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

DEFENDANTS JOHNSON & JOHNSON AND JANSSEN PHARMACEUTICALS INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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PRELIMINARY STATEMENT

The seven-week trial of the State's case has established one truth beyond dispute: Opioid abuse in Oklahoma is a tremendously complex social problem, a crisis with no easy solutions. The State's chosen fix—an unprecedented expansion of public nuisance liability against a single manufacturer whose specialized products made up a tiny fraction of the opioid medications lawfully prescribed to Oklahoma pain patients—is a blunt and legally unsupportable response. As Janssen's prior briefs have explained, the State rested its public nuisance claim on radical theories unmoored from more than a century of Oklahoma case law. In addition to those fundamental legal defects, the State undeniably failed to prove its case at trial.

At the heart of the State's case is the premise that stray promotional statements by Janssen over the course of two decades somehow caused Oklahoma's opioid abuse crisis. Never once, however, did the State identify a single Oklahoma doctor who was misled by a single statement Janssen made. Instead, its experts, who espoused one-sided anti-opioid views rejected by the FDA, Oklahoma's Drug Utilization Review Board, and Oklahoma doctors who treat the State's pain patients, criticized handpicked promotional statements and opined in conclusory terms that such statements caused the opioid abuse crisis.

As the Proposed Findings of Fact below demonstrate, however, the evidence at trial showed those criticisms to be baseless—extensive scientific evidence and clinical experience supported each of the statements the State's experts now criticize. The State's experts were thus left to rest their causation opinions on extensive legally protected conduct, such as scientific speech by third parties like the American Pain Society and federally authorized sales of raw materials by Janssen and Johnson & Johnson ("J&J") subsidiaries. But they offered no explanation how any ***arguably actionable conduct by Janssen*** contributed to the State's injuries. The State introduced no evidence explaining how Janssen's promotion of its own infrequently

prescribed or abused opioid medicines caused a crisis fueled both by illegal drugs and illicit diversion and abuse of other companies' oxycodone and hydrocodone pills. Nor did the State show that a handful of obscure "unbranded" marketing materials from the late 2000s could have caused a crisis that began more than a decade earlier. Equally lacking was the State's "remedy" evidence, which consisted of little more than a state administrator's conclusory testimony that dozens of programs costing billions of dollars are needed to address substance abuse in Oklahoma. In sum, the State failed to prove that Janssen misleadingly promoted opioids, that any of Janssen's promotions caused any harm in Oklahoma (let alone a crisis of opioid abuse), or that its proposed remedy was a prudent and justified response to the present crisis. Those failures of proof alone warrant judgment against the State on its public nuisance claim.

As explained in the Proposed Conclusions of Law below, the State's theories also suffered from profound legal defects that no evidence could cure. To begin with, the State's trial evidence did not depict anything remotely recognizable as a public nuisance under controlling Oklahoma law. The Oklahoma Supreme Court has authoritatively construed Oklahoma's nuisance statute to regulate "a class of wrongs which arises 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." *Briscoe v. Harper Oil Co.*, 1985 OK 43, ¶ 9, 702, 702 P.2d 33, 36. And Oklahoma courts have always honored that limitation, recognizing nuisance claims only in cases involving real property use or narrow categories of conduct historically considered "nuisances per se." The State's case, far from challenging or vindicating property use, sought to implicate national and international commercial activity such as poppy production in Tasmania, lobbying activities in Washington, D.C., and promotional materials created in New Jersey. As countless courts have explained in rejecting similar attempts to

expand public nuisance law, such theories threaten to jettison traditional product-liability rules and impose virtually boundless liability whenever the State—or a private plaintiff—alleges that commercial activity caused diffuse harm.

The State's attempt to present its attack on Janssen's business as a traditional nuisance case only underscores how dramatically its theories would expand liability for Oklahoma and out-of-state businesses. If sales representatives' use of the Internet in their own homes or visits to Oklahoma doctors sufficed to establish a nuisance, truly any commercial activity in the state would be actionable. If anecdotal testimony about an opioid-impaired driver on Oklahoma roads were enough, then countless enterprises—from alcohol manufacturers to cellphone software developers—could face nuisance liability. The State's quest to regulate a complex social problem through the public nuisance statute recognizes no limiting principle or end point. It has no support in 130 years of Oklahoma nuisance law.

This case illustrates the absurd results that flow from such legal distortions. The trial evidence showed that Janssen's products played no role in causing Oklahoma's opioid abuse crisis. Although the State took potshots at stray promotional statements plucked from three decades of Janssen documents, one State document after another confirmed that the crisis was driven by the massive diversion and abuse of hydrocodone and oxycodone pills. Janssen never marketed oxycodone or hydrocodone pills. The State studiously avoided presenting evidence about the market share or abuse rates of the products Janssen actually promoted, but Janssen proffered unrebutted evidence showing that its products accounted for only a minuscule fraction of Oklahoma's opioid prescriptions and were never widely diverted or abused like competing medications. Instead, they were prescribed by licensed Oklahoma doctors who deemed Janssen's medications appropriate therapy to treat their patients' pain. The State's expert

witnesses criticized certain claims Janssen made in promoting its medications, yet never explained how promoting infrequently prescribed, rarely abused drugs could have caused a crisis fueled by widespread diversion and abuse of other manufacturers' products. Nor did they explain how a handful of "unbranded" promotions in the late 2000s could have caused a crisis that, by the State's own account, began years earlier.

Indeed, despite conclusory assertions by the State's experts that Janssen's marketing was a cause of the opioid crisis, the State did not identify a single Oklahoma doctor influenced in any way by any of the statements the State criticizes—branded or unbranded. The State's central claim was that Oklahoma doctors were misled about addiction. But the evidence showed that doctors have always understood that opioids can be addictive, and Janssen's long-acting opioids have long featured a prominent black-box warning about the risks of abuse, misuse, overdose, and death. An example is Duragesic's black-box warning from 2005, which stated:

> DURAGESIC contains a high concentration of a potent Schedule II opioid agaonist, fentanyl. Schedule II opioid substances which include fentanyl ... have he highest potential for abuse and associated risk of fatal overdose due to respiratory depression.... Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse, abuse, and addiction.[1]

The labeling of Janssen's other opioid medications contained similarly prominent warnings about opioid risks. One Oklahoma physician after another dismissed as absurd the notion that Janssen induced Oklahoma physicians to disregard these known risks.

