You know it's real and you are entitled to all of the emotions, both good and bad, associated with your pain," "You deserve to be treated fairly and respectfully even if the cause of your pain is unknown," and "You have the right to know the *reasons* why your parents, teachers, and medical team are making decisions that affect your life." Common-sense statements like these should be non-controversial and are cannot in good faith be characterized as the "marketing of opioids to children."

Meanwhile, the contents of Janssen's only direct program for youth—Smart Moves, Smart Choices—affirmatively *warned* teens, their parents, and their educators about the *dangers* of teen prescription drug abuse, including the abuse of prescription opioids. Janssen and the National Association for School Nurses ("NASN") launched Smart Moves, Smart Choices in 2008. The program targeted populations with the greatest need for education on prescription drug

abuse: teens in "hard hit communities."[156] The program featured classroom curricula, a series of educational DVDs, and high school assemblies—including one at Boulevard Academy in Edmond, Oklahoma—with local officials and drug-abuse counselors.[157] The program's website offered free educational materials for teens, parents, and teachers nationwide.[158]

These materials, which are designed to "begin a conversation about teen Rx abuse," convey that opioid medications are among the "most commonly abused" prescription medications, "can lead to addiction," "can cause severe respiratory depression that can lead to death," and are no safer to abuse than heroin or cocaine.[159] Janssen expanded Smart Moves, Smart Choices in 2014 to include Start Smart, a similar program for elementary and middle school students and their parents.[160]

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[156] Janssen Trial Ex. J1050, April 16, 2008 NASN Press Release; Ex. J450, Slide presentation, "Smart Moves, Smart Choices 2009 Program Success," at 3.
[157] *Id.*; Janssen Trial Ex. J3336, Slide presentation, "Smart Moves, Smart Choices: A Prescription Drug Abuse Prevention Program 2008: Roll Out Plan" at 2.
[158] Janssen Trial Exs. J3014-J3022, Smart Moves, Smart Choices materials.
[159] Janssen Trial Ex. J2402, Copy of 2011 Get Smart, Take Action Teen Prescription Drug Abuse Awareness School Tool Kit at JAN-MS-0083583; *id.* at JAN-MS-00835591.
[160] Janssen Trial Ex. J3037, Start Smart Medicine Safety Tips; Ex. J3040, [Poster] Start Smart Their Drug of Choice.

The State's narrative about Janssen's outreach to children is thus doubly false—the State fabricates Janssen's efforts to "promote" opioids to children and ignores Janssen's efforts to keep children safe.

4. Janssen's Sponsorship of Continuing Medical Education Programs was Appropriate and Did Not Influence Content.

Just as lawyers must attend legal education programs, physicians must attend continuing medical education ("CME") programs to maintain their licensure. These seminars are typically presented by physicians and are aimed to help other physicians improve their knowledge, skills, and professional performance.

The State has asserted that Janssen paid physicians to make misrepresentations to other physicians at CME events. The State, however, has never identified a single such misrepresentation. Nor can it. The evidence will show that Janssen exercised no control over the content of any CME program that it sponsored. Since 2002, CME programs must be fully

independent from their corporate sponsors to be accredited.[161] And even before then, no Janssen employees ever gave, assisted, or supervised a CME program. Though Janssen financially supported certain CMEs through charitable grants, these programs were independently organized.

The testimony in this case confirms this. For example, Dr. Scott Fishman, a KOL who worked with Janssen, testified generally about the nature of CMEs and repeatedly emphasized that the funding of a CME program has no bearing on the content of a CME presentation.[162] As he explained, "[t]he speaker and the content [of a CME program] by rule should be separated from any funders. So I often have no idea who's funding a CME program that I will give regardless of what the topic is."[163] Similarly, Dr. Portenoy testified that there "[wa]s nothing false or misleading" in the CMEs he participated in and that "[t]here was never any effort on the part of a funding company, the sponsor, to change my messages or ask me to use specific slides."[164]

5. Janssen's relationships with KOLs were appropriate.

The State also levels broader criticisms of Janssen's practice of consulting with KOLs. KOLs are independent healthcare providers with in-depth experience in a relevant field, and they are engaged by all sorts of pharmaceutical and medical-device companies—not just the makers of opioids. KOLs are hired for a variety of purposes across the lifecycle of a medication; they may, for example, advise a company internally or promote a company's medications externally.

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[161] *See* Janssen Trial Ex. J2115, ACCME Standards for Commercial Support of Continuing Medical Education Presentation; *see also* Ex. J778, Guidance Document: Support of Continuing Medical Education [CME] Activities at 1-2.
[162] S. Fishman (Feb. 26, 2010) Dep. Tr. at 332-24, 288-292.
[163] *Id.* at 288-89.
[164] R. Portenoy (Jan. 24, 2019) Dep. Tr. at 464-65.

Pharmaceutical companies pay KOLs the fair market value of their time during these engagements, just like any company paying a consultant for his or her time.

Janssen's engagement of KOLs included uncontroversially beneficial initiatives. For instance, KOLs helped Janssen develop the Pain Assessment and Documentation Tool ("PADT"), which assists doctors in creating clinical data for patients taking opioids.[165] Several government entities, including the National Institute on Drug Abuse and Oklahoma's own Health Care Authority, have endorsed the use of the PADT.[166]

The State has nonetheless accused Janssen of forging nefarious associations with KOLs. Yet, the allegation is cast only in generalities. Typically, the State alleges that Janssen and other manufacturers somehow deployed KOLs to spread allegedly misleading marketing messages.

The State has no evidence to support this allegation. To the extent the State criticizes KOLs' delivery of speakers' bureau programs, it identifies no misstatements made during these presentations, as discussed above. To the extent the State criticizes the delivery of CMEs by doctors who happen to be engaged as KOLs for Janssen, this allegation is not actionable because Janssen does not work with KOLs in connection with CMEs. As discussed above, such programs are put on by third parties over which Janssen has no influence, and—in any event—the State has identified no misrepresentations in CMEs sponsored by Jansen.

Moreover, Janssen is not responsible for every statement made before Janssen's engagement of a KOL or after, simply by virtue of a KOL engagement. Contrary to the State's

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[165] Janssen Trial Ex. J3634, Janssen Pharmaceutica, Progress Note, Pain Assessment and Documentation Tool (PADT) (2003); Ex. J3355, [PDF] PADT Guidebook.
[166] Janssen Trial Ex. J2718, NIDA: Pain Assessment and Documentation Tool (PADT); Ex. J2719, SoonerCare Oklahoma Health Care Authority Pain Management Program; Ex. J2169, Pain Assessment and Documentation Tool from OKHCA Pain Management Toolkit.

insinuations, Janssen does not and cannot control KOLs. All KOLs criticized by the State are pain-management experts who expressed clear opinions about opioids in numerous peer-reviewed, published articles ***before*** Janssen engaged them. And all KOLs deposed in this action uniformly testified that the compensation they received from opioid manufacturers did not influence the content of their presentations or publications.[167]

6. Janssen's Associational Activities Promoted the Interest of Proper Pain Management—Not the Improper Use of Opioids.

In the American medical system, advocacy groups—from the American Cancer Society to the March of Dimes—play a leading role educating doctors, patients, and policymakers; raising public awareness of emerging health issues; and lobbying for constituents. These organizations often collaborate with industry to promote the interests of patients, caregivers, and doctors.

As the medical profession turned its attention to pain treatment beginning in the 1970s, a number of advocacy groups emerged to campaign for greater awareness and improved treatment of pain. And pharmaceutical companies, including Janssen, recognized that their goals aligned with some of these new organizations. For example, Janssen and advocacy groups both aimed to identify and address areas of unmet need, provide tools and resources to persons living with pain, and share advances in pain management through educational programs.[168] Janssen and J&J have always engaged with these groups responsibly and within legal bounds.

J&J and/or Janssen contributed to several types of organizations:

- *Medical societies*: These groups represent healthcare professionals in fields related to pain management. The American Academy of Pain Medicine, for

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[167] *See, e.g.,* R. Portenoy (Jan. 24, 2019) Dep. Tr. at 398-400, 471; L. Webster (Feb. 18, 2019) Dep. Tr. at 271; S. Fishman (Feb. 26, 2019) Dep. Tr. at 332; C. Argoff (Dec. 18, 2018) Dep. Tr. at 285-86.
[168] *See* R. Kohn (Feb. 22, 2019) Dep. Tr. at 14-15, 36, 57, 62-66, 71.

example, represents more than 1,000 pain-management specialists. Others include the American Pain Society, the American Geriatrics Society, the American Society of Pain Management Nursing, and the Academy of Integrative Management.

- *Patient-advocacy groups*: These groups advocate for Americans suffering from chronic pain. The American Chronic Pain Association, for example, offers peer support and pain-management education to patients, their family members, and their caregivers. Others include the American Pain Foundation, the National Pain Foundation, and the U.S. Pain Foundation.

- *Academic/educational groups*: These groups, often affiliated with top universities, educate the public and provide opportunities for academic researchers to collaborate and expand knowledge in the field of pain management and treatment. The Pain & Policy Studies Group, for example, is a global research program within the University of Wisconsin Medical School. Others include the American Society of Pain Educators and the Joint Commission.

- *Policy groups*: These groups are nonprofit, nonpartisan advocacy and service organizations that interface with government agencies in support and opinion leading. The Federation of State Medical Boards, for example, supports state medical boards in licensing and discipline of medical professionals. Others include the Cancer Action Network, the Center for Practical Bioethics, and the Pain Care Forum.

The State alleges that some or all of these third-party advocacy groups spread false marketing messages on Janssen's behalf, though, it has rarely identified specific statements it contends are misleading. This claim fails on the facts and the law. Janssen's contributions to these third-party groups are neither nefarious nor actionable. The First Amendment, as discussed below, protects Janssen's free-speech and associational rights—rights Janssen exercised by contributing to these groups. That conduct cannot render Janssen liable for any statements these groups made. And to the extent they engaged in petitioning activity, that activity too is constitutionally protected. The State criticizes the Pain Care Forum, for example, for allegedly

seeking to "influenc[e] policy."[169] But any such protected activity cannot form the basis for the State's claim.

The State further alleges that Janssen went beyond mere funding to also "direct[] and control[]" these groups' activities. Petition at ¶ 63. But the State has no evidence of this, because Janssen did no such thing. For example, Janssen had no control over the drafting of anydocuments published by any advocacy group. It had no control, for instance, over the drafting of the American Academy of Pain Medicine/American Pain Society Guidelines—practice guidelines for chronic opioid therapy that were published in the peer-reviewed *Journal of Pain*. Nor did Janssen have control over the drafting of the American Geriatrics Society Guidelines, which were published in the peer-reviewed *Journal of the American Geriatric Society* and were reviewed by more than a dozen medical societies. Each of the organizations identified by the State is an independent entity, with its own members, goals, and strategies. And critically, the State has never identified any evidence showing that Janssen directed or controlled any of these activities. The State likewise cannot establish, for the reasons discussed in connection with Janssen's branded promotion and unbranded materials, that advocacy organizations funded by Janssen made false or misleading statements, or that any challenged statements caused Oklahoma's opioid abuse crisis.

D. Illegal Diversion of Oxycodone and Hydrocodone and Public-Policy Failures Drove the Abuse and Misuse of Prescription Opioid Medications—Not Janssen's Products or Marketing.

The State alleges that pharmaceutical marketing, coinciding with the launch of OxyContin in 1996, caused an increase in opioid prescribing, which led to increases in opioid abuse and the use of street drugs such as heroin and street fentanyl. But the facts on the ground

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[169] State's Mot. for De-Designation (Feb. 26, 2019) at 9.

tell another story. The increase in prescription opioid abuse in Oklahoma that began around 2000 and peaked in 2009 was largely driven by the diversion and illicit use of opioid medications. International drug cartels greatly exacerbated the crisis, pumping heroin and illegal street fentanyl into Oklahoma and other states. And meanwhile, as the crisis intensified, the State and the federal government consistently failed to take any action—and in some cases enforced rules that exacerbated the crisis—despite mounting evidence of a severe public-health problem caused by street drugs and unlawful diversion of prescription medications.

1. Oklahoma's Medicaid Program and Other Healthcare Payers' Push for Lower Costs Encouraged Doctors to Prescribe Cheap, Easy-to-Abuse Opioids Instead of More Expensive Treatments.

Healthcare payers' efforts to minimize costs prioritized generic oxycodone and hydrocodone over branded medications with lower abuse rates, like Duragesic and Nucynta, and encouraged opioid prescriptions over alternative pain-management options. Oklahoma's Medicaid program provides a case study in how payers have pushed doctors to prescribe more opioid medications in ways that prioritize cost savings over safety and long-term effectiveness. The State program, like other payers, tightly restricts its coverage of abuse-deterrent opioids and alternative pain-management options such as physical therapy and mental-health treatment. At the same time, it placed far fewer restrictions on cheaper—but more easily abused—opioids such as oxycodone and hydrocodone. For at least a decade following OxyContin's launch, SoonerCare imposed no prior-authorization requirement on prescription opioids. On July 1, 2008, the State began sorting drugs into tiers governing how and when they could be prescribed. Oklahoma's Medicaid program covered Tier 1 drugs without any prior authorization from the Oklahoma Health Care Authority.[170] Oxycodone and hydrocodone are and have always been Tier 1 drugs.

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[170] *See, e.g.*, Janssen Trial Ex. J1644, DURB Meeting Packet (Jul. 9, 2014) at Appendix H.