Basic causation rules reject holding product manufacturers liable for harms their conduct did not cause. The State insists that its resort to public nuisance law allows it to escape hornbook causation requirements, and to obtain a massive judgment based on speculation that Janssen's

[1] Janssen Trial Ex. 2769, 2005 Duragesic Label at 1-2 (*admitted June 4, 2019*).

promotion of its own rarely abused medication made a difference to sales of other manufacturers' medications. But that is precisely the kind of result countless courts have rejected when warning that expansion of public nuisance doctrine threatens limitless liability for product manufacturers.

Going beyond Janssen's own marketing, the State tried to hold Janssen responsible for the speech of third-party organizations and doctors. In so doing, it provided no proof that Janssen influenced, much less controlled, those third parties—only conclusory speculation by its experts. The First Amendment fully protects the right of advocacy groups and prominent doctors to take public positions on debated medical questions. Although the State insisted Janssen disseminated such third-party statements, its evidence on actual dissemination was exceedingly scarce, and the State did not identify a single Oklahoma physician exposed to, much less influenced by it.

The First Amendment likewise fully protects the lobbying efforts the State attacks. That is so even if, as the State claims, Janssen's lobbying was intended to promulgate messages the State disagrees with. The First Amendment bars liability for any lobbying intended to secure favorable government action—period. It thus forecloses the State's challenge to basic petitioning activities.

The State gets no further by observing that a Janssen subsidiary, Noramco, and a J&J subsidiary, Tasmanian Alkaloids, produced raw materials for opioid medications. Oklahoma law bars liability for the sale of non-defective raw materials, and a comprehensive federal regulatory program authorized and painstakingly regulated the importation, manufacture, and sales of those materials, preempting any state liability for them. When the unrebutted trial evidence showed that Noramco and Tasmanian Alkaloids supplied their products under strictly regulated

importation and manufacturing quotas established by the DEA to ensure adequate supply of medical-grade raw materials to meet the medical and research needs of the United States, the State retreated from its contention that Noramco or Tasmanian Alkaloids did anything improper, and shifted instead to an argument that their sales supplied a motivation for Janssen to engage in "unbranded" marketing of opioids as a class. But the State offered nothing but speculation for that theory, which the trial evidence refuted: Janssen did not engage in unbranded marketing of opioids until the late 2000s—three decades after it acquired Noramco—and internal Janssen documents demonstrate that those limited efforts were intended to help Janssen launch its Nucynta tapentadol products, not to promote its competitors' medications.

The State coupled its unprecedented theories of liability with a demand for an unprecedented and unsupportable remedy: a multibillion-dollar payment by Janssen to "abate" Oklahoma's opioid crisis. Because the Oklahoma nuisance statute defines a public nuisance to consist of the defendant's ***conduct***—not resulting injuries—judicial abatement remedies have always taken the form of a court order either barring or mandating some conduct by the defendant. ***No Oklahoma court has ever awarded a plaintiff a cash recovery to abate a nuisance.*** And no American court has ever entered an order creating dozens of government policy initiatives and determining how they should be funded. The State nevertheless proposes repurposing a statute historically applied to padlock brothel doors or clip overgrown hedges to bankroll a roster of government programs for decades to come. Not only is that demand unprecedented, but the State's experts provided only conclusory testimony that these proposed spending programs are necessary or would be effective in resolving the opioid abuse crisis—and many involve services already provided by the State, the federal government, and private insurers. The State's request to be compensated for expenses it is already incurring or expects to

incur amounts to an ill-disguised request for future damages or imposition of a penalty—not abatement. And it violates fundamental separation of powers principles, which hold that the legislature and executive, not the courts, have exclusive authority to evaluate the wisdom of policy proposals and determine how government programs should be funded. This proposed remedy has no precedent in American legal history. And not one word of the nuisance statute or Oklahoma caselaw authorizes it.

In a final demand, the State asserts that the opioid abuse crisis—a collection of diverse harms suffered by individual Oklahomans—is a single indivisible injury warranting joint and several liability. That claim is irreconcilable with a century of caselaw finding indivisible injuries only in cases involving harm to a particular person or property from multiple concurrent causes, or harm from commingled water pollution. And it threatens liability completely out of proportion to the conduct alleged against Janssen—the promotion of infrequently prescribed, rarely abused medicines and a few limited statements published more than a decade after the crisis's inception.

A court is "not a legislature charged with formulating public policy," *Demore v. Kim*, 538 U.S. 510, 528 (2003) (marks omitted), "and it is elementary that the courts have no power to legislate." *Stillwater Floral Co. v. Murray*, 1962 OK 235, ¶ 8, 380 P.2d 694, 696. Yet the State asks this Court to enact revolutionary changes to the law: unprecedented expansion of public nuisance doctrine, unprecedented relaxation of settled causation requirements, unprecedented component-supplier liability, unprecedented judicially-legislated remedies, and unprecedented joint and several liability. Those demands would be unsupportable in any case, but they are especially untenable in a case where the evidence showed that the products Janssen promoted were seldom prescribed or abused, that Janssen published just a handful of unbranded

promotional statements years after the opioid abuse crisis started, and that the raw materials subsidiaries, which never marketed opioids, sold their medical-grade ingredients in full compliance with comprehensive federal regulations. Both the facts and the law warrant entry of judgment for Janssen on the State's public nuisance claim.

PROPOSED FINDINGS OF FACT

I. INTRODUCTION

1. This case came before the Court for a bench trial that began on May 28, 2019 and concluded on July 15, 2019. The Court sat for 33 trial days, during which 46 witnesses appeared live or by prior deposition testimony presented in Court. The Court received 874 exhibits into evidence, and the parties presented an additional 225 Court exhibits.[2]

2. Based on its review of all the evidence, the Court has made credibility findings that are reflected in these Findings of Fact and Conclusions of Law. The Court's decision in this matter does not rely on any testimony or exhibits that are not specifically cited herein.

3. The State's sole claim seeks recovery under 50 O.S. § 1 *et seq.* for what the State alleges is a public nuisance. The only remedy sought by the State is abatement, pursuant to 50 O.S. § 11.

4. Based on the Findings of Fact entered below, and for the reasons fully explained in the Court's Conclusions of Law, the Court finds that the State failed to carry its burden of proof at trial and enters Judgment for Defendants.

[2] In discussing the evidence as admitted at trial, Janssen does not waive its objections to the admission or exclusion of evidence or the qualifications of the State's expert witnesses.