To receive coverage for a "Tier 2" opioid—which includes Duragesic and immediate-release Nucynta—patients must jump through hoop after hoop, which may include 30-day trials with cheaper Tier 1 drugs.[171] The State erects even more obstacles for Tier 3 opioid products like Nucynta ER, requiring patients to demonstrate an allergy to *all* Tier 2 medications or undergo 30-day trials with *two* Tier 2 medications.[172] These obstacles have led Oklahoma's Medicaid program to cover vastly more prescriptions for cheap hydrocodone than for Duragesic, Nucynta, and Nucynta ER. And the proof is in the numbers: In 2013, for instance, the State covered 338,798 hydrocodone claims, but only 231 claims for Nucynta, 79 for Duragesic, and 74 for Nucynta ER.[173] By placing fewer restrictions on the most easily abused and diverted opioids like hydrocodone and oxycodone, the State enabled and encouraged the very prescribing it now claims was "medically unnecessary."

2. Oklahoma Officials Knew About Improper Prescribing and Drug Diversion but for Years Failed to Curb The Practices.

While its own Medicaid system encouraged doctors to prescribe easy-to-abuse opioids and warning signs mounted, the State for years did nothing to curb the prescribing and diversion of opioid medications. As early as 2002, diverted opioids and other pharmaceuticals were readily available in most parts of Oklahoma.[174] But neither Duragesic nor Nucynta were frequently diverted; "[o]xycodone and hydrocodone were."[175] Prescriptions for those drugs surged in the late 1990s and into the 2000s. And the members of the State's DURB more than a decade ago said they believed those products were being prescribed irresponsibly and diverted illegally.

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[171] *Id.*
[172] *Id.*
[173] *Id.*
[174] *See* Janssen Trial Ex. J784, Oklahoma Drug Threat Assessment, National Drug Intelligence Center, U.S. Department of Justice at 30-31.
[175] Janssen Trial Ex. J3805, DUR Board Meeting Packet at 59.

Concerned about the abuse of OxyContin, an oxycodone product, the DURB conducted multiple reviews of OxyContin utilization in 2003. Materials for one 2003 meeting show that although OxyContin is indicated for only twice-daily use, patients prescribed OxyContin on average received prescriptions for 2.9 pills per day between April 2002 and March 2003. In other words, on average, patients received just shy of 50% more than the maximum daily dosage of OxyContin.[176] Meanwhile, prescriptions for hydrocodone were also increasing in Oklahoma and across the country. DURB utilization reports from 2000, the first year of data available in the State's productions, show hydrocodone-acetaminophen combination products such as Vicodin and Lortab were the most commonly prescribed drugs for all of Oklahoma's Medicaid program—more common than medications for blood pressure and asthma.[177] Outside of the Medicaid system, hydrocodone was the most commonly prescribed narcotic in Oklahoma by far: In the second half of 2008 alone, "physicians prescribed 95 million pain killer tablets and capsules—70 percent of which were for hydrocodone."[178]

Materials presented at DURB meetings make clear that the State knew about actual—not just potential—abuse and diversion of prescription opioids. In 2001, DURB reviewed a letter from Purdue Pharma that described "[r]eports of illegal misuse, abuse, and diversion of Oxycontin."[179] In 2004, DURB received a DAWN report stating that "abuse of opioid pain relievers has been recognized as a serious and growing public health problem" and observed that "[o]xycodone and hydrocodone were the most frequently named pain relievers, accounting for

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[176] Janssen Trial Ex. J812, DUR Packet for July 8, 2003 Meeting.
[177] Janssen Trial Ex. J773, DUR Packet for July 8, 2003 Meeting at 84.
[178] Janssen Trial Ex. J573, 2009 PMP Grant Application at 1.
[179] Janssen Trial Ex. J734, DUR Packet for Aug. 14, 2001 Meeting at 34.

40 percent (47,594 mentions) of the opioid pain relievers involved in [] ED visits."[180] And in 2008, Mark Woodward of the Oklahoma Bureau of Narcotics ("OBN") explained that Oklahoma ranked number one in prescription drug abuse and that its top drug problem was hydrocodone. He went on to explain that there were "several hundred Oklahomans who are seeing more than ten doctors" and that one notorious Oklahoman had visited more than 60.[181]

DURB members, in the company of high-ranking state agents, stated at meetings that hydrocodone and oxycodone products were being diverted and abused, either because of improper prescribing practices or "doctor shopping"—the practice of gathering multiple drug prescriptions from different doctors. For example, the minutes of a 2004 DURB meeting reflect that Dr. Dan McNeill (then-Chairman of DURB), when reviewing narcotic analgesic utilization, stated that he "c[ould]n't imagine that this is responsible prescribing."[182] During a 2009 meeting, Dr. Brent Bell voiced concerns about blatant abuse of prescription opioids. He noted that 25% of patients with a high number of prescriptions for opioids had four or more prescribing physicians.[183] Chairman John Muchmore agreed that "that's a warning sign, isn't it?"[184] But notwithstanding specific recommendations from countless members and attendees, these red flags were all but ignored.

DURB also recognized that Oklahoma had a flourishing underground market for pharmaceutical sales. At a 2008 meeting, Chairman Dr. McNeill explained that "there is underground pharmaceutical sales that is very rampant," especially where "people may die and

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[180] Janssen Trial Ex. J3805, DUR Board Meeting Packet at 59.
[181] Janssen Trial Ex. J456, DURB Packet for May 14, 2008 Meeting at 8.
[182] State Trial Ex. 1545, University of Oklahoma, DUR Board Memo (Nov. 4, 2004), at OKAG-00012709.
[183] Janssen Trial Ex. J1150, DUR Meeting Recording and Transcription at 33-34.
[184] *Id*. at 34.

leave quite a store of medications behind, long-acting narcotics; they get around, they get sold underground."[185] At a meeting in 2006, Dr. Val Vorse told the DURB: "[M]ost of these folks are not getting it from their physician or a physician, they're getting it on the internet or on the street. And … patients tell me that they think that a lot of it's coming over the border from Mexico."[186] At the same meeting, DURB member Dr. Bell, a pediatric psychiatrist, said he saw patients who were using OxyContin and were "getting it from grandma and aunts and uncles."[187]

The State not only failed to take action to curb the rampant diversion and abuse of prescription drugs, but also—as discussed above—affirmatively encouraged the prescribing of immediate-release hydrocodone and oxycodone by placing them in the Medicaid program's Tier 1. The State knew that this practice increased the likelihood of abuse and diversion.[188] There was only one reason that the State's Medicaid program favored hydrocodone-combination and oxycodone instant release products over all others: they were cheaper.[189]

The State also permitted physicians to prescribe narcotics without consulting its prescription monitoring program ("PMP"), even as the opioid abuse crisis accelerated. Few doctors in fact used the PMP, which meant that it rarely achieved its aims of detecting and stopping doctor shopping.[190] Even OBN, which had access to the full PMP database, took two years to catch one doctor shopper who "obtained 4,533 dosage units of pain relievers, mostly Hydrocodone (Lortab) from 195 different healthcare professionals, including doctors and

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[185] *Id.* at 13-14.
[186] Janssen Trial Ex. J939, DUR Meeting Recording and Transcription at 29.
[187] *Id*. at 29.
[188] Janssen Trial Ex. J1514, DUR Meeting Recording and Transcription at 78 ("Well, the more you put in a bottle, the more you encourage diversion.").
[189] *Id.* at 52.
[190] Janssen Trial Ex. J573, 2009 PMP Grant Application at 3.

dentists, and filled the prescriptions at 105 separate pharmacies, statewide."[191] Despite evidence of improper prescribing and diversion, OBN's policy was always to "trust doctors to do the right thing."[192] "Trust" under these circumstances, however, amounted to a dereliction of duty.

Other abuses also went unchecked. OBN rarely took action against pill mills despite its agents observing "various infractions of the law" such as "pre-signed prescriptions that were handed to patients … without the doctor being present."[193] Employee theft of narcotics "is a growing trend in Oklahoma."[194] [redacted].[195] At one nursing home, elderly patients' names were used to fraudulently obtain painkillers which were sold on the black market.[196] And for some time, a group of individuals in the Tulsa area were "prolific" at forging prescriptions for narcotics.[197]

Melton Edminsten, former Chief of the OBN Diversion Division, testified that that he "[a]bsolutely" "[b]egged" for additional OBN diversion agents, given the severity of the diversion crisis in Oklahoma.[198] But for a decade, requests for additional diversion agents were not answered.

3. Drug Cartels Have Poured Heroin and Street Fentanyl into Oklahoma.

Today, prescription opioids are quickly taking a back seat to illicit fentanyl and heroin. Illicit fentanyl began showing up in Oklahoma at least as early as 2013. That year, all OBN

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[191] Janssen Trial Ex. J634, State's Top "Doctor Shopper" Charged at 1.
[192] M. Stewart (Jan. 22, 2019) Dep. Tr. at 179-180.
[193] M. Woodward (Feb. 12, 2019) Dep. Tr. at 51.
[194] M. Stewart (Jan. 22, 2019) Dep. Tr. at 200.
[195] Janssen Trial Ex. J2942, OKMB-00008019 ¶¶ 4-7.
[196] M. Woodward (Feb. 12, 2019) Dep. Tr. at 173.
[197] M. Edminsten (Mar. 12, 2019) Dep. Tr. at 56-57.
[198] *Id.* at 46.

agents and College of Pharmacy personnel were informed that fentanyl powder caused 22 people to overdose in Lorain County.[199] They were also informed that illicit fentanyl was being sold as heroin.[200]

Since then, illicitly manufactured fentanyl—which typically comes from China and Mexico—has appeared repeatedly in Oklahoma. Sometimes it is mixed into heroin; other times it is pressed into counterfeit pills; and still other times it makes its way into gummy candies or nasal sprays that are hard to identify.[201] OBN has repeatedly seized illicit fentanyl in recent years: in 2016, for example, it seized seven pounds of heroin laced with fentanyl, and in 2017, it seized 8.8 pounds of fentanyl and dismantled a fentanyl lab in rural Cleveland County.[202]

III. JANSSEN SHOULD PREVAIL ON THE STATE'S PUBLIC NUISANCE CLAIM

As Janssen's summary judgment motion explained, the State's claim goes miles beyond what Oklahoma public nuisance law permits. By staking its case on the marketing and sale of highly regulated prescription medications, the State flouts a century of Oklahoma caselaw expressly confining nuisance actions to conduct or injuries involving property use. And in asking for a cash recovery to address ***injuries*** it blames on the alleged nuisance, the State contravenes the plain text of Oklahoma's nuisance statute, which allows the State to abate only ***conduct***—not the harms that allegedly result from conduct.

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[199] Janssen Trial Ex. J296, Email from Sandra G. LaVenue to John Foust; Cindy Hamilton re: Request for Information from NADDI at 1.
[200] *Id*.
[201] Janssen Trial Ex. J622, 2018 OBN Drug Threat Assessment; J624, 2017 OBN Oklahoma Drug Threat Assessment; J1774, Email from Eric Pfeifer to NAME Listserv and Mitchell Weinerg at 1.
[202] Janssen Trial Ex. J622, 2018 OBN Drug Threat Assessment; J624, 2017 OBN Oklahoma Drug Threat Assessment.

In a May 6 hearing before this Court, the State insisted that Oklahoma's public nuisance statute must be read with an eye toward the identically worded nuisance statutes of the Dakotas.[203] Four days later, a North Dakota trial court confirmed that the State's public nuisance theory here is fundamentally misconceived: In dismissing the North Dakota Attorney General's public nuisance claim against Purdue, that court explained that "[n]o North Dakota court has extended the public nuisance statutes to cases involving the sales of goods." *North Dakota ex rel. Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-cv-01300, Slip Op. at 27 (N.D. D.Ct. May 10, 2019). So too here, the evidence at trial will show that the State's case has nothing whatsoever to do with property use in Oklahoma, but instead targets the marketing and sale of products on a national market. That total disconnect from a hundred years of controlling Oklahoma nuisance precedents will require entry of judgment for Janssen.

A. Oklahoma's Public Nuisance Statute Regulates Real Property—Not Product Sales.

The State's lone claim against Janssen relies on a statute that has nothing to do with marketing or prescription drugs or product liability—a statute that, for more than a century, has been used exclusively for property-based disputes over the likes of loud businesses, illegal dumping, and foul-smelling pets. Public nuisance is not and has never been a magic bullet for social problems allegedly traceable to the sale of goods or services. Rather, courts have long applied Oklahoma's nuisance statute exclusively to the misuses of real property and public spaces, or the interferences with others' use and enjoyment of their real property. The State now proposes using that statute for the first time to regulate public health problems allegedly traceable to the sale of lawful, highly regulated, non-defective products. That radical invitation violates the Oklahoma

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[203] Hr'g Tr. (May 6, 2019) at 17-18.

Supreme Court's explicit definitions of public nuisance. And it makes no sense: A set of rules developed to police obnoxious neighbors is not up to the challenge of effectively regulating product sales or fairly apportioning liability for state-wide public health problems.