II. JANSSEN MADE INNOVATIVE MEDICATIONS TO MEET PATIENT NEEDS

A. Prescription opioids are essential medications for millions suffering from chronic non-cancer pain.

5. Chronic pain is a pervasive, debilitating, and costly heath condition. Opioids remain a vital treatment option for chronic pain. Multiple Oklahoma physicians credibly testified that long-term opioid therapy remains a critical tool for pain treatment. Dr. Schick testified that opioid medications make "a huge difference" in the lives of his patients.[3] Dr. Halford added that many of his patients "would suffer tremendously" if opioid medications were not available.[4] Dr. Phillips testified from personal experience that his mother used a fentanyl patch for 3 years and did "quite well."[5]

6. Clinical evidence demonstrates that long-term use of opioids to treat pain benefits patients by helping them work and perform daily activities and by generally improving their quality of life. Dr. Muchmore testified about his patients, one with Cushing syndrome who uses opioids to help him sleep through the night, another with Paget's disease who takes long acting opioids to enable her to "ambulate" and "get around and go to church and do all the things she needs to do," and another with sickle cell disease who relies on opioids.[6] Dr. Phillips also testified about the benefits his patients received, including a patient who was able to return to work after an injury to her lower back, another who after suffering nerve damage during surgery can now work, coach his son's sports teams, and hunt due to opioid therapy, and an elderly woman coping with a fractured spine.[7] Oklahoma physicians have treated chronic-pain patients

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[3] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 191:21-192:9.

[4] July 8, 2019 (PM) Trial Tr. (Halford Test.) at 50:6-16.

[5] July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 40:6-23.

[6] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 18:19-19:4, 19:20-20:2, 20:7-11.

[7] July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 36:13-40:5.

for years—in some cases decades—without those patients developing opioid use disorder ("OUD").[8]

7. Studies demonstrate that opioids can be safe and effective for long-term use in chronic-pain patients.[9] Consistent with these studies, the Food and Drug Administration ("FDA") recognizes that "[w]hen prescribed and used properly, opioids can effectively manage pain and alleviate suffering."[10]

8. In 2012, Physicians for Responsible Opioid Prescribing ("PROP") filed a petition

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[8] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 187:18-25 (patients have been on opioid medications for up to 10 years and have been kept on the medications because they help maintain function); *see also* Webster Depo. Tr. at 394:8-15 (played July 10, 2019) (patients have taken opioids for over a decade and have not developed OUD); July 8, 2019 (PM) Trial Tr. (Halford Test.) at 19:11-12 (patients have been on chronic opioid therapy for over 20 years); Portenoy Depo. Tr. at 373:15-376:23 (played May 29, 2019) (testifying that his patients have benefitted from chronic opioid therapy and providing examples).

[9] State Ex. 2523, Simpson Study at 2 (month long, peer-reviewed study of approximately 50 chronic low back pain patients found that patients who used a transdermal fentanyl patch instead of oral opioids for the management of their pain saw significant improvement in their pain relief) (*admitted May 30, 2019*); *see also* Janssen Ex. 3945, Allan Study at 1 (two month long peer-reviewed crossover study involving over 250 patients analyzed patients taking oral morphine and using a transdermal fentanyl patch and found that patients preferred the transdermal patch because they experienced fewer adverse events and enhanced quality of life measures) (*admitted July 9, 2019*); Janssen Ex. 706, Dellemijn Study at 1 (in a 12-week peer-reviewed open label trial, clinicians found that long-term transdermal fentanyl can be "effective in noncancer neuropathic pain without clinically significant management problems.") (*admitted July 9, 2019*); State Ex. 2521, Milligan Study at 4 (12-month long clinical trial studying over 500 patients concluded that transdermal fentanyl was effective in treating chronic non-cancer pain and that patients reported a stable global efficacy rating during the study period, demonstrating that the drug was effective in relieving pain over that time) (*admitted May 30, 2019*); Janssen Ex. 3946, Tapentadol Prolonged Release for Chronic Pain: A Review of Clinical Trials and 5 Years of Routine Clinical Practice Data at 4 (discussing an active comparator study conducted over 12 weeks involving 965 patients with chronic low back pain who used oral oxycodone and tapentadol ER, demonstrating that that patients taking tapentadol ER over this period experienced a significant reduction in their pain and fewer adverse events than they had while taking oxycodone), 5 (discussing clinical trial that studied osteoarthritis pain or low back pain in 1,117 patients over one year using oxycodone and tapentadol ER determined that patients experienced significant pain relief with both medications) (*admitted July 9, 2019*).

[10] Janssen Ex. 1576, FDA Response to PROP Petition at 2 (*admitted June 13, 2019*).

with the FDA seeking, among other things, to restrict the duration of treatment with opioids by adding "a maximum duration of 90-days for continuous (daily) use [of opioids] for non-cancer pain."[11] PROP cited, as one basis for the request, that long-term "safety and effectiveness of managing [chronic non-cancer pain] with opioids has not been established."[12] While the FDA recognizes the need for more data regarding the safety of long-term opioid use, it rejected PROP's request, concluding that the current data did not support such a limitation.[13] PROP made other requests for labeling changes, all of which were limited to "non-cancer pain."[14] But the FDA declined to change opioid labeling to distinguish between cancer and non-cancer pain, explaining that "a patient without cancer, like a patient with cancer, may suffer from chronic pain, and PROP has not provided scientific support for why labeling should recommend different treatment for such patients."[15]

9. Oklahoma officials recognize the medical necessity of opioids. Although they have long recognized the challenge posed by illicit drugs and criminal diversion of prescription opioids,[16] the State—and the local Oklahoma doctors that testified in this case—also knew that prescription opioids are critical to proper pain treatment, and that restricting access to prescription opioids could negatively impact the lives of tens of thousands of Oklahomans.[17]

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[11] Janssen Trial Ex. 1460, PROP Petition at 2 (admitted June 13, 2019).

[12] *Id.*

[13] Janssen Trial Ex. 1576, FDA Response to PROP Petition at 14-17 (admitted June 13, 2019).

[14] *See id.* at 9.

[15] *Id.* The FDA also stated that it was not aware of any "physiological or pharmacological basis upon which to differentiate the treatment of chronic pain in a cancer setting or patient from the treatment of chronic pain the absence of cancer...."

[16] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 67:22-69:9; Court Ex. 212.

[17] Janssen Ex. 1522, DURB Meeting Packet for February 11, 2003 Meeting at 14-15 (minutes showing that Dr. Crenshaw, a doctor in rural Oklahoma, explained to DURB that prior authorizing OxyContin would lead him not to prescribe it, which would "leave somebody

State and federal agencies have repeatedly acknowledged that efforts to combat diversion and abuse must be balanced with the need to preserve legitimate medical use and should not interfere with the ability of pain patients to receive needed medical treatment.[18] Those decisions confirm that prescription opioids, properly prescribed and taken as directed, did not cause the State's opioid abuse crisis—and instead have alleviated the suffering of countless Oklahomans.