Although the Oklahoma statute defining nuisance, 50 O.S. § 1, is broadly worded, the Supreme Court has clarified that "[n]uisance, as defined in 50 O.S. § 1 … is a class of wrongs which arises from an unreasonable, unwarranted, or unlawful use by a person or entity of property lawfully possessed." *Briscoe v. Harper Oil Co.*, 1985 OK 43, ¶ 9, 702 P.2d 33, 36. Oklahoma courts have ruled accordingly time and again. In *Laubenstein v. Bode Tower, L.L.C.*, 2016 OK 118, ¶¶10-12, 392 P.3d 706, 710, the Supreme Court explained "that a nuisance 'arises from an unreasonable, unwarranted, or unlawful use' of property," and in turn "demands evidence of substantial interference with the use and enjoyment of property." Similarly, in *Nichols v. Mid-Continent Pipe Line Co.*, 1996 OK 118, ¶8, 933 P.2d 272, 276, the Court found that the statute "encompasses the common law's … public nuisance concepts," which it described as "a field of tort-like liability which allows recovery of damages for wrongful interference with the use or enjoyment of rights or interests in land." Those are just recent examples in a long line of cases stating this limitation on nuisance liability.[204]

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[204] *See, e.g., Morain v. City of Norman*, 1993 OK 149, ¶14, 863 P.2d 1246, 1249-50 ("In *Briscoe v. Harper Oil. Co*. … we noted that a nuisance was 'an unreasonable, unwarranted, or unlawful use by a person or entity of property lawfully possessed, but which works an obstruction or injury to the right of another' … Thus, in order to find City liable for nuisance, the flooding to the plaintiffs' properties must have been caused by City *using lawfully possessed property* in an unreasonable, unwarranted or unlawful manner (misfeasance) or failing to perform some duty (nonfeasance)" (emphasis added)); *Dobbs v. City of Durant*, 1949 OK 72, ¶5, 206 P.2d 180, 182 ("No princip[le] is better settled than that where a business is conducted in such a manner as to interfere with the reasonable and comfortable enjoyment by others of their property or which occasions material injury to the property, a wrong is done to the neighboring owners for which an action will lie[.]"); *McPherson v. First Presbyterian Church of Woodward*, 1926 OK 214, 248 P. 561, 562 ("Though every one has the right to the reasonable use and enjoyment of his own

This limitation applies to public and private nuisances alike: "A nuisance, public or private, arises where a person uses his own property in such a manner as to cause injury to the property of another." *Fairlawn Cemetery Ass'n v. First Presbyterian Church, U. S. A. of Okla. City*, 1972 OK 66, ¶14, 496 P.2d 1185, 1187. The only difference between public and private nuisance under the statute is that "[a] public nuisance … affects at the same time an entire community or neighborhood, or any considerable number of persons." 50 O.S. § 2. The Oklahoma Supreme Court's public nuisance cases have uniformly involved harms related to real property or public spaces. *See, e.g.*, *Smicklas v. Spitz*, 1992 OK 145, ¶¶3-4, 846 P.2d 362, 364-65 (maintenance of earthworks affecting owners of property along river); *Mackey v. State ex rel. Harris*, 1972 OK 37, 495 P.2d 105, 108 (operation of saloon declared a nuisance because "the location chosen by the respondent in this case is such that it annoys the neighborhood, a residential area"); *Crushed Stone Co. v. Moore*, 1962 OK 65, 369 P.2d 811, 813 (operation of quarry impacting nearby landowners); *Boudinot v. State ex rel. Cannon*, 1959 OK 97, ¶1, 340 P.2d 268, 269 (keeping dozens of cats on residential property caused noise and odor impairing the enjoyment of nearby homes); *McPherson*

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property, he may not so use it as to unreasonably deprive an adjacent owner of the lawful use and enjoyment of his property, one using his property in an unwarrantable manner, and thereby injuring the comfort, health, and safety of another, creates a 'nuisance,' which may be abated at the suit of the person so injured."); *Moore v. Texaco, Inc.*, 244 F.3d 1229, 1231 (10th Cir. 2001) ("Oklahoma law defines nuisance by statute as a class of wrongs arising from an unreasonable, unwarranted, or unlawful use by a person or entity of property lawfully possessed, but which works an obstruction or injury to the right of another."); *McCormick v. Halliburton Co.*, 2014 WL 1328352, at *3 (W.D. Okla. Mar. 31, 2014) ("It is clear under Oklahoma law that a nuisance claim may be stated based upon wrongful interference with the use or enjoyment of a person's rights or interests in land."); *Escott Rentals LLC v. Canadian Hills Wind, LLC*, 2012 WL 2995701, at *1 (W.D. Okla. 2012) (a public nuisance "transgresses the just restrictions upon use or conduct which the proximity of other persons or property imposes" (quoting *Briscoe*, 1985 OK 43, ¶9, 702 P.2d 33, 36)).

v. First Presbyterian Church of Woodward, 1926 OK 214, 248 P. 561, 566 (construction of gas station emitting noise and odor harming nearby church).

Here, the State attempts to shoehorn a sprawling case about marketing claims, drug addiction, and epidemiology into the narrow and well-defined boundaries of a tort that "arises where a person uses his own property in such a manner as to cause injury to the property of another." *Fairlawn Cemetery Ass'n*, 1972 OK 66, ¶14, 496 P.2d at 1187. Try as the State might, its case simply does not fit. Courts have regularly refused to transform public nuisance into a product-liability tort. For example, in *Texas v. American Tobacco Co.*, 14 F. Supp. 2d 956 (E.D. Tex. 1997), Texas sued tobacco companies under a number of theories, including public nuisance, seeking just the kind of recovery Oklahoma seeks here: "costs incurred in providing medical care and other benefits to its citizens … as the result of the citizens' use of cigarettes and smokeless tobacco products" based on the companies' "manufacturing, advertising, distributing and selling tobacco products." *Id*. at 960-61, 973. The court refused to "accept the State's invitation to expand a claim for public nuisance beyond its grounding in real property." *Id.* at 973.

Rightly so. The sales and marketing of lawful products is already regulated by "well-developed bodies of law covering strict products liability, negligence, and warranty theories." Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. CIN. L. REV. 741, 744 (2003). Oklahoma courts have often considered legal challenges to the sales and marketing of medical products under those causes of action. *See, e.g.*, *Edwards v. Basel Pharm*., 1997 OK 22, 933 P.2d 298; *In re Okla. Breast Implant Cases*, 1993 OK 11, 847 P.2d 772; *McKee v. Moore*, 1982 OK 71, 648 P.2d 21; *Tansy v. Dacomed Corp.*, 1994 OK 146, 890 P.2d 881. Product-liability law includes extensive protections, developed over decades, to ensure that courts mete out liability proportional to a manufacturer's liability fault. *See, e.g.*, *McNair v. Johnson & Johnson*, 818 S.E.

2d 852, 861 (W. Va. 2018) ("branded manufacturers cannot be held strictly liable for failure to warn of another[] manufacturer's product").

Public nuisance law, which evolved to address hazards like loud businesses and leaky oil wells, unsurprisingly lacks similar protections. Recognizing this crucial difference, courts have rightly "enforced the boundary between the well-developed body of product liability law and public nuisance law" for fear of turning nuisance law into "a monster that would devour in one gulp the entire law of tort." *People v. Sturm, Ruger & Co.*, 309 A.D. 2d 91, 97 (N.Y. App. Div. 2003). "All a creative mind would need to do is construct a scenario describing a known or perceived harm of a sort that can somehow be said to relate back to the way a company or an industry makes, markets and/or sells its nondefective, lawful product or service, and a public nuisance claim would be conceived and a lawsuit born." *Id.* at 96.

The implications of extending broadly worded nuisance rules to encompass harms from product sales would be "staggering." *In re Firearm Cases*, 126 Cal. App. 4th 959, 991 (2005). "General Motors could be sued by someone who was hit by a Corvette that had been stolen by a juvenile. The plaintiff would allege that General Motors knew that cars that can greatly exceed the speed limit are dangerous, and through advertising … it increased the attractiveness of the car … and thus increased the likelihood that a juvenile would steal a Corvette and operate it in an injurious manner." *Id.* (quoting *Ileto v. Glock, Inc.*, 370 F.3d 860, 862 (9th Cir. 2004) (Callahan, J., dissenting from denial of rehearing en banc)). Imaginative plaintiffs' lawyers have brought such claims against oil producers, including Oklahoma corporations, on the theory that they misled the public about the risks of climate change. *See, e.g.*, *County of San Mateo v. Chevron Corp.*, 294 F. Supp. 3d 934, 937 (N.D. Cal. 2018) (remanding public nuisance action against oil and energy companies "seek[ing] abatement of greenhouse gas emissions"), *appeal docketed*, No. 18-15502

(9th Cir.). They have targeted lead-paint manufacturers for decades-old advertisements that allegedly led to contemporary health hazards. *See In re Lead Paint Litig.*, 924 A.2d 484, 486-87 (N.J. 2007). They have even sued cellular phone manufacturers alleging they cause accidents from distracted driving. *See Modisette v. Apple Inc.*, 30 Cal. App. 5th 136, 141-42 (2018).

In its opposition to Janssen's summary judgment motion, the State attempted to distinguish these cases by asserting that they rested on other states' distinctive nuisance statutes.[205] That claim was a blatant misrepresentation to this Court: All of those cases involved ordinary common law nuisance claims governed by principles similar to those Oklahoma courts have long embraced. For example, *Sturm* did not, as the State asserts, address a claim under New York statutory law,[206] but a "common-law public nuisance cause of action." 309 A.D.2d at 92. Nor did *American Tobacco* arise under a Texas nuisance per-se statute, as the State told this Court—after explaining why the statute was inapplicable, the court went on to ***additionally*** reject a common-law public nuisance claim for lack of any connection to property use. *See* 14 F. Supp. 2d at 973 ("***Neither*** may the State maintain an action for damages under a public nuisance theory…." (emphasis added)). Finally, the State's representation to this Court that *In re Lead Paint* "dealt with" New Jersey's Lead Paint Act was false: The court discussed the Lead Paint Act only to reject the plaintiffs' claim that the Act bolstered their ***common-law public-nuisance*** claim's plausibility. *See* 924 A.2d at 486; *see also id.* at 487 ("[W]e are called upon to consider only whether these plaintiffs have stated a cognizable claim based on the common law tort of public nuisance."). The State's need to mischaracterize

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[205] State's Resp. to J&J and Janssen's Mot. Summ. J. at 21-22 ("[redacted]").

[206] *See id.* at 22.

multiple cases only underscores how far removed its claim is from the common law of public nuisance.

The massive, sudden expansion of Oklahoma's public nuisance statute would also violate due process, which requires a "fair warning … that intelligibly communicates the parameters of conduct to be proscribed" prior "to imposition of penalty, civil or criminal." *State ex rel. Okla. Bar Ass'n v. Minter*, 2001 OK 69, n.55, 37 P.3d 763, 774; *see Sessions v. Dimaya*, 138 S.Ct. 1204, 1229 (2018) (Gorsuch, J., concurring) ("[I]f the severity of the consequences counts when deciding the standard of [vagueness] review, shouldn't we … take account of the fact that … civil laws regularly impose penalties far more severe than those found in many criminal statutes?"). Longtime precedent limiting public nuisance to land-use interferences, coupled with the elusive wording of the nuisance statute (targeting conduct that "annoys … others" and "[o]ffends decency," for example), deprived Janssen of fair notice that Oklahoma's public-nuisance statute might subject it to billions of dollars in abatement liability for prescription drug marketing. *See, e.g.*, *Walker v. Dugger*, 1962 OK 88, ¶13, 371 P.2d 910, 913 ("[i]f there is a fair doubt as to whether the act charged is embraced in the prohibition, that doubt is to be resolved in favor of the person against whom enforcement of the statute is sought").

Trial will confirm that the State is not pursuing a public-nuisance case at all, but a product-liability case alleging harms from the marketing and sale of goods. That basic disconnect from a century of public-nuisance precedent will require the Court to enter judgment for Janssen.

B. Because Janssen No Longer Markets Opioid Medications, There Is No Public Nuisance for the State to Abate.

The State not only asks for this Court to ignore more than a century of precedent and reinterpret Oklahoma's public nuisance statute—it also demands a remedy dramatically different from that which the statute authorizes. The Oklahoma nuisance statute provides the State with a

single remedy: "abat[ing]" the "public nuisance." 50 O.S. § 11. It likewise makes plain that the "nuisance" the State can "abate" is the defendant's *conduct*—not the allegedly resulting harms: "A nuisance consists in unlawfully *doing an act, or omitting to perform a duty*." *Id.* § 1 (emphasis added). Here, trial will show that the State does not seek to abate any "act" or "omi[ssion]" by Janssen. If it did, it could seek only to enjoin Janssen from its allegedly misleading marketing of opioid medications—a moot point, as Janssen stopped promoting opioid products altogether in 2015. Instead, the State seeks to "[redacted]"[207]—that is, to address the harms allegedly resulting from Janssen's actions. But the opioid epidemic is not conduct by Janssen and, under Oklahoma law, cannot constitute a nuisance; it is the "injury" or "damage" allegedly resulting from such conduct. *Briscoe*, 1985 OK 43, ¶¶9-11, 702 P.2d at 36. Because Oklahoma law does not grant the State authority to collect for such injuries, the Court should grant summary judgment in Janssen's favor.

1. The State's Only Permissible Remedy Is Abatement of the Public Nuisance.

Oklahoma law gives the State a single civil remedy in a public nuisance suit: abatement of the nuisance itself. Title 50, Section 8 of the Oklahoma Statutes states that "[t]he remedies against nuisance are: 1. Indictment or information, or, 2. A civil action, or, 3. Abatement." The sections that follow spell out who is entitled to pursue those remedies, and under what circumstances:

- ***Indictment or Information*.** Section 9 instructs that "the remedy by indictment or information is regulated by the law on crimes and punishment and criminal procedure."
- ***Civil action.*** Section 10 provides that "[a] private person may maintain an action for a public nuisance if it is specially injurious to himself but not otherwise."

[207] Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D. at 1.

- ***Abatement.*** Section 11 states that "[a] public nuisance may be abated by any public body or officer authorized thereto by law." And Section 12 directs that a private individual can abate a nuisance "which is specially injurious to him."

That is the sum total of the nuisance statute's remedies for public nuisance. And, as Section 10 allows only private persons to bring civil actions, public entities have just two options: They can pursue "indictment or information" under Section 9, or they can "abat[e]" the "public nuisance" under Section 11. There is no third way.

That limitation lines up with longstanding public nuisance principles. Under the common law, "[t]he remedies usually available [for public nuisance] are those of criminal prosecution and abatement by way of an injunctive decree or order." Keeton & Prosser, *Prosser and Keeton on the Law of Torts* § 90, at 643 (5th ed. 1984); *see In re Lead Paint Litig.*, 924 A.2d 484, 498 (N.J. 2007) ("the public entity, as the modern representative of the sovereign in public nuisance litigation, has only the right to abate"). Oklahoma cases embody this principle: In more than a century of Oklahoma public nuisance cases, no court has ever granted the State any remedy other than indictment or abatement. Quite the contrary, public entities consistently request—and courts consistently grant—only injunctive relief to abate the public nuisance itself. *See, e.g.*, *State ex rel. Field v. Hess*, 1975 OK 123, ¶¶1-3, 540 P.2d 1165, 1167; *Curlee v. State ex rel. Edmondson*, 1957 OK 72, ¶¶1-4, 309 P.2d 1064, 1064-65; *State ex rel. Whetsel v. Wood*, 1952 OK 175, ¶¶1-3, 248 P.2d 612, 613; *State ex rel. King v. McCurdy*, 1935 OK 412, ¶¶1-2, 43 P.2d 124, 124; *State ex rel. King v. Friar*, 1933 OK 501, ¶¶1-4, 25 P.2d 620, 621.

2. The State Impermissibly Seeks to Abate an Injury, Rather than a Public Nuisance.

The State's theory that Janssen's actions caused a public nuisance fatally misunderstands nuisance law. Under Oklahoma law, a nuisance is not an injury or condition *caused by* an action—a nuisance is the action *itself*. An opioid abuse crisis simply does not fit that definition of a "public

nuisance." *See* 50 O.S. § 1. As described by the State, the crisis is not an action but the harm that allegedly flows from Janssen's actions: the marketing of legal, FDA-approved opioid medications, which Janssen ceased in 2015. With no nuisance to abate, the State is left seeking to remedy *harms*—and Oklahoma law does not allow it to do so.

Oklahoma law distinguishes between a nuisance and its consequences. A "nuisance consists in unlawfully doing an act, or omitting to perform a duty." 50 O.S. § 1. By contrast, "'[d]amage' or 'injury', as ordinarily used in nuisance cases is the *result* of the nuisance." *Briscoe*, 1985 OK 43, ¶9, 702 P.2d at 36. Put another way, "[n]uisance is a wrong, and damage is the result." *Oklahoma City v. Page*, 1931 OK 764, ¶10, 6 P.2d 1033, 1036.

The State's authority to abate a public nuisance, then, begins and ends with stopping the conduct that constitutes the nuisance. The Oklahoma State Court made that clear in *Magnolia Petroleum Co. v. Wright*, 1926 OK 196, ¶2, 254 P.2d 41, 42, where it explained that a government body's power to "abate and remove" "a nuisance" is the "power [to] *prevent any act or omission of any duty* … which *act or omission* … annoys, injures, or endangers the comfort, lives, health, or safety of others." (emphasis added). That power does *not* include the right to seek redress for the conduct's *consequences*. *See Atchison, Topeka & Santa Fe Ry. Co. v. Kelly*, 1928 OK 256, ¶10, 266 P. 775, 776 ("The defendant might abate its nuisance, but could not, by so doing, restore plaintiff's premises.").

That eviscerates the State's claim. The State can demand only that Janssen stop or start some particular conduct, yet it has not done so. For good reason: Janssen stopped promoting opioids when it divested its Nucynta franchise in 2015.[208] No "act or omission" remains for the

[208] Moskovitz (Aug. 28, 2018) Dep. Tr. at 51, 247.

State to abate. 50 O.S. § 1. Instead, the State advances an "abatement plan" that simply proposes having Janssen pay for a grab bag of proposed programs that the State promises will "target[]" the opioid abuse crisis over the next 30 years.[209]The State's experts concede that this plan does not ask Janssen to stop doing (or do) anything.[210]

This demand for cash exposes the State's "abatement plan" for what it really is: a straightforward attempt to recover nuisance damages—damages Oklahoma law does not permit the State to seek.[211] Indeed, the State's experts acknowledge that its "abatement plan" attempts to address the *injuries* it believes Janssen caused: "[T]he defendants caused the opioids crisis and, therefore, … should pay the cost to abate the opioid crisis."[212] But the "damage" or "injury" that is "the *result* of the nuisance," is *not* a nuisance. *Briscoe*, 1985 OK 43, ¶9, 702 P.2d at 36. And so the State's demand for monetary recovery to address such alleged injuries is not an action to "abate" a "public nuisance," 50 O.S. § 11, but a demand for damages, *see, e.g.*, *Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1029 (10th Cir. 2007) (applying Oklahoma law) ("one aspect of damages the victim of a temporary nuisance can recover is the cost of restoring the land to its former condition") (internal quotation marks omitted); *Briscoe*, 1985 OK 43, ¶13, 702 P.2d at 37 ("costs of restoring the temporary abatable injury to the well site" are "damages"); *Thompson v. Andover Oil Co.*, 1984 OK CIV APP 51, ¶19, 691 P.2d 77, 83 ("Damages adjudged in an action

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[209] T. White (Apr. 11, 2019) Dep. Tr. at 271; J. Hawkins (Mar. 6, 2019) Dep. Tr. at 54; Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D. at 8, 9.
[210] J. Hawkins (Mar. 6, 2019) Dep. Tr. at 231; T. White (Apr. 11, 2019) Dep. Tr. at 252.
[211] If this Court disagrees and concludes that the State's demand for cash payments represents nuisance abatement, the State would be required to establish its entitlement to relief by clear and convincing evidence. *See, e.g.*, *Edwards v. Bd. of Cty. Comm'rs of Canadian Cty.*, 2015 OK 58, ¶12, 378 P.3d 54, 59 ("the right to injunctive relief must be established by clear and convincing evidence and the nature of the injury must not be nominal, theoretical, or speculative").
[212] T. White (Apr. 11, 2019) Dep. Tr. at 258.

predicated on a nuisance theory may include clean-up costs") (internal quotation marks omitted). Because Janssen no longer promotes opioids, there is no remotely conceivable public nuisance for the State to abate—and because Oklahoma law allows the State to seek such abatement only, it has nothing left to ask for.

IV. THE STATE CANNOT MEET ITS BURDEN TO PROVE CAUSATION

The State's theory of causation is equally unprecedented, and fatally flawed. As the Court knows, at trial, the State will not offer evidence that any statement by Janssen influenced a single Oklahoma doctor to write a single prescription that harmed a single patient. Instead, it will try to prove causation through allegations that a "brilliant multifaceted campaign"—allegedly involving innumerable actors including other manufacturers, well-respected medical and patient groups, and the nation's leading pain doctors—"infiltrated every part of the discussion surrounding opioids," causing increased prescriptions, which the State claims caused the opioid abuse crisis.

That theory will fail for multiple reasons, not least that it targets far more than the law allows. The First Amendment strictly shields public statements by advocacy organizations and doctors about important public health issues like chronic pain and opioid therapy. It likewise protects Janssen's efforts to petition federal and state government bodies about public policy. And federal statutory law preempts the State's attempt to impose liability on Janssen for conduct that complied with DEA and FDA mandates. The State cannot prove causation against Janssen by pointing to the federal protected conduct of dozens of independent actors.

But the State's theory fails even on its own terms, relying on conclusory expert assertions that do not withstand scrutiny. Those experts assert, for instance, that because opioid prescriptions and deaths rose during the same period, the deaths ***must*** have been caused by the prescriptions, rather than illicit diversion, enforcement failures by the State, or the social and

policy problems that caused exponential rises in alcohol, methamphetamine, benzodiazepine, and muscle-relaxant overdoses over the same time period. The unsubstantiated say-so of fringe experts—about federally protected activity, no less—will provide no basis for the Court to conclude that Janssen caused an opioid abuse crisis in Oklahoma.

A. The State Cannot Prove Causation Through Federally Protected Conduct.

Under the Constitution's Supremacy Clause, state courts cannot impose liability for conduct protected by federal constitutional or statutory law—even for public nuisance. *See, e.g.*, *Napro Dev. Corp. v. Town of Berlin*, 376 A.2d 342, 349 (Vt. 1977) ("The sword of public nuisance is a blunt one, admirably designed to curb noxious odors or to quell riots, but illsuited to the delicate sphere of the First Amendment where legal overkill is fatal."). This Court therefore must exclude from its causation analysis activities beyond the reach of any state tort action. These include expressions of non-commercial speech, like a nonprofit's public advocacy, which the First Amendment protects, as well as certain commercial activities, like Noramco's API sales, for which federal law preempts state tort liability. *See, e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588 (6th Cir. 2013) (preempted theory cannot serve as "link in the causal chain" of state-law tort action). Once trial begins, this Court will see that the State's theories rest almost entirely on such non-actionable, federally protected conduct.

Third parties' core First Amendment speech. The State will try to build its case in large part around public statements that third parties—not Janssen—made about medical issues. Among other things, it will try to hold Janssen liable for:

- Nonprofit organizations' public advocacy on pain issues, like the American Pain Society's advocacy of pain as a "fifth vital sign."[213]

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[213] State's Omnibus Resp. to Motions to Dismiss for Failure to State a Claim at 2-3 (Oct. 30, 2017); Kolodny Dep. (Mar. 27, 2019) Tr. at 105.

- Prominent doctors' public statements about pain treatment and opioid therapy, including at continuing medical seminars, and even in books.
- Respected medical societies' publication of guidelines on the prescribing of pain medications.

The State's attempts to cast such statements as part of a sinister conspiracy over which Janssen served as "kingpin" will not withstand scrutiny. The trial evidence will show that doctors, advocacy organizations, and professional organizations formed sincerely held beliefs that chronic pain represented a serious public-health challenge for which opioids provided a valuable treatment option. And they formed those beliefs years before Janssen released its Duragesic or Nucynta products.

Moreover, those third parties' public statements in books, conferences, treatment guidelines, and other media addressed matters of indisputable public concern: the suffering of tens of millions of Americans. *See, e.g.*, *Magnusson v. New York Times Co.*, 2004 OK 53, ¶ 12, 98 P.3d 1070, 1075 ("Public health is clearly a matter of public consonance."). They never constituted commercial speech. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561 (1980) (defining "commercial speech" as "expression related solely to the economic interests of the speaker and its audience"); *United States* v. *United Foods, Inc.,* 533 U. S. 405, 409 (2001) ("commercial speech [is] usually defined as speech that does no more than propose a commercial transaction"). Such speech "on public issues occupies the highest rung of the hierarchy of First Amendment values and is entitled to special protection." *Connick v. Myers*, 461 U.S. 138, 145 (1983) (internal quotation marks omitted). It cannot be the basis for liability under state tort law, in Oklahoma or anywhere else. *See, e.g.*, *Snyder v. Phelps*, 562 U.S. 443, 451 (2011).

The State may believe that those third parties got things wrong, but "[t]he erroneous statement is inevitable in free debate," *New York Times Co. v. Sullivan*, 376 U.S. 254, 271

(1972), and courts therefore have rejected a "general exception to the First Amendment for false statements." *United States v. Alvarez*, 567 U.S. 709, 718 (2012). It likewise does not matter that Janssen had financial relationships with some—and only some, of the third parties whose speech the State condemns: "[M]aking contributions" to "organizations that participate in public debate" is an "activit[y] that enjoys substantial First Amendment protection." *In re Asbestos School Litig.*, 46 F.3d 1284, 1294 (3d Cir. 1994) (Alito, J.). Such conduct can be targeted with tort liability only if the "donation was specifically intended to advance activities ***not*** protected by the First Amendment." *Id.* at 1291 (emphasis added). Here, by contrast, third parties' speech falling squarely within the First Amendment cannot be used to hold Janssen liable for the opioid epidemic. *See, e.g.*, *Gaylord Entm't Co. v. Thompson*, 1998 OK 30, ¶ 42, 958 P.2d 128, 148-49 ("If the [defendants] '*conspired*' to participate in activities and aims that are constitutionally protected, their conduct lacks actionable attributes. A conspiracy to carry on activity that is lawful and shielded by fundamental law cannot be deemed tortious.").

In short, the First Amendment precludes this Court from finding that Janssen caused the opioid abuse crisis by affiliating with others who spoke publicly and wrote about an issue of indisputable public importance. In light of that straightforward constitutional principle, wide swaths of evidence the State will present to establish a "brilliant multifaceted campaign" become irrelevant to causation.

Lobbying. The State will also seek to hold Janssen liable for [redacted]"[214]—that is, for Janssen's constitutionally protected lobbying efforts. Among other

[214] State Mot. for De-Designation (Feb. 26, 2019) at 11.

things, the State claims that Janssen "tried to get laws passed that would make opioids more widely used,"[215] including a federal law "requir[ing] the Institute of Medicine to come out with a report on chronic pain in America."[216] But the First Amendment protects the "right of the people … to petition the Government," precluding the State from seeking liability for Janssen's attempts to inform and influence government policy. U.S. Const. amend. I. Under the Noerr-Pennington doctrine, the Petition Clause immunizes "activities comprising mere solicitation of governmental action with respect to the passage and enforcement of laws." *C.H. (Skeet) Smith Trucking Co. v. Bill Hodges Trucking Co.*, 671 F. Supp. 1329, 1333 (W.D. Okla. 1987). That protection extends to lobbying efforts aimed at "all departments of the government," including administrative agencies. *California Mot. Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). The State's evidence that Janssen—like countless others—lobbied federal and state government bodies and agencies thus targets constitutionally protected activity that cannot establish causal responsibility for the State's injuries.