B. Janssen's opioid medications offered superior benefits to chronic and acute pain patients with reduced risks compared to other opioid medications.

10. Janssen's opioid medications are no exception, and in fact were shown at trial to offer superior benefits and minimized risks compared to other prescription opioids.

11. Janssen develops many types of medications to help meet patients' needs.[19] The Johnson & Johnson Credo states that Janssen's first "responsibility is to the doctors, nurses, and patients, to mothers and fathers and all others who use [its] products and services."[20] And Janssen employees "every day [] go out and try[] to better healthcare of Oklahomans, people

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hurting") (*admitted June 25, 2019*). As discussed below, following these remarks, restrictions on OxyContin utilization were not imposed for over two years. Janssen Ex. 895, DURB Meeting Packet for April 12, 2005 Meeting at 38 (explaining that "no quantity limit [is] currently being applied to this drug [OxyContin]") (*admitted June 25, 2019*).

[18] *See supra* n._[11]; Janssen Ex. 802, DURB Packet for March 11, 2003 Meeting at 85 (*admitted June 25, 2019*) ("DEA is taking a measured, reasonable approach to dealing with OxyContin and other drugs of abuse, and is committed to ensuring that there are adequate supplies of pain medications for those with legitimate needs while we strive to protect the public from the consequences of abuse."), 89 ("Please be assured that the DEA understands your responsibility to pain sufferers and those seeking to diminish their suffering. Physicians should not hesitate to prescribe suitable medications for pain relief, even if dosages to properly control pain entail the risk of hastening death."). [The *id.* referred to the entire previous note, so I changed it to *see supra*. The next two cites were both to the same exhibit number, so I condensed the format for brevity.]

[19] *See* July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 56:20-57:14 (testifying that Janssen "develop[s] products that can help better [patients'] healthcare.").

[20] State Ex. 1044, Johnson & Johnson Code of Business Conduct at 2 (*admitted May 30, 2019*).

within [their] region and across the United States."[21]

12. One area of patient need is chronic pain, commonly defined as pain that persists for more than three months or "past the time of normal tissue healing."[22] Chronic pain is a serious public health problem with severe human and economic costs. The FDA has recognized that chronic pain "affects millions of Americans" and "contributes greatly to national rates of morbidity, mortality, and disability."[23] In 2018, the Centers for Disease Control and Prevention ("CDC") reported that "20.4 percent (50.0 million) of U.S. adults had chronic pain and 8.0 percent of U.S. adults (19.6 million) had high-impact chronic pain" (i.e., chronic pain that frequently limits life or work activities).[24] And a few months ago, the Department of Health and Human Services Inter-Agency Task Force reported that the "cost of pain to our nation is estimated at between $560 billion and $635 billion annually."[25]

13. Chronic pain exacts an emotional toll on its sufferers. Patients with untreated or inadequately treated pain may experience anxiety and depression, disengage from their families,

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[21] July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 57:4-6.

[22] Janssen Ex. 382, CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016 at 3 (*admitted June 14, 2019*); June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 64:1-5 ("[T]ypically, the definition that we use [for chronic pain] is the pain lasts for three months or beyond the expected period of time where you would expect the injury to have resolved.").

[23] Janssen Ex. 1576, FDA Response to PROP Petition at 2 (internal citation omitted) *(admitted June 13, 2019)*.

[24] Janssen Ex. 1971, CDC Morbidity and Mortality Weekly Report, Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States 2016 at 2 (*admitted June 13, 2019*); *see also* June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 80:8-21, 81:6 (when shown this data, agreeing that "many people suffer with chronic pain, that it is highly prevalent").

[25] Janssen Ex. 3931, Pain Management Best Practices Inter-Agency Task Force Report at 17 (*admitted June 13, 2019*); *see also* Janssen Ex. 1971, CDC Morbidity and Mortality Weekly Report, Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States 2016 at 3 (*admitted June 13, 2019*) ("Chronic pain contributes to an estimated $560 billion each year in direct medical costs, lost productivity, and disability programs.").

or even commit suicide due to the difficulty of living in pain.[26]

14. Physicians in Oklahoma know the effects of chronic pain and make daily decisions about how best to care for patients suffering from chronic pain.[27] Yet providing adequate treatment for chronic pain remains a challenge in Oklahoma, and the number of patients visiting physicians for pain treatment continues to rise.[28]

15. Physicians can treat pain in many ways, but every option presents risks, often serious ones.[29] And not every therapy is effective for every patient, so physicians must make individualized treatment decisions.[30] Nonsteroidal anti-inflammatory drugs ("NSAIDs"), for example, can relieve pain, but they can also cause stomach ulcers[31] and harm patients who have diabetes or kidney disease.[32] NSAIDs have also been shown to increase the risk of

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[26] *See* Webster Depo. Tr. at 322:21-22, 322:24-323:1, 323:3-324:22 (played July 10, 2019) (discussing consequences of undertreated pain and a patient who committed suicide after having his opioid dose tapered); *see also* July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 32:11-34:1 (explaining how inadequately treated chronic pain can affect patients).

[27] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 173:3-5 (testifying that the "vast majority" of his practice is for the treatment of chronic pain); *see also* July 8, 2019 (PM) Trial Tr. (Halford Test.) at 13:4-7 (stating that approximately 95 percent of his practice deals with chronic pain).

[28] *See* July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 30:16-31:7 (explaining how the nation is aging and "as people get older, they tend to have more pain" so the number of patients with pain "will never decrease, short of some new treatment that can cure chronic pain."); *see also* July 8, 2019 (PM) Trial Tr. (Halford Test.) at 17:3-12 (testifying that there is a "very real need [for treatment of chronic pain in Oklahoma] and there's a lot of evidence").

[29] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 41:6-7 ("all drugs have risks").

[30] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 174:23-175:9 (explaining how doctors must assess each patient to determine which treatment modality is best for them); *see also* July 3, 2019 (AM Sess. 2) Trial Tr. (Toal Test.) at 33:17-23 (testifying that patients recover differently so treatment must be tailored to the individual patient); July 8, 2019 (PM) Trial Tr. (Halford Test.) at 41:19-25 (noting that every medical decision is based on an individual assessment of the patient).

[31] *See* July 8, 2019 (PM) Trial Tr. (Halford Test.) at 34:3-23 (testifying about NSAIDs and stating that they are the second-leading cause of ulcers).

[32] *See* July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 40:11-15 (testifying that he rarely prescribes NSAIDs because many of his patients have diabetes or kidney issues and these drugs

cardiovascular-related events, such as heart attacks and strokes.[33]

16. Janssen developed opioid medications to address these patient needs and provide physicians with another tool to treat pain. And Janssen designed its opioid medications to provide unique benefits for pain patients while also deterring abuse, misuse, and diversion.

III. JANSSEN'S PROMOTION OF ITS MEDICINES WAS NOT A CAUSE OF THE OPIOID CRISIS

17. The State's attempt to connect Janssen to Oklahoma's opioid abuse crisis rested not only on Janssen's own statements, but on sprawling evidence about legally protected activities and conduct by third parties—from Janssen and J&J subsidiaries' federally authorized sales of active pharmaceutical ingredients ("APIs") for other manufacturers' medications to constitutionally protected speech by doctors and advocacy organizations like the American Pain Society. As explained in the Conclusions of Law that follow, none of that protected activity can furnish a basis for this Court to conclude that Janssen caused Oklahoma's opioid abuse crisis. *See infra* 146-156.

18. The State's evidence on Janssen's own promotional acts was far more limited, challenging three narrow types of conduct: (1) Janssen's branded promotion of its Duragesic fentanyl patch and a single month-long promotion of the Ultracet tramadol-acetaminophen pill; (2) a handful of "unbranded" promotional materials from the late 2000s discussing pain treatment options, including opioids; and (3) Janssen's possible dissemination of third-party

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can worsen those conditions); *see also* Janssen Ex. 3606, FDA Guide to Safe Use of Pain Medicine (April 4, 2019) at 3 (*admitted June 14, 2019*) (stating that NSAIDs can cause stomach bleeding and kidney damage); *see also* Janssen Ex. 3805, DURB Meeting Packet Oct. 12, 2004 at 18 (*admitted June 26, 2019*) ("All of the NSAID drugs have risks when taken chronically, especially of gastrointestinal bleeding, but also liver and kidney toxicity.").

[33] *See* Janssen Ex. 382, CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016 at 14 (*admitted June 14, 2019*) (stating that NSAIDs have "cardiovascular risks" and that their labels disclose "risks for heart attack and stroke").

statements about opioids, of which the State provided only limited circumstantial evidence.

19. Notably lacking from the State's case was evidence of a single Oklahoma prescriber misled by Janssen. Indeed, the State failed to establish that many of the materials it criticized were distributed in Oklahoma at all. *See infra* 57-58.

20. Moreover, as explained below, the trial evidence showed that the statements criticized by the State's expert witnesses were not misleading at all—they have substantial scientific and clinical support, and they align with the views of mainstream Oklahoma doctors and the FDA. Additionally, Janssen's branded promotions could not have caused the opioid abuse crisis because ***Janssen's medications*** did not cause the opioid abuse crisis—they were rarely prescribed and even more rarely diverted or abused, and they had no logical link to a crisis driven by rampant diversion and abuse of hydrocodone and oxycodone pills. Nor could a handful of unbranded marketing materials including general discussions of opioid pain therapy in the late 2000s have caused a crisis that—by the accounts of the State's own experts—began in 1996. And the State's limited circumstantial evidence that Janssen disseminated third-party statements, consisting almost entirely of comments clipped from internal Janssen documents, allows only for speculation whether such dissemination occurred at all, much less with a frequency that could have influenced prescribing habits in Oklahoma. In short, the State failed to demonstrate both that Janssen's statements were misleading or that they contributed to Oklahoma's opioid abuse crisis in any way.

A. Duragesic

1. Background

21. Duragesic is a transdermal patch that delivers a controlled dose of

pharmaceutical-grade fentanyl through the skin over a span of 72 hours.[34] ALZA Corporation ("ALZA"), a company later acquired by Janssen, developed Duragesic in response to a governmental call to action: Develop new opioids formulations to better treat chronic pain.[35]

22. Duragesic's innovative transdermal formulation introduced a new way to deliver fentanyl. Before Duragesic, only healthcare professionals could administer fentanyl, and they could only do so through two methods of administration: intravenous or intramuscular injection.[36]

23. To get approval to market Duragesic, ALZA submitted a 64-volume new drug application ("NDA") to the FDA, including results from short-term and long-term clinical trials on Duragesic.[37] The FDA found Duragesic was "safe and effective for use as recommended" and approved it for sale on August 7, 1990.[38] Janssen began to market Duragesic in 1991.[39]

24. Although Duragesic's FDA-approved indication has evolved, it has always covered chronic non-cancer pain and has never been limited to treating only cancer pain.[40]

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[34] June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 66:2-4, 67:15-25.

[35] *See id.* at 102:19-103:6.

[36] *See id.* at 103:7-24.

[37] *See* Janssen Exs. 2792-2842, Duragesic NDA 12-12-1987 Vols. 2-64 (*admitted June 27, 2019*).

[38] *See* Janssen Ex. 2843, Duragesic NDA Medical Officer Reviews Vols. 1-5 at 2 (*admitted June 27, 2019*).

[39] *See* May 31, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 113:13-14.

[40] *See, e.g.*, Janssen Ex. 2762, 1990 Duragesic Label (*admitted June 4, 2019*); Janssen Ex. 2763, 1993 Duragesic Label (*admitted June 4, 2019*); Janssen Ex. 2768, 2003 Duragesic Label (*admitted June 4, 2019*); Janssen Ex. 2769, 2005 Duragesic Label (*admitted June 4, 2019*); Janssen Ex. 2774, 2014 Duragesic Label (*admitted June 4, 2019*); Janssen Ex. 2776, 2018 Duragesic Label (*admitted June 4, 2019*); June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 102:5-7.

Initially, Duragesic was indicated for "chronic pain in patients requiring opioid analgesia."[41] Beginning in 1993, Duragesic was indicated for "chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means."[42] In 2005, this indication was changed to "persistent, moderate to severe chronic pain."[43] And in 2014, it was changed to pain "severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate"—the same indication in effect today.[44]

25. The Court finds that the evolution of Duragesic's approved indication over time demonstrates the active engagement of the FDA, Janssen's federal regulator, which brings its unparalleled expertise to the evaluation of the benefits and risks of prescription opioid medications.