Noramco's federally regulated API sales. As explained above, the federal Controlled Substances Act regulated every milligram of API that Noramco produced and sold. The DEA determined the amount of opioid API necessary to meet the country's medical needs and, based on that determination, authorized Noramco to produce a set amount of API. *See* 21 U.S.C. § 826(a) (requiring DEA to consider "estimated medical … needs of the United States"); 21 C.F.R. § 1303.11 (similar). Likewise, the DEA determined the amount of API Noramco's customers—including Purdue—could purchase "to ensure an adequate and uninterrupted supply of basic classes of controlled substances." 21 C.F.R. § 1303.12(a). DEA quotas explicitly

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[215] Hr'g Tr. (Apr. 11, 2019) at 80-81.
[216] *Id.* at 82-83.

"authorize[d]" Purdue, as a matter of federal law, "to procure and use … [a]ll quantities of [API] necessary to manufacture" its drugs. *Id.*

The State may believe the DEA got things wrong when it authorized Purdue to purchase API for its opioid medications, but under federal law, that is the DEA's call to make—not the State's. Imposing tort liability on Noramco for supplying products that the DEA authorizes pharmaceutical manufacturers to obtain would improperly challenge the agency's choices and undermine the operation of a delicate regulatory scheme—with unpredictable and potentially harmful results. *See, e.g.*, U.S. Government Accountability Office, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should be Improved*, GAO-15-202 (2015) (finding that DEA failure to meet quota-setting deadlines resulted in repeated shortages for prescription analgesics). Federal law therefore preempts the State's Noramco theory, just as it preempts any attempt by the states to countermand federal authority, and the State cannot point to Noramco's API sales to establish causation. *See, e.g.*, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (state laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" are preempted); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588 (6th Cir. 2013) (preempted theories cannot serve as "link in the causal chain").

Oklahoma law likewise does not permit liability for Noramco's sales of raw materials to pharmaceutical manufacturers.In particular, Oklahoma does not recognize tort liability for a component supplier that has no role in making the finished product. Such a supplier has no duty to warn the finished product's end-user about the component's risks, and can be held liable "only … when [it] substantially participates in the design of the final integrated product." *Swift v. Serv. Chem., Inc.*, 2013 OK CIV APP 88, ¶¶21-22, 310 P.3d 1127, 1133. The drug manufacturers that

bought API from Noramco "made a substantial change in the way the [API] was packaged and distributed, and in instructing how [it] should be used." *Id.* And no principle of Oklahoma law authorizes holding a component supplier liable for marketing transgressions allegedly committed by the finished product manufacturers in the marketing and distribution of their own finished products. For these reasons, the State cannot hold Janssen liable for the conduct of the manufacturers to whom it sold API.

Marketing Consistent with Label. Finally, federal law blocks the State's attempt to predicate liability on promotional statements—including representations that opioids are appropriate treatments for chronic non-cancer pain—that mirrored the FDA-approved labels of Janssen's medications. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, preempts state-law claims seeking to impose a duty to alter FDA-approved labeling where there is "clear evidence" the FDA would not allow the label change. *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, Slip Op., at 8 (May 20, 2019). That restriction extends to marketing no less than to the physical labels affixed to drugs, *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013), because FDA regulations define "labeling" to include "virtually all communication with medical professionals" about a medication. *Del Valle v. PLIVA, Inc.*, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011), *R. & R. adopted sub nom. Del Valle v. Qualitest Pharm. Inc.*, 2012 WL 2899406 (S.D. Tex. June 22, 2012), *aff'd sub nom. Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014). Courts thus hold that federal law preempts state-law claims where, as here, they would require a pharmaceutical manufacturer to make statements about safety or efficacy that conflict with FDA-mandated statements. *See, e.g.*, *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017).

At trial, the State will ask the Court to do exactly what federal law forbids: find Janssen liable for promotional statements that accurately reflected its medications' FDA-approved labels. Most notably, multiple State experts asserted in their depositions that Janssen should not have promoted its long-acting opioid medications for the treatment of chronic non-cancer pain.[217] But that is precisely the use for which the FDA-approved labels indicate those drugs: "the management of pain in opioid-tolerant patients severe enough to require daily, around-the-clock, long-term opioid treatment." *See supra* Section II.B.[218] By theorizing that Janssen should not have promoted Janssen's long-acting opioid medications for chronic pain, the State claims that Janssen's labeling should have unilaterally narrowed those medications' FDA-approved indications. *See* 21 C.F.R. § 202.1(l)(2) (defining marketing materials as "labeling").

As the Supreme Court recently reaffirmed, federal law preempts such a state-law claim "when there is 'clear evidence' that the FDA would not have approved the [label change] that state law requires." *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, Slip Op., at 8 (May 20, 2019) (internal quotation marks omitted). Here, the evidence could not be clearer: In 2013, the FDA *explicitly rejected* a petition by the State's lead expert, Andrew Kolodny, that sought to revise the indications of long-acting opioids to exclude long-term non-cancer pain, finding that his proposal lacked scientific support. *See supra* Section II.B. Earlier this month, a North Dakota trial court recognized that this rejection showed the FDA would not allow manufacturers to

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[217] *See, e.g.*, A. Kolodny (Mar. 27, 2019) Dep. Tr. at 131 (describing chronic opioid therapy as a "dangerous practice that lacks evidence to support it"); D. Clauw (March 26, 2019) Dep. Tr. at 29 (""Q: Do … you disagree with the FDA's conclusion that opioids are appropriate for treatment of long-term chronic pain? A: Yes."); A. Fugh-Berman (March 6, 2019) Dep. at 230 ("The promotion of opioids for … noncancer-related pain was entirely unethical, because there was not evidence available that opioids were effective for chronic pain.").

[218] The FDA-approved label for Duragesic also includes language about the concept of pseudoaddiction. *See supra* Section II.C.2.

unilaterally change their marketing to omit reference to chronic non-cancer pain. *See North Dakota ex rel. Stenehjem*, No. 08-2018-cv-01300, Slip Op. at 14. The State accordingly cannot assert that Janssen's promotion of those drugs for that condition caused the opioid abuse crisis.

B. The State's Evidence Will Not Support a Finding Of Cause-in-Fact.

Once the Court removes from consideration the mountain of evidence about First Amendment-protected and federally regulated activities, the State's allegations of a "brilliant multifaceted campaign" shrink to just a handful of Janssen call notes and a few unbranded promotional materials released in the late 2000s. The notion that Oklahoma's abuse crisis was caused by a smattering of one-off statements handpicked by the State—many of them made *after* opioid prescribing peaked—does not warrant serious consideration, and this Court will hear no credible evidence supporting it.

But even if the Court wished to analyze causation based on *all* of the protected conduct the State challenges, the State's causation evidence will still fail as it neither evaluates the impact of Janssen's specific conduct nor considers the impact of any other factors that could have contributed to increased opioid prescriptions or the opioid abuse crisis.

1. The State will not measure the impact of Janssen's alleged conduct.

The State will offer no way to evaluate the impact of the conduct it tries to attribute to Janssen. The State has consistently implied that Janssen is responsible for every public statement ***any*** doctor, researcher, or non-profit organization made about the importance of treating chronic pain and the benefits of opioid therapy. But at trial the State will present evidence about only a fixed number of such statements—a claim by a key opinion leader here, a treatment guideline there—that it will try to connect to Janssen. To prove causation, it will have to provide a sound way to evaluate the impact of those specific statements—and ***only*** those statements—on Oklahoma doctors. The State has no evidence from which such an analysis can proceed.

The State will try to make that showing with conclusory expert testimony that pharmaceutical marketing and a "brilliant multifaceted campaign" drove increased opioid prescriptions. But courts have routinely held that, in cases challenging pharmaceutical marketing, "the nature of prescriptions thwarts any attempt to establish proximate cause through generalized proof." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010). As a North Dakota court recently recognized in dismissing that state's claims against Purdue, "[i]n cases that assert claims for fraudulent or deceptive pharmaceutical marketing, 'a fraud-on-the-market theory cannot plead the necessary element of causation because the relationship between the defendants' alleged misrepresentations and the purported loss suffered by the patients is so attenuated … that it would be effectively nonexistent.'" *See North Dakota ex rel. Stenehjem*, No. 08-2018-cv-01300, Slip Op. at 14 (quoting *In re Actimmune Ktg. Litig.*, 614 F. Supp. 2d 1037, 1054 (N.D. Cal. 2009)). And they have consistently rejected purported proof of causation by "simplistic" statistical evidence such as "correlation evidence." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 96 (2d Cir. 2015).

Here, the State's experts will not even offer that. Those experts—many of whom have no expertise whatsoever in drug marketing—will not identify a single Oklahoma doctor who relied on any statement in any way linked to Janssen. Nor will they limit their opinions to marketing or public statements with any Janssen connection. Nor, for that matter, will they opine on any such statements' effects in Oklahoma. Instead, they will assert—in strikingly general terms—that statements made as part of a "brilliant multifaceted campaign"—misleading or otherwise, associated with Janssen or otherwise, disseminated in Oklahoma or otherwise—caused the State's injuries. Their conclusory opinions will offer no basis to conclude that the specific statements the State attempts to trace to Janssen caused any harm in Oklahoma.

Dr. Andrew Kolodny. Kolodny acknowledged in his deposition that he has no training or education in marketing yet considers himself an expert in the "marketing tactics of opioid manufacturers and their deceptive marketing and sales tactics."[219] When pressed on his alleged marketing expertise, he concedes, "I don't know if marketing is a fair term to use," and that he only "guess[es] to some extent [he does] have that marketing experience."[220] A longtime opponent of opioid medications, Kolodny believes that "Defendants' widespread and deceptive marketing and promotion of opioids … caused the opioids crisis that currently plagues Oklahoma."[221] But he has never conducted a study or test to validate that hypothesis. Instead, he relies on: (1) a paper reviewing incomplete medical examiner data that purports to show some correlation between prescription opioid sales and unintentional overdose deaths; (2) a decade-old study purportedly finding that most people who died of prescription-opioid-related overdoses in Utah had been prescribed an opioid for chronic pain; and (3) national studies showing that doctors who received payments from drug manufacturers prescribed more opioids.[222] None of these papers speaks to how Janssen's allegedly misleading messages influenced opioid prescriptions in Oklahoma—nor does anything else in Kolodny's deposition testimony.

Dr. Danesh Mazloomdoost. Mazloomdoost, a Kentucky physician, similarly conceded in his deposition that he has no formal training in pharmaceutical marketing, yet opined that Oklahoma's entire "opioid epidemic is directly attributable to focused pharmaceutical marketing."[223] *See, e.g.*, *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J.

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[219] A. Kolodny (Mar. 27, 2019) Dep. Tr. at 81.
[220] *Id*. at 81-83; State's Expert Disc. Ex. J at 9-10.
[221] State's Expert Disc. Ex. J at 3-5, 8.
[222] A. Kolodny (Mar. 27, 2019) Dep. Tr. at 152-153.
[223] D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 28.

2006) (doctor not qualified to opine on specific effects of particular marketing efforts because he lacked "specialized expertise regarding sales or market analysis" and "had conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field"). He bases his opinion on his "personal experience with … representatives of pharmaceutical companies" in Texas and Kentucky, conversations with other physicians, and his review of "something in the ball park" of ten call notes[224] that were provided to him by the State.[225] He is "strongly suspicious that what [he had] seen in Kentucky … is very similar to what exists in Oklahoma" based on supposed "parallels and correlations" between the "rural" and "impoverished" populations in both States. *Id.* at 171; 176-177; 272.

Renzi Stone. Stone, the owner of a marketing and communications firm, admits he has no expertise in prescribing behavior—and his deposition testimony reveals a lack of even basic knowledge about the pharmaceutical industry, including the meaning of the acronym "FDA" or

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[224] The fact that nearly every State causation expert mentioned call logs as a basis for their causation opinion only highlights the State's lack of evidence. *See, e.g.*, Janssen Trial Ex. J249, A. Fugh-Berman Dep. Ex. 9 - Call notes. Call logs—informal notes of sales representatives' contacts with providers—have several glaring shortcomings as causation evidence. *First*, they provide limited information, often saying nothing about what message a salesperson conveyed to a physician or how a physician reacted to that information. D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 281 (noting that "the content of their conversations were—was not disclosed."). *Second*, they constitute a miniscule sample: State experts report reviewing call logs numbering "in the tens," D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 173, representing interactions with only a handful of Oklahoma physicians. *Third*, they are unlikely to be representative because the State hand-selected them out of a large number of available call logs produced by the defendants, *see* A. Fugh-Berman (Mar. 6, 2019) Dep. Tr. at 292 (the call logs she received from the State were a "very small subset of what is apparently available."); D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 172 ("So I -- I received it from -- in the documents that I reviewed provided by the legal team."). *Fourth*, the State did not provide these call logs to experts until *after* the experts had already asserted their causation opinions. *See, e.g.,* A. Fugh-Berman (Mar. 6, 2019) Dep. Tr. at 82. *Fifth*, none of the State's experts identifies a reliable method to draw statewide conclusions about causation from the cherry-picked notes of sales representatives—and there is none.

[225] D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 169-171.

anything about that agency's role in overseeing drug makers' marketing.[226] Yet Stone opines that defendants' marketing "ultimately created the opioid crisis as we know it today" based on his "sales and marketing experience," as well as "read[ing] books and articles" and discussions with friends. *Id.* at 193, 209.