26. Duragesic's product labels warn about the serious risks associated with the drug, including abuse, misuse, diversion, and addiction.[45] Like the drug's indications, its warnings were updated over time too; Janssen added a black-box warning in 1993[46] and additional warnings and precautions later, as it learned of new risks or the need for stronger language.[47]

27. When Duragesic's patent expired in 2005,[48] Janssen significantly decreased its

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[41] Janssen Ex. 2762, 1990 Duragesic Label at 5 (*admitted June 4, 2019*).

[42] Janssen Ex. 2764, 1993 Duragesic Label at 6 (*admitted June 4, 2019*).

[43] Janssen Ex. 2769, 2005 Duragesic Label at 1 (*admitted June 4, 2019*).

[44] Janssen Ex. 2774, 2014 Duragesic Label at 4 (*admitted June 4, 2019*); Janssen Ex. 2776, 2018 Duragesic Label at 1 (*admitted June 4, 2019*).

[45] *See, e.g.*, Janssen Ex. 2769, 2005 Duragesic Label at 11 (misuse, abuse and diversion), 23 (drug abuse and addiction) (*admitted June 4, 2019*).

[46] Janssen Ex. 2764, 1993 Duragesic Label at 1 (*admitted June 4, 2019*).

[47] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 96:9-18.

[48] *See* June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 45:24-25.

marketing of the drug, ultimately ceasing active promotion around 2007.[49] Janssen still sells Duragesic.[50]

28. Despite its nearly 30 years on the market, Duragesic has never captured a significant market share in Oklahoma. State expert Dr. Andrew Kolodny testified that as of 2000, nearly 10 years after its introduction, Duragesic was "hardly prescribed."[51] And Duragesic's market share remained small in the years that followed:

- From 1996 to 2017, Duragesic, Nucynta, and Nucynta ER made up 0.82 percent of opioid prescriptions reimbursed by SoonerCare, the State's Medicaid program.[52]
- From 2004 to 2018, Duragesic, Nucynta, and Nucynta ER made up 0.36 percent of all opioid prescriptions reimbursed by HealthChoice, the health plan for State employees.[53]
- From 2008 to 2017, Duragesic, Nucynta, and Nucynta ER made up 0.20 percent of all Oklahoma reimbursements for opioid prescriptions made by BlueCross BlueShield, one of the largest private insurers in the country.[54]

29. Duragesic also has never been subject to widespread abuse, misuse, or diversion in Oklahoma. Though Duragesic, like any drug, can be abused and misused, its design and formulation deterred abuse and misuse. Outside consultants attributed Duragesic's low abuse rates to the product's design, which made it difficult to extract, purify, or measure a controlled

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[49] *See id.* at 45:21-46:3.

[50] *See id.* at 45:9-12.

[51] June 11, 2019 (PM) Trial. Tr. (Kolodny Test.) at 170:8.

[52] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 34:15-21, 35:5-36:11, 37:10-15; *see* Court Ex. 201 at 1-2.

[53] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 34:22-25, 36:12-18; *see* Court Ex. 201 at 1.

[54] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 35:1-4, 36:12-20; *see* Court Ex. 201 at 1. Even when including the Sandoz generic fentanyl patch, Janssen's market share still remained less than 1.1 percent in SoonerCare, and even less in HealthChoice (0.81%) and BlueCross BlueShield (0.38%). *See* Court Ex. 201 at 1.

dose of fentanyl.[55] State witness John McGregor said he never abused a fentanyl patch because he was "scared of it"—he explained, "that patch to us addicts was the next level that we did not want to tangle with unless you had a death sentence, really. So no, I did not."[56]

30. Data produced by the State confirm that few Oklahomans died from overdosing on Duragesic: Out of 14,132 medical examiner reports from 2000 to 2018, only 48 mention Duragesic and only 23 of those identified fentanyl as the sole cause of death.[57] Oklahoma's Chief Medical Examiner confirmed that these figures were unsurprising,[58] and explained that most of those deaths resulted from misuse, such as application of multiple patches or oral ingestion.[59] By contrast, over just the 11-year period between 2007 and 2017, the State reported 1,328 hydrocodone deaths and 1,454 oxycodone deaths.[60]

31. Likewise, an analysis of SoonerCare claims from 1996 to 2017 demonstrates low

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[55] *See* Janssen Ex. 862, Assessment of Abuse Potential of Fentanyl Transdermal Systems in the U.S., prepared by Pinney Associates at 21 (*admitted June 27, 2019*) (reporting "the rates of abuse of [Duragesic] ha[d] been relatively low," attributing this to the product's design, which made it difficult to "extract[] and purify[] the fentanyl."); Janssen Ex. 907, Prescription Drug Research Center Duragesic Surveillance Program, Sentinel Network & Media Review Baseline Update Part IA at 6 (*admitted June 27, 2019*) (stating that "the average abuser has no way to measure or control dosing" from a Duragesic patch); Janssen Ex. 2643, Assessment of the Abuse of Transdermal Fentanyl at 5 (*admitted June 27, 2019*) (transdermal fentanyl was "less subject to abuse than other potent opioids because of its chemical formulation.").

[56] June 7, 2019 (AM) Trial Tr. (McGregor Test.) at 37:20-38:8.

[57] Court Ex. 85 at 5; *see also* June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 153:1-156:2 (testifying about figures listed in Court Ex. 85). The State provided testimony that a total of 6,137 Oklahomans died of a drug overdose from 2000 to 2017. June 25, 2019 (AM) Trial Tr. (White Test.) at 82:11-83:2.

[58] June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 154:14-17 (not surprised that only 48 reports containing fentanyl in the cause of death mentioned Duragesic patches), 154:22-155:2 (no reason to dispute that only 23 reports containing fentanyl alone in the cause of death mentioned Duragesic patches).

[59] June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 19:10-21, 101:6-9.

[60] Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System: Data Update (2007-2017) at 9 (*admitted June 18, 2019*).

numbers of addiction cases in patients who received Duragesic prescriptions in Oklahoma: Only 0.13 percent of patients diagnosed with OUD had received a Duragesic prescription in the 12 months before diagnosis.[61] By contrast, 2.46 percent had received an oxycodone prescription and 41.51 percent received a hydrocodone prescription.[62]

2. Janssen promoted its medicines, including Duragesic, through sales representatives.

32. Janssen sales representatives "detailed" Duragesic and other Janssen medications in Oklahoma, visiting healthcare providers and providing information about the risks and benefits of Janssen's medications. As with all Janssen's branded promotion, federal law required Janssen's detailing to be consistent with the FDA-approved package insert.[63]

33. Janssen sales representatives often detailed doctors in representatives' own communities—doctors who treated their friends and family—and they worked to build relationships and maintain credibility with them by providing accurate information. As Janssen district manager Jason Flanary explained, the company's "representatives work on a daily basis with the doctors they go to church with, that they see at the grocery store, that they see at the ball fields. And it's very important that our Janssen specialists are able to maintain their credibility in front of their customers. And the way that we do that is being as knowledgeable as we can in the therapeutic areas that we work."[64] Meeting with sales representatives is one of the ways physicians keep informed about available medications, new medications, and how medications

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[61] *See* Court Ex. 207 at 1-2; July 11, 2019 (AM) Trial Tr. (Marais Test.) at 77:6-22.