Dr. Adriene Fugh-Berman. Among the State's experts, only Fugh-Berman, a professor of pharmacology and physiology, has experience in pharmaceutical marketing, yet she offers no scientific basis for her opinion that misleading marketing was the "primary cause of the opioid epidemic."[227] Fugh-Berman does not cite to and did not conduct any analysis specific to Oklahoma,[228] *id*. 260:12-262:15, or to Janssen marketing. Rather, she bases her opinion on a study about marketing's general effect on prescribing behavior. She also points to documents and statements that, by her interpretation, show some of defendants' sales staff believed that marketing activity could increase prescribing.[229] But she explains no methodology translating the subjective beliefs of salespeople about opioid marketing generally into proof that *alleged misrepresentations attributable to Janssen* caused the Oklahoma epidemic—nor does she explain how the call logs and marketing materials she reviewed do so.

None of the State's experts identifies a "reliable method for determining causation" from the specific documents or public statements that the State attributes to Janssen. *Christian v. Gray*, 2003 OK 10, ¶ 36, 65 P.3d 591, 607. And none identifies any way to test or verify their assertions about causation—a statistical analysis, a formula, data, anything. *Cf. BancFirst v. Ford Motor Co.*, 2011 WL 2215014, at *4 (W.D. Okla. June 6, 2011) ("Rather than

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[226] R. Stone (Mar. 15, 2019) Dep. Tr. at 81, 118.
[227] A. Fugh-Berman (Mar. 6, 2019) Dep. Tr. at 34.
[228] *Id*. at 260-62.
[229] *Id*. at 11.

methodology, Medcalf offers simply the 'ipse dixit of the expert.'"), *aff'd*, 489 F. App'x 264 (10th Cir. 2012). Instead, these experts all say that they have read select materials and believe that misleading pharmaceutical marketing—which the State defines to encompass nearly every positive statement any medical organization has ever made about opioids—primarily caused Oklahoma's opioid abuse crisis. Such bare opinions, unsupported by any method or scientific analysis, are no basis to rule for the State on the causation question here: whether Janssen's conduct increased prescriptions of *all* opioids, and thus led to the far-reaching social harms associated with the abuse and misuse of legal and illegal opioids in Oklahoma. *City of New Haven v. Purdue*, 2019 WL 423990, at *4 (Conn. Sup. Ct. Jan. 8, 2019); *see Boyle v. ASAP Energy, Inc.*, 2017 OK 82, ¶ 38, 408 P.3d 183, 196 (expert evidence of causation must offer "more than subjective belief or unsupported speculation"); *Christian*, 2003 OK 10, 65 P.3d at 601-02 ("When an injury is of a nature requiring a skilled and professional person to determine cause and the extent thereof, the scientific question presented must necessarily be determined by testimony of skilled and professional persons."). Without sufficient expertise or any hint of meaningful analysis, these experts' testimony amounts to nothing more than *ipse dixit*, or unsupported say-so, which Oklahoma courts reject. *Id.* at 607 ("An expert's opinion on causation must be more than *ipse dixit.*").

2. The State will not address any other factors that could have contributed to increased prescriptions or the opioid abuse crisis.

The State's experts will fail to address *any* of the countless factors other than marketing that could have driven opioid prescriptions and the opioid abuse crisis. Their opinions make no accounting of the effects of the FDA's approval of novel opioid medications like OxyContin, the medical community's increased emphasis on treating chronic pain (which began before Duragesic hit the market in 1990, *see supra* Section II.A.1), a rise in the number of patients

suffering from medical conditions associated with chronic pain, and insurance reimbursement practices favoring prescription drugs over costlier treatments—all of which could have contributed to higher opioid prescription rates. They likewise make no attempt to account for rampant diversion of prescription drugs, including opioids—which state agencies recognized as a major public health issue as early as 1990. Nor can they account for social and economic trends that have led to skyrocketing overdose rates for benzodiazepines, muscle relaxants, methamphetamine, and cocaine. And they offer no opinion on policy failures by the State that fed the rising epidemic. *See supra* Section II.D.

Ignoring the opioid abuse crisis's complex and wide-ranging roots, the State's experts point to a single factor—pharmaceutical marketing—and assert without explanation that ***it*** was the crisis's cause. Because their testimony fails to account for *any* of these other factors, it cannot and will not show that Janssen's marketing caused the State's injuries. *See, e.g.*, *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1193 (W.D. Okla. 2017) ("'expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes'" renders causation testimony inadmissible) (quoting *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310 (11th Cir. 2014)).

C. The State Cannot Prove Proximate Cause.

Evidence at trial will also conclusively show that Janssen's marketing did not proximately cause the State's alleged harms. The "proximate cause of an event must be that which in a natural and continuous sequence, unbroken by an independent cause, produces the event[.]" *Gaines v. Providence Apartments*, 1987 OK 129 ¶ 4, 750 P.2d 125, 126-27.

The evidence in this case will show no "natural and continuous sequence," much less an "uninterrupted" one, connecting Janssen's marketing and promotion of its opioid products to the State's alleged injuries. The problem of opioid abuse and misuse arises from many factors having

nothing to do with Janssen's alleged conduct—from physicians' independent prescribing decisions, to widespread diversion of other manufacturers' opioid products, to doctor shopping, to criminal enterprises from foreign countries, and federal and state governments' failures to combat them. The evidence at trial will refute the State's contention that Janssen's marketing of medications, which accounted for only a miniscule portion of opioid medications prescribed in Oklahoma and were not widely diverted or abused, could have proximately caused a diverse phenomenon arising from such varied sources.

Decisions of Prescribing Physicians. The State ignores that physicians exercise independent judgment in determining whether a particular medication is appropriate for a particular patient. *See McKee v. Moore*, 1982 OK 71, ¶ 8, 648 P.2d 21, 24 (physician has a duty "to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product"). The evidence at trial will show that the medical community was well aware of the risks associated with opioid medications, and that prescribing decisions are based on more than simply manufacturer marketing and are often tailored to individual patients.

Janssen, for its part, continually warned doctors that its opioid products carried risks of addiction, abuse, misuse, and diversion—in FDA-approved labels,[230] FDA-regulated branded marketing that educated doctors about the risks and benefits of Duragesic, Nucynta, and Nucynta ER,[231] and unbranded promotional materials, which often discussed the benefits of non-opioid pain-treatment options. In fact, according to the State's experts, [redacted]

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[230] *See* Janssen Trial Exs. J2762-J2776, Duragesic Labels since 1990; Janssen Trial Exs. J2777-J2790, Nucynta and Nucynta ER Labels since 2008.

[231] *See, e.g.*, Janssen Trial Ex. J3369, General Policy and Procedure for the Review and Approval of Advertising, Promotional and Field Sales Force Training Materials.

[redacted]"[232] Any addictions or overdoses resulting from the remaining [redacted]% of medically proper prescriptions would not be the proximate result of Janssen's marketing—they would be consistent with the inherent risks of a physician's justified decision to prescribe a medical justified treatment for a patient with an often-debilitating health condition. *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶ 27, 242 P.3d 549, 560 (bone putty manufacturer not liable for patient's allergic reaction where manufacturer "warned of the risk of an antigenic reaction from using its product, [the physician] … decided it was [nevertheless] appropriate to use the bone putty based upon her experience with bone putty and Plaintiff's needs, and the Plaintiff had an antigenic reaction").

Illicit Diversion and Criminal Trafficking. The evidence will also show that independent third parties significantly contributed to opioid abuse and misuse through illegal diversion and criminal trafficking of opioids—largely oxycodone, hydrocodone, and black-market street fentanyl.

The evidence will show that improper diversion of pharmaceutical products has had an impact on Oklahoma's prescription drug abuse problem since at least 1980, before any of Janssen's opioid products were created or entered the market.[233] By the early to mid-2000s, State agencies like DURB recognized that overprescription and diversion of oxycodone was a problem in Oklahoma and that there was an underground market for pharmaceutical sales.[234] Prescription

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[232] Janssen Trial Ex. J2025, James L. Gibson Supp. Disc., Ex. G-1 at 48.
[233] M. Edminsten (Mar. 12, 2019) Dep. Tr. at 37.
[234] *See* Janssen Trial Ex. J734, Drug Utilization Review Board Meeting Packet (Aug. 14, 2001) at 34; Ex. J965, Drug Utilization Review Board Meeting Packet (Nov. 8, 2006) at 7; Ex. J456, Drug Utilization Review Board Meeting Packet (May 14, 2008) at 8; Ex. J939, Drug Utilization Review Board Meeting Tr. (Mar. 8, 2006) at 29; Ex. J1034, Drug Utilization Review Board

opioids (especially oxycodone and hydrocodone) were being easily diverted by doctor-shopping patients, their family members, and pharmacy and pain-clinic employees.[235] Prescription opioid theft was particularly rampant from 2008 to 2017, when pharmacy break-ins "where over a thousand [opioid] tablets [were] stolen" were "fairly common" in Oklahoma, occurring as often as once or twice a week.[236] Pill mills—sometimes owned by individuals without medical licenses—are yet another source of improper opioid diversion, and they have recently been linked to numerous fatal overdoses in the State.[237] Diversion remains a problem in Oklahoma, years after Janssen stopped marketing its products. The 2017 Oklahoma Drug Assessment Report concluded that "diversion of pharmaceutical drugs continues to increase."[238] The 2018 Oklahoma Drug Threat Assessment acknowledged that diversion of pharmaceutical drugs "remains a threat in Oklahoma," which "is a source of diverted opioids for other parts of the country."[239] Janssen did not proximately cause addiction or abuse stemming from black-market diversion of its competitors' opioids. *See, e.g.*, *Price v. PurduePharma Co.*, 920 So. 2d 479, 485-86 (Miss. 2006) (pharmaceutical company did not proximately cause addiction resulting from illegally obtained and improperly used opioids).

Janssen's experts also will explain how drug trafficking and organized crime are major drivers of the current opioid abuse crisis in Oklahoma. Transnational criminal organizations in Mexico and Columbia are the principal suppliers of heroin, illicit fentanyl, and counterfeit pills.

Meeting Tr. (Feb. 13, 2008) at 13-14; Ex. J1150, Drug Utilization Review Board Meeting Tr. (Jul. 8, 2009) at 33-35.

[235] *See id*.

[236] C. Hamilton-Fain (Feb. 19, 2019) Dep. Tr. at 62.

[237] Janssen Trial Ex. J311, Profiting from Pain: Clinics Help Fuel Prescription Pill Epidemic, The Oklahoman and Oklahoma Watch (Dec. 5, 2014) at 4.

[238] Janssen Trial Ex. J1811, 2017 Oklahoma Drug Threat Assessment at 5.

[239] Janssen Trial Ex. J515, 2018 Oklahoma Drug Threat Assessment at 10.

Chinese entities are the principal source of illicitly manufactured fentanyl. As explained above (II.D.3), this Court will see how these activities have led to the "spike" in "overdose deaths that we have seen ratchet up across the United States and certainly in Oklahoma as well."

Janssen could not have reasonably foreseen the evolution of diversion and drug trafficking when it first began promoting Duragesic more than three decades ago, or even in the late 2000s when it began promoting Nuycnta ER with its crush-resistant coating. It would strain credulity to consider Janssen's legal marketing of these products the proximate cause of pill mills, pharmacy break-ins, illicit Chinese fentanyl, and imported heroin in 2018. *See Lefthand v. City of Okmulgee*, 1998 OK 97, ¶ 8, 968 P.2d 1224, 1226 ("[T]he act of a third person in committing an intentional tort or crime is a supervening cause which relieves the initial …actor from liability for resulting harm or injuries[.]").

***Government Failures*.** The State similarly ignores evidence that federal and state lawmakers abdicated their responsibilities to combat this criminal conduct. The evidence at trial will show that Oklahoma officials knew the State was experiencing abuse and diversion problems, but consistently failed to take action to combat those problems. The State Board of Pharmacy was aware that pharmacy break-ins were a frequent occurrence contributing to illicit opioid diversion, but the State did little about it—in fact, the State employed the same number of narcotic agents investigating diversion in 2009, the year opioid deaths in Oklahoma peaked, as it did three decades earlier in 1980.[240] The State also placed some of the most widely abused and diverted opioid medications, like hydrocodone and oxycodone, on its least-restricted Medicaid formulary, simply because they were cheaper than less frequently abused drugs. And the State

[240] M. Edminsten (Mar. 12, 2019) Dep. Tr. at 71.

kept these medicines on its least-restricted tier despite knowing that they were particularly subject to abuse and diversion. Janssen does not bear responsibility for the State's adoption of policies that encouraged prescriptions of other manufacturers' more frequently abused drugs.

The State likewise waited until late 2015 to require physicians to review the Prescription Monitoring Program Registry to assess the prescription-drug history of their patients before prescribing narcotics, which would have allowed them to detect and deter doctor shopping. And it failed to adequately regulate pill mills: Even after many overdose deaths were linked to these clinics, the State took no regulatory action. Expert testimony at trial will identify similarly serious federal failures, including the DEA's failure to interdict illicit opioids that originate outside the United States—an important driver of the opioid abuse crisis that has "greatly expanded the availability of illegal or illicit opioids."[241]

As a highly regulated opioid manufacturer, Janssen is part of an expansive state and federal regulatory regime—it depends on other market participants, including government entities, to take reasonable and necessary steps to combat illegal diversion of prescription medications and the broader illegal drug trade. When those entities fail or abdicate their responsibilities, as they have here, Janssen cannot be held liable for the results. *See Egervary v. Young*, 366 F.3d 238, 250-51 (3d Cir. 2004) (government actor's failure "to properly apply the governing law and procedures … must be a superseding cause, breaking the chain of causation").