[62] *See* Court Ex. 207 at 1, 3; July 11, 2019 (AM) Trial Tr. (Marais Test.) at 77:23-78:6, 79:7-80:4.

[63] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 34:15-22; July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 43:12-45:9; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 49:11-50:5.

[64] July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 25:21-26:12, 54:18-55:16 ("[W]e don't build value by deceiving customers.").

are indicated for use.[65] While pharmaceutical representatives can provide information about a medication, the Oklahoma physicians who testified said their prescribing decisions are based on individualized assessments of their patients' needs and not influenced by sales representatives.[66]

34. When detailing, sales representatives used Janssen-provided sales aids and other promotional materials.[67] Janssen's Promotional Review Committee reviewed these materials to ensure that they were consistent with the applicable FDA-approved package insert and that they included the same strong warnings and important safety information.[68]

35. If the Promotional Review Committee approved a piece of branded material, the regulatory reviewer on the Committee would send the piece through a Form 2253 submission to the FDA.[69] All PRC-approved branded promotional materials were sent to the FDA.[70] Additionally, Janssen conducted an annual review of branded promotional pieces.[71]

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[65] *See* July 3, 2019 (AM) Trial Tr. (Toal Test.) at 48:7-13 ("Q. What role do pharmaceutical representatives play? A. Pharmaceutical reps are there to tell you about their product, tell you if there are any innovations or changed any indicated for that medicine. If it's an old medicine, if it's a new medicine, they're there to tell you about what the medicine is to do. Basically, why they think you ought to consider using it.").

[66] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 175:13-176:4; July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 12:23-13:3; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 48:20-49:10; July 3, 2019 (AM) Trial Tr. (Toal Test.) at 48:14-49:7; July 12, 2019 (PM) Trial Tr. (Phillips Test.) at 47:18-48:6.

[67] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 85:18-86:14; July 2 (PM) Trial Tr. (Diesselhorst Test.) at 65:21-66:4, 66:8-13.

[68] June 4, 2019 (AM) Trial Tr. (Deem Eshleman Test.) at 88:21-95:15, 101:17-102:7; Court Ex. 21, Promotional Materials Approval Process; Janssen Ex. 3369, Advertising and Promotion Operating Procedure (*admitted June 4, 2019*).

[69] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 93:24-95:15; 97:22-98:10; Court Ex. 27.

[70] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 93:24-95:15; 97:22-98:10; Court Ex. 27.

[71] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 98:6-10.

36. Many detail visits were brief, lasting roughly 30 seconds;[72] others lasted 20 to 30 minutes.[73] On average, each lasted approximately three minutes.[74]

37. The State asserted that, according to Janssen's call notes, Janssen sales representatives detailed doctors 140,351 times between 1994 and 2016.[75] Dr. Laurentius Marais, an expert in the statistical analysis of medical and pharmaceutical claims data and the application of computational, econometric, mathematical, and statistical methods to the quantification of data sources, analyzed the call-note data. In an analysis unchallenged at trial, he determined that there were approximately 30,000 duplicate entries, and that the actual number of detail visits was 110,478. Of these, Dr. Marais calculated that only 78,729 detail visits were with physicians, as opposed to nurses or other non-prescribers.[76]

38. Dr. Marais also calculated that Janssen sales representatives detailed Oklahoma doctors 4.6 times per year on average, with a median of 3.2 visits per year—i.e., 50 percent of doctors who were detailed saw Janssen sales representatives more than 3.2 times per year, and 50 percent of doctors who were detailed saw Janssen sales representatives fewer than 3.2 times per year.[77] Dr. Marais calculated that doctors who were detailed spent an average of 9.6 minutes per year with Janssen sales representatives.[78]

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[72] July 2, 2019 (PM) Trial Tr. (Diesselhorst Test.) at 97:19-23.

[73] July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 46:7-16.

[74] *Id.* at 17:1-6.

[75] *See, e.g.*, Court Ex. 7; June 3, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 25:7-24, 76:23-77:2.

[76] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 23:10-22, 85:20-87:18; Court Ex. 208, Marais calculations, at 2.

[77] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 86:1-88:4; Court Ex. 208, Marais calculations, at 2.

[78] *Id.*

39. In addition to sharing information through sales representatives, Janssen also had a group of Medical Science Liaisons who could provide medical information to inquiring physicians.[79] The State pointed to a presentation regarding psychological dependence on opioids the liaisons could use with customers, which references the Porter & Jick letter.[80] Janssen's citation of Porter & Jick prominently disclosed that the study was limited to hospital patients and made clear that its results represent an extreme low-end estimate of addiction potential.[81] Janssen cited Porter & Jick as one data point about addiction potential alongside another study showing high addiction potential in a high-risk patient population.[82] The State has pointed to no evidence that Janssen ever presented this deck to any prescribing physicians in Oklahoma.

40. The State offered no evidence that a single Oklahoma doctor was misled by a Janssen sales representative or promotional communication. Moreover, it would simply not be credible to conclude that Oklahoma doctors' prescribing habits were altered by visits that averaged 9.6 minutes per year. The risks associated with opioids, including addiction and overdose, are well-known within the medical community—they are taught in medical school[83] and prominently emphasized in the medications' labeling.[84] In response to a question regarding the State's suggestion that Oklahoma physicians are unaware of these risks, the Chairman of the State's Drug Utilization Review Board ("DURB"), Dr. Muchmore, testified, "I think that's utter

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[79] *See* May 30, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 96:24-97:4.

[80] *See* State Ex. 740, Psychological Dependence with Opioids: Focus on Duragesic Promotional Slide Deck (Nov. 5, 2002) at 7 (*admitted May 30, 2019*).

[81] *See id.* at 7, 9.

[82] *See, e.g., id.* at 8-9; June 3, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 68:20-69:14.

[83] *See* July 8, 2019 (PM) Trial Tr. (Halford Test.) at 31:2-16; July 12, 2019 (PM) Trial Tr. (Phillips Test.) at 27:7-18.