Lapse in Time. The State ignores the significant amount of time that has passed between Janssen's marketing and the harms alleged, which stretch years into the future. The State seeks to impose liability on Janssen for every dollar allegedly needed to prevent opioid addiction for the

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[241] B. Bagley (Mar. 26, 2019) Dep. Tr. at 138.

next 30 years. But the evidence at trial will show that Janssen stopped promoting Duragesic in 2008 and its Nucynta products in 2015. The State essentially asks the Court to impose liability on Janssen for a heroin overdose in 2045 allegedly caused by Duragesic marketing in 2005, or an oxycodone addiction developed in 2030 as an alleged result of Nucynta ER promotions in 2010. It will offer no evidence connecting such remote injuries to any conduct of Janssen's.

In sum, the evidence at trial will show the State's injuries were inflicted by a wide range of causes that had nothing to do with Janssen—among them, abuse of other manufacturers' drugs, rampant third-party criminal conduct, and policy and enforcement failures by the State. That attenuation will only grow more glaring over the next three decades. Proximate cause limitations exist precisely to foreclose this type of remote, limitless liability. *See Graham v. Keuchel*, 1993 OK 6, ¶ 13, 847 P.2d 342, 349 ("Lapse of time … may cause the duty to prevent harm to another, threatened by the original actor's negligent conduct, to shift from that actor to [a] third person. When this happens the third person's failure to prevent the threatened harm may be a supervening cause.").

V. THE STATE HAS NO EVIDENCE THAT ITS "ABATEMENT PLAN" WILL REMEDY THE OPIOID ABUSE CRISIS

The Oklahoma nuisance statute grants the government a single remedy—abatement. As explained above, the statute does not allow the State to "abate" harms or injuries, like the opioids epidemic. It can abate only the conduct that constitutes the public nuisance. But the State's attempt to "abate" the opioid abuse crisis fails for an additional reason—the evidence at trial will show that the State is not entitled to relief because it has no proof the remedy it seeks will eliminate or even reduce the harms it alleges.

The State's proposed "abatement" remedy calls for a staggering $[redacted] billion payment to fund government programs and services purportedly required to "[redacted]

[redacted]."[242] The programs and services in the State's plan—including a health information exchange, specialized drug courts, a 24/7 addiction and mental health helpline, and much more,[243] cover a breathtaking range of basic government functions and would provide the State a windfall by funding programs that address much more than just opioids.[244] The State wants to force Janssen to fund each of the programs and services for 30 years, ending in 2048.[245]

The State developed its "abatement" plan solely for this litigation.[246] Two employees of the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS)—Jessica Hawkins and Terri White—created, compiled, or reviewed the services and programs included in the plan.[247] Hawkins made some of the initial recommendations and compiled other recommendations from various sources and agencies.[248] State expert Dr. Christopher Ruhm then did a mathematical calculation to determine the present value of those plan costs over 20, 25, and 30-year periods.[249]

Not only does the State lack any evidence that its plan will effectively address its injuries, the plan's structure actually ***presupposes*** that the expenditures in the plan will be

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[242] *See* Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D. at 3, 36, 49 56; J. Hawkins (Mar. 6, 2019) Dep. Tr. at 54.
[243] *See* Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D. at 16, 19, 43, 49, 56.
[244] J. Hawkins (Mar. 6, 2019) Dep. Tr. at 220 (admitting that the drug courts would not necessarily "exclude problems like methamphetamine, cocaine, marijuana"); *id*. at 222-24 (the health information exchange "will have all of the health-related information for the citizens of the state," not just opioid-related information).
[245] *See* Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D.at 4, 9, 14-65; J. Hawkins (Mar. 6, 2019) Dep. Tr. at 293.
[246] J. Hawkins (Mar. 6, 2019) Dep. Tr. at 56.
[247] *Id.* at 17.
[248] *Id.* at 58-59.
[249] C. Ruhm (Mar. 28, 2019) Dep. Tr. at 49.

ineffective. The State demands Janssen pay for the same services at approximately the same level of inflation-adjusted spending—[redacted]—every year between now and 2048.[250] That demand is inconsistent with the premise that the plan will improve anything: If it did, the necessary spending would go down over time, as the plan reduced the problem of opioid abuse and misuse. Indeed, Hawkins admitted that some costs should have "an anticipated reduction" if the abatement plan "is going to be successful."[251] The State's plan, by contrast, appears to assume that the crisis will persist at the same scale, requiring the same level of spending, for thirty years. The State's failure to build in such "an anticipated reduction" betrays that even ***the State*** does not anticipate its plan will address opioid abuse and addiction in Oklahoma. Indeed, its expert testified that "30 years may not even be enough."[252]

The State's abatement demand lacks support in Oklahoma's nuisance statute, and demands that Janssen pay $[redacted] billion toward programs whose efficacy is purely speculative. *See, e.g.*, *Dickerseon v. Fears*, 1951 OK 247, Syll. ¶ 3, 236 P.2d 472 (plaintiffs cannot recover "such damages or compensation" as "is too uncertain and speculative to warrant recovery").

VI. THE STATE CANNOT ESTABLISH JOINT AND SEVERAL LIABILITY

The State's effort to impose joint and several liability on Janssen fails under Oklahoma law and violates due process. Contrary to the State's theory, its alleged injury—a catalog of individual harms to individual Oklahomans—is divisible, and liability could therefore be apportioned based on Janssen's limited market share. Making Janssen pay the entire $[redacted] billion cost of the State's proposed plan would impose a disproportionate and fundamentally

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[250] *See* Janssen Trial Ex. J2026, Supplemental Exhibit S - Christopher J. Ruhm, Ph.D. at T-3; C. Ruhm (Mar. 28, 2019) Dep. Tr. at 92-93, 117, 127, 135-36, 172.
[251] J. Hawkins (Mar. 6, 2019) Dep. Tr. at 212.
[252] *Id.* at 293.

unfair burden on a company whose opioid pain medications made up only a miniscule share of Oklahoma opioid prescriptions.

A. Title 23, Section 15 Does Not Entitle the State to Joint and Several Liability.

Oklahoma law does not grant the State an automatic right to joint and several liability. The State has strained to suggest that 23 O.S. § 15 somehow entitles it to such liability here, relying on that statute for the proposition that "[a]ll the State must show for joint and several liability to attach is that a defendant is a cause … of the State's injuries," and that "[o]nce proven, all defendants become responsible for damages jointly and severally."[253] But Section 15 says nothing of the sort.

As an initial matter, the statute governs only "liability for damages." *Id.* While Janssen maintains that the cash recovery sought by the State constitutes "damages" (and thus requires a jury trial), the State took the position that its cash "abatement" remedy was not damages,[254] and this Court implicitly accepted that view by denying a jury trial. As long as that ruling remains the law of the case, Section 15, which applies only to "damages," has no role to play.

But even in a damages action, not one word in that provision would entitle the State to joint and several liability. Joint and several liability is a "common law rule." *Fuller v. Odom*, 1987 OK 64, 741 P.2d 449, 454. Before the Legislature passed 23 O.S. § 15 in 2011, a century of Oklahoma caselaw already addressed joint and several liability, holding that it applied in certain specific circumstances—but not others. *Compare, e.g.*, *S. H. Kress & Co. v. Bradshaw*, 1940 OK 70, ¶27, 99 P.2d 508, 514 (multiple persons who caused false imprisonment are jointly and

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[253] State's Combined Reply re: Briefing on the Legal Authority to Sever Claims and Consolidate Actions at 2-3 (Apr. 2, 2019).
[254] Hr'g Tr. (Apr. 11, 2019) at 32 (arguing that the proposed abatement remedy is "fundamentally different" than "future or past damages").

severally liable); *with Delaney v. Morris*, 1944 OK 51, ¶ 8, 145 P.2d 936, 939 (no joint and several liability where water pollution to property originated from separate streams). Section 15 abrogated that body of law for ***most*** litigants, directing that, as a general matter, civil actions for damages "shall be several only." *See* 23 O.S. § 15(A). But it said nothing about actions brought by the State. For such actions, the statute simply does "not apply." *Id.* § 15(B). It defies logic to suggest that a statute that does "not apply" somehow gives the State an automatic right to joint and several liability. The statute's inapplicability simply means that the statute does not abrogate the common law with respect to the State—if the State wants joint and several liability, it must satisfy the common law's requirements for such an award.

The State cannot satisfy the common law's requirements for joint and several liability for multiple reasons. To begin, its alleged injury is divisible. Although the State insists that it is entitled to joint and several liability because its injury is indivisible,[255] that basis for joint liability applies only when the acts of different defendants "combine to produce directly ***a single injury.***" *Northup v. Eakes*, 1918 OK 652, ¶ 9, 178 P. 266, 268 (emphasis added). The evidence in this case will show that the State's asserted injury—the opioid abuse crisis—is not singular but a collection of individual harms to individual Oklahomans. Litigants routinely demonstrate—and courts routinely determine—causation for such harms on a patient-by-patient basis. The State's refusal to do so here does not change the fundamentally individualized nature of its asserted injury. Moreover, as courts confronted with analogous claims have consistently concluded, a defendant's market share provides a reasonable basis to apportion damages.

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[255] Hr'g Tr. (Apr. 11, 2019) at 21; Hr'g Tr. (Apr. 4, 2019) at 19.

1. The State's Alleged Injuries Are Divisible.

In more than a century of joint and several liability cases, Oklahoma courts have found injuries indivisible in only four circumstances, none of which is present here: (1) a singular personal injury caused by multiple events occurring close in time; (2) property damage; (3) commingled water pollution; and (4) cattle that die from drinking commingled water pollution. *See* Appendix A (collecting cases). Each of those injuries is ***conceptually*** indivisible—there is no way to tease them out into their constituent parts or allocate blame for them among different defendants. In other words, they are not "theoretically 'capable of apportionment.'" *United States v. NCR Corp.*, 688 F.3d 833, 838 (7th Cir. 2012).

The alleged harms here fall "far[] afield" from those scenarios. *Wholesale Price Litigation*, 491 F. Supp. 2d 20, 101 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009). The opioid abuse crisis encompasses numerous individual doctors who allegedly misunderstood the safety and efficacy of opioid medications, along with numerous individual patients or drug users who allegedly became addicted as a result. That is not a commingled stream or singular physical injury: It is a collection of smaller harms, each with its own cause. Janssen's responsibility (or lack thereof) for any patient's addiction can be determined—not just theoretically, but practically—using ordinary causation principles that courts routinely apply in product liability cases. *See, e.g., Timmons v. Purdue Pharma Co.*, 2006 WL 263602, at *4 (M.D. Fla. 2006) (granting summary judgment for lack of causation on failure-to-warn and fraud claims alleging that inadequate warnings caused plaintiff's opioid addiction). Courts have ***always required*** that sort of individualized proof in pharmaceutical-marketing cases. *See supra* Section IV.B.

This Court will hear extensive evidence at trial demonstrating that the State's claim is not based on a single injury but a raft of individual injuries. State experts, for instance, will rely on call notes—informal notes of sales representatives' contacts with providers—to assert that

Janssen and Teva influenced individual Oklahoma practitioners.[256] Craig Box, whose son died of a drug overdose, will testify about the personal impact of that loss.[257] Others will testify about their experiences with opioid use disorder.[258] Such evidence readily lends itself to an individualized analysis of individual harms: Did any Janssen sales representative's statement recorded in a call note cause a doctor to write an improper prescription that harmed an Oklahoma resident? Did Janssen cause a doctor to write Austin Box an opioid prescription? Did it cause a doctor to write a prescription to the State's witnesses who suffered from opioid use disorder? Each of those individual injuries has identifiable causes. And a claim that simply bundles such individual harms together is the definition of a divisible injury that can—and must—be apportioned. *See* Restatement (Second) of Torts § 433A ("Damages are to be apportioned among two or more causes where … there are distinct harms.").

The State's refusal to present the individualized proof that would address those questions—or even to deliver the statistical analysis it promised earlier in the litigation—does not somehow transform its divisible injury into an indivisible one: Divisibility does not turn on a plaintiff's selection of evidence but on whether it suffered a "single injury" rather than a collection of discrete harms. *Delaney*, 1944 OK 51, 145 P.2d at 938. Nor does the State's choice to fashion a claim encompassing **so many** distinct harms that an individualized causation analysis would be difficult and time-consuming make its injuries indivisible. *See Cayuga Indian Nation of New York v. Pataki*, 79 F. Supp. 2d 66, 72 (N.D.N.Y. 1999) (holding Indian tribe's claim against 7,000 landowners living on wrongfully taken land did not allege "a single,

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[256] A. Fugh-Berman (Mar. 6, 2019) Dep. Tr. at 82; D. Mazloomdoost (Mar. 7, 2019) Dep. Tr. at 170; R. Stone (Mar. 15, 2019) Dep. Tr. at 114.
[257] C. Box (Mar. 15, 2019) Dep. Tr. at 9-10.
[258] L. Cambra (Nov. 15, 2018) Dep. Tr. at 12; J. McGregor (Mar. 15, 2019) Dep. Tr. at 11.

indivisible injury, but rather … is more accurately viewed as divisible" even though "division or allocation among the defendants of the damages … will not be an easy task"). To hold that the practical burdens created by the staggering size of the State's claim somehow compel joint and several liability would be to perversely reward the State for bringing sprawling suits too large to prove by conventional means. The State cannot first take away Janssen's individualized defenses and then exploit that maneuver to impose joint and several liability. In assessing the State's evidence, the Court should consider only those individual harms, if any, for which Janssen bears specific liability.

2. Apportionment Could Be Reasonably Determined By Market Share.

Moreover, the alleged injuries could easily be apportioned—and therefore would have to be apportioned—based on market share. Under the common law, all that is needed is a "reasonable basis" for apportionment, not a perfect one. Restatement (Second) of Torts § 433A(1)(b) (1965). Even where apportionment is "difficult," a basis that provides a "rough estimate" of individual responsibility is preferable to saddling a defendant with liability for harm caused by someone else. *Id*. § 433A cmt. b. As explained above, the evidence will show that the State lacks a viable public nuisance claim against Janssen. But there is no question that a manufacturer's market share would provide a reasonable basis for apportioning any hypothetical liability.

Courts often use market share to apportion liability where manufacturers of related or interchangeable products caused alleged harms. In a series of recent cases, some under public-nuisance theories, states and municipalities sued gasoline manufacturers whose products contained an additive that contaminated groundwater. The "fungible nature" and "commingling of many suppliers' products during transportation and distribution," *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 379 F. Supp. 2d 348, 362 (S.D.N.Y. 2005), made it difficult to

determine the damage caused by a particular manufacturer's product. Those courts therefore embraced market share as a reasonable way to "approximate the harm caused" by each manufacturer. *Id.* at 376; *see State v. Exxon Mobil Corp.*, 126 A.3d 266, 296 (N.H. 2015).

Market share would also serve as a "reasonable" basis for apportioning damages because "reasonableness" is determined under the circumstances. *See Waller ex rel. Estate of Hunt v. Danville, VA*, 556 F.3d 171, 175 (4th Cir. 2009) ("Reasonableness in law is generally assessed in light of the totality of the circumstances."). Here, the Court will recall that the State opposed Janssen's efforts to secure "participant level claims data," which Janssen needed to "tak[e] discovery from the prescribers and patients" and determine "how, if at all, Defendants' marketing impacted Oklahoma patients and prescribers, and whether that impact, if any, caused the prescriptions at issue to be written."[259] That data would have allowed Janssen to establish the lack of harm attributable to its marketing by gathering doctor- and patient-specific evidence in performing sampling, case studies, or some other methodology to quantify the lack of harm attributable to Janssen's marketing. But the State barred Janssen from obtaining it.

Furthermore, the State repeatedly promised a statistical model to prove causation—"how many doctors bought into" marketing messages[260]—but never provided one. The State's refusal to produce individualized evidence from which Janssen could demonstrate lack of harm—and then its refusal to provide the aggregate measurements it promised as an alternative—only strengthens the conclusion that market share would be a reasonable basis for apportioning damages.

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[259] Def's Mot. to Compel Discovery Regarding Claims Data (Sept. 7, 2018) at 1-4.
[260] Hr'g Tr. (Dec. 5, 2017) at 136-37.

There is no question that Janssen's share of the Oklahoma market was negligible during the period relevant to this litigation. Janssen's medications accounted for [redacted] of the [redacted] opioid medications reimbursed by Oklahoma Medicaid between January 1996 and December 2017—or [redacted]%.[261] The figures for HealthChoice, a private insurance plan for Oklahoma government employees, were similarly low: Janssen's medications constituted [redacted] of a total of [redacted] opioid prescriptions reimbursed between January 2004 and June 2018—[redacted]%.[262] These market share percentages should cap any hypothetical liability. The State would no doubt find that result unsatisfactory. But the State made the strategic choice to sue only three families of manufacturers, settle with Purdue, and then attempt to recover an extraordinary sum from a single company that marketed its drugs responsibly.

B. The State's Own Fault Precludes Joint and Several Liability.

Joint and several liability would also be inappropriate because the State's own conduct—from its failure to monitor opioid prescriptions and police unethical doctors to its policies that encouraged hydrocodone and oxycodone for Medicaid patients over other less frequently abused medications—directly enabled widespread opioid abuse and misuse in Oklahoma. As will be demonstrated at trial, the State cannot hold Janssen jointly and severally liable for harms that ***the State*** helped create.

Under Oklahoma law, a plaintiff that contributes to a nuisance cannot recover at all—not one cent—unless it can produce evidence separating out the damage its own conduct caused from the damage attributable to the defendants. *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, ¶ 6, 204 P. 906, 908. In *Walters*, riparian landowners brought a nuisance suit alleging that oil

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[261] Janssen Trial Ex. J2122.
[262] Janssen Trial Ex. J2121.

companies had dumped refuse into a stream running through the plaintiffs' property. *Id.*, ¶ 1, 204 P.2d at 906. But the plaintiffs themselves had contributed to that pollution by allowing their lessee to dump similar refuse into a drainage ditch, where "mingling with the salt water and waste oil from defendants' wells [it] caused the pollution and damage complained of." *Id.*, ¶ 2, 204 P.2d at 907. The Supreme Court held, "as a sound elementary principle of justice," that the plaintiffs' contribution to the nuisance required the ***plaintiffs*** to apportion damages:

> [W]here a riparian landowner sues a group of separate leaseholders for damages for polluting a stream, and the evidence shows that part of the damage inflicted was occasioned by the defendants and part by a tenant of the plaintiff, not a party to the action, either with the plaintiff's consent or as the result of the ordinary use of the premises by the tenant, ***the plaintiff will not be entitled to recover from the defendants sued, unless he is able to produce evidence which will enable the court to separate the amount of damage inflicted by the group of defendants sued from the amount of damages resulting from the acts of the tenant, and to enter judgments against the defendants for the damages thus shown.***

Id., ¶ 4, 204 P.2d at 908 (emphasis added). If the law were to give plaintiffs a free pass on their portion of fault, then plaintiffs everywhere would be allowed "to mulct the defendants … not only for their own acts, but for the acts of plaintiffs[.]" *Id.*; *see also City of Weatherford v. Luton*, 1941 OK 305, ¶ 5, 117 P.2d 765, 767 (plaintiff's contribution to nuisance "would not defeat his right to recover *for so much of the damage as was fairly attributable to the wrong of the [defendant]*" (emphasis added)).

That principle bars joint and several liability here. The State cannot make Janssen pay the entire cost to clean up damage the State itself helped cause through years of omissions and policies that affirmatively encouraged the prescription of cheap but easily abused drugs. If it were to recover at all, the State would have to "separate the amount of damage inflicted by the

group of defendants from the amount resulting from [its own] acts." *Walters*, 1922 OK 52, ¶ 4, 204 P.2d at 908.

Oklahoma's comparative negligence regime requires a similar conclusion. Under those statutory principles, "[d]efendants are severally liable if the plaintiff is assigned ***any*** degree of comparative responsibility, and a negligent plaintiff may only recover from each tortfeasor that tortfeasor's proportionate share of responsibility based on degree of fault." *Am. Agency Sys., Inc. v. Marceleno*, 2002 OK CIV APP 79, ¶ 18, 53 P.3d 929, 935 (citing *Nat'l Union Fire Ins. Co. v. A.A.R. W. Skyways, Inc.*, 1989 OK 157, ¶ 14, 784 P.2d 52, 56 (emphasis added)). And "[w]hen a nuisance results from negligent conduct of the defendant, the contributory negligence of the plaintiff is a defense to the same extent as in other actions founded on negligence." *City of Tulsa v. Tyson Foods*, 258 F. Supp. 2d 1263, 1301 (N.D. Okla. 2003) (vacated pursuant to settlement). The State has alleged that defendants breached a "duty to disclose the whole truth, and not disclose partial and misleading truths," when making representations about opioids.[263] Such a "failure to perform [a] duty" is textbook negligence. *Smith v. City of Stillwater*, 2014 OK 42, ¶ 22, 328 P.3d 1192, 1200. Accordingly, Oklahoma's comparative negligence statute applies, and the State's massive contributions to the opioid abuse crisis preclude joint and several liability. *See Estate of Miller ex rel. Miller v. Thrifty Rent-a-Car Sys., Inc.*, 609 F. Supp. 2d 1235, 1242 (M.D. Fla. 2009) (applying Oklahoma law).

C. Holding Janssen Jointly and Severally Liable for the Entire Cost of Oklahoma's Opioid Abuse Crisis Would Be Disproportionate and Unconstitutional.

Finally, joint and several liability would be improper because it would be drastically disproportionate to Janssen's negligible percentage of opioid prescriptions in Oklahoma. Such

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[263] Petition ¶ 123.

outsized liability would not only violate common-law principles, but also trample constitutional protections forbidding punitively disproportionate liability.

The Due Process Clause precludes tort liability so large that it lacks any meaningful connection to the harm proximately caused by the defendant's own conduct. Due process prohibits the "arbitrary" imposition of tort liability. *Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994); *accord State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 417, 420 (2003). As part of that guarantee, due process prohibits liability that is "grossly excessive" or "wholly disproportioned to the offense." *BMW v. Gore,* 517 U.S. 559, 575 (1996). The same proportionality concerns limit joint and several liability as a matter of common law. *See* Restatement (Second) of Torts 433B cmt. e (1965) (recognizing that cases requiring defendants to prove apportionability "all have involved a small number of tortfeasors, such as two or three").

The State's bid to exact joint and several liability threatens to impose precisely such impermissibly disproportionate punishment. Janssen was one manufacturer among many: [redacted] different opioid medications were sold by other manufacturers during the years relevant to this lawsuit. And Janssen at all times had miniscule market share.[264] *See supra* Section II.B. Nor were manufacturers the only market participants: In the federal opioids multidistrict litigation, the municipal plaintiffs in the first case scheduled for trial have named ***twenty-two*** defendants, including not just manufacturers, but drug distributors and pharmacies as well. Yet here, the State has pointed the finger at just two potential tortfeasors and asks them to jointly and severally shoulder a $[redacted] billion bill to fund a wish list of government programs for a 30-year period.

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[264] *See* Janssen Trial Ex. J2122.

Allowing the State to hold one of dozens of market participants liable for such an astronomical demand would impose "grossly excessive" liability "wholly disproportioned to the offense." *BMW v. Gore* 517 U.S. 559, 575 (1996). For that reason, the evidence at trial—including Janssen's low market share and its drugs' low rates of abuse and diversion—will foreclose joint and several liability.

VII. JANSSEN IS ENTITLED TO A CREDIT AGAINST THE PURDUE SETTLEMENT FOR ANY AWARD OF JOINT AND SEVERAL LIABILITY

Under Oklahoma's contribution statute, Janssen and J&J would be entitled to a settlement credit of $270,000,000 against any joint and several award to account for the State's settlement[265] with Purdue. *See* 12 O.S. § 832(H); *Price v. Sw. Bell Tel. Co.*, 1991 OK 50, 812 P.2d 1355, 1360.

VIII. CONCLUSION

For all the foregoing reasons, Defendants Janssen and Johnson & Johnson respectfully submit that judgment should be entered in their favor on the State's public nuisance claim.

[265] *See* Settlement Agreement (Apr. 2, 2019) at 7-9.

Dated: May 24, 2019

Respectfully submitted,

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CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), and by agreement of the parties, this is to certify on May 24, 2019, a true and correct copy of the above and foregoing has been served via electronic mail, to the following:

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Appendix A

Cases Finding Indivisible Injury

Case	Injury
Johnson v. Ford Motor Co., 45 P.3d 86, 91-92 (Okla. 2002)	Physical Injury
Blackmer v. Cookson Hills Elec. Co-op, Inc., 18 P.3d 381, 383, 386 (Okla. Ct. App., Div. 2, 2000)	Property Damage
Brigance v. Velvet Dove Rest., 756 P.2d 1232, 1233-34 (Okla. 1988)	Personal Injury
Lee v. Volkswagen of Am., Inc., 688 P.2d 1283, 1288 (Okla. 1984)	Personal Injury
Boyles v. Oklahoma Nat. Gas Co., 619 P.2d 613, 615, 617 (Okla. 1980)	Personal Injury
Laubach v. Morgan, 588 P.2d 1071, 1072-74 (Okla. 1978)	Personal injury
Green v. Sellers, 413 P.2d 522, 525, 528 (Okla. 1966)	Personal injury
Wilson v. Shawnee Mill. Co., 292 P.2d 147, 148-49, 151 (Okla. 1956)	Property damage
Stevens v. Barnhill, 266 P.2d 463, 464 (Okla. 1954)	Personal injury
W.L. Hulett Lumber Co. v. Bartlett-Collins Co., 241 P.2d 378, 379-80, 383 (Okla. 1952)	Property damage
Oklahoma Ry. Co. v. Ivery, 204 P.2d 978, 979 (Okla. 1949)	Personal injury
M. & D. Motor Freight Lines v. Kelley, 202 P.2d 215, 217-20 (Okla. 1948)	Personal injury
All Am. Bus Lines v. Saxon, 172 P.2d 424, 426, 429 (Okla. 1946)	Personal injury
Pure Oil Co. v. Taylor, 155 P.2d 529, 530-31, 534 (Okla. 1944)	Injuries to cattle from contaminated streams
Cities Serv. Gas Co. v. Eggers, 98 P.2d 1114, 1116, 1119 (Okla. 1940)	Water contamination
Ironside v. Ironside, 108 P.2d 157, 158, 161-62 (Okla. 1940)	Personal injury
Garrett v. Haworth, 83 P.2d 822, 823-24, 826-27 (Okla. 1938)	Property damage
Oklahoma City v. Miller, 65 P.2d 990, 990-91 (Okla. 1937)	Water contamination
Oklahoma City v. Tyetenicz, 52 P.2d 849, 850 (Okla. 1935) *overruled in part on other grounds by Oklahoma City v. Eylar*, 61 P.2d 649 (Okla. 1936)	Water contamination

Case	Injury
Kanola Corp. v. Palmer, 30 P.2d 189, 189-91 (Okla. 1934)	Injuries to cattle from contaminated streams
Burt Corp. v. Crutchfield, 6 P.2d 1055, 1056 (Okla. 1931)	Property damage
Comar Oil Co. v. Hackney, 250 P. 93, 96-100 (Okla. 1926)	Property damage/Water contamination
Jueschke v. Seeley, 224 P. 341, 341-42 (Okla. 1924)	Personal injury
Northup v. Eakes, 178 P. 266, 267-69 (Okla. 1918)	Property Damage