[84] *See* July 8, 2019 (PM) Trial Tr. (Halford Test.) at 30:17-31:1; July 12, 2019 (PM) Trial Tr. (Phillips Test.) at 28:14-21.

nonsense. I think every physician is aware."[85]

41. Multiple Oklahoma doctors confirmed that Janssen sales representatives did not improperly influence their prescribing decisions.[86] Dr. Kyle Toal, an expert in the standards, customs, and practices of Oklahoma doctors, testified that he was unaware of any sales representative ever influencing the prescribing decisions of any doctor in his network.[87]

42. Oklahoma doctors have long been aware of the risks associated with opioid medications.[88] Dr. Muchmore testified that to suggest otherwise was "utter nonsense."[89] And they read the FDA-approved package inserts that include the indications, usage, and warnings for opioid medications.[90]

3. The information in Duragesic promotional materials subject to the 2004 Warning Letter is supported by data and clinical experience.

43. The State offered two primary criticisms of Janssen's marketing of Duragesic, both focused on a promotional file card used by sales representatives in 2004,[91] which the FDA

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[85] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 14:10-18.

[86] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 12:23-13:3, 16:7-21, 48:4-25 ("I'm aware of no physician who said they were pushed to give more opioids. None of our clinical pharmacists are aware of anybody pushing to give more people opioids"); July 8, 2019 (PM) Trial Tr. (Halford Test.) at 57:6-9 ("I don't think I'm influenced at all."); July 3, 2019 (AM) Trial Tr. (Toal Test.) at 95:21-96:3; June 28, 2019 (PM) Trial Tr. (Schick Test.) at 174:5-8, 240:5-241:2.

[87] July 3, 2019 (AM) Trial Tr. (Toal Test.) at 31:25-32:9, 49:8-23.

[88] *Id.* at 42:9-22; July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 27:7-18; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 29:17-19.

[89] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 12:2-5, 13:7-10, 14:10-14 ("Q. [I]n this case, the State has maintained that Oklahoma physicians are unaware of the risks and benefits of opioid medications. Do you agree? A. I think that's utter nonsense. I think every physician is aware.").

[90] July 8, 2019 (PM) Trial Tr. (Halford Test.) at 29:20-30:11, 45:16-46:25; July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 27:19-28:13; July 3, 2019 (AM) Trial Tr. (Toal Test.) at 42:23-25.

[91] State Ex. 2524, Duragesic File Card (*admitted May 30, 2019*).

challenged in a Warning Letter dated September 2, 2004.[92]

44. First, the State criticized the file card's reliance on three studies to highlight the drug's potential to improve functionality and quality of life for chronic pain patients.[93] The FDA, however, did not conclude that the studies were flawed, that Janssen misrepresented them, or that they were irrelevant to functionality or quality-of-life claims. Rather, the FDA found that because all three studies were "open-label" or "uncontrolled," [94] they did not meet the definition of "substantial evidence or substantial clinical experience" on which to base promotional claims under federal regulations.[95] But the information on the file cards was neither inaccurate nor misleading:

a. Under FDA regulations, "substantial evidence" requires "adequate and well-controlled studies."[96] An advertising claim that lacks such support is "false or misleading" within the regulatory definition,[97] even if it is accurate, contains prominent disclaimers about its limitations, and is supported by the cited data. Because the three studies cited in the file card were published in peer-reviewed journals and because their data were sound, disseminating the results was not misleading, even if the FDA

[92] State Ex. 38, 2004 FDA Warning Letter (*admitted May 30, 2019*).

[93] *See id.* at 2-3 (discussing Simpson, Milligan, and Allan studies) (*admitted May 30, 2019*); *see* State Ex. 2523, Simpson Study (*admitted May 30, 2019*); State Ex. 2521, Milligan Study (*admitted May 30, 2019*); Janssen Ex. 3945, Allan Study (*admitted July 9, 2019).*

[94] In an "open-label" study, subjects know the medicines they take. *See* July 9, 2019 (AM) Trial Tr. (De La Garza Test.) at 65:21-66:11. An "uncontrolled" study is one that lacks a comparison or control group to the group taking the drug being studied. *See id.* at 103:18-21 (explaining how a controlled study uses an active comparator).

[95] State Ex. 38, 2004 FDA Warning Letter at 2-3 (emphasis added) (*admitted May 30, 2019*).

[96] 21 C.F.R. § 314.126.

[97] 21 C.F.R. § 202.1(e)(6).

found that they did not meet the agency's standards.

b. An FDA assertion in a warning letter that a statement is "false and misleading" does not prove the assertion.[98] Warning letters are "advisory," they "do not constitute an official agency determination," and they do not "bind or otherwise obligate or commit the [FDA] to the views expressed."[99]

c. The overwhelming weight of the evidence adduced at trial shows that opioids generally and Duragesic specifically can improve functionality for patients with chronic pain. Physicians from Oklahoma and elsewhere testified that they witnessed improvements in function from patients on long-term opioid therapy. Examples included a formerly bedridden patient who became able to sit at the dinner table for the first time in years[100]; patients who regained the ability to work and to coach their children's sports teams[101]; and an 84-year-old woman who, despite a fractured spine, was able to continue living independently.[102] Other physicians testified that opioid therapy was crucial for function and recovery in their patients.[103]

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[98] *Schering–Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008) (listing cases).

[99] *Id.* (internal quotation marks omitted).

[100] *See* Webster Depo. Tr. at 318:2-19, 318:20-319:25, 320:2-321:2 (played July 10, 2019).

[101] *See* July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 38:4-39:7.

[102] *See id.* at 39:8-40:5.

[103] *See* June 28, 2019 (PM) Trial Tr. (Schick Test.) at 191:21-192:9; July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 18:6-10, 19:20-20:2; July 3, 2019 (AM) Trial Tr. (Toal Test.) at 35:19-37:1; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 50:6-16; July 12, 2019 (AM) Trial Tr. (Phillips

45. Second, the State questioned the use of DAWN data in the file card. The FDA found that the file card's presentation of DAWN data suggesting that Duragesic was "less abused than other opioids"[104] did not satisfy the "substantial evidence" standard for comparative claims.[105]

a. But the FDA did not state that the DAWN data cited in the file card were incorrect. Nor did the FDA prohibit use of DAWN data—in fact, the FDA, the DEA, and the State have all relied on DAWN data.[106] Instead, the FDA declared that DAWN data alone cannot provide a basis for comparisons and requested additional data to support the claim.[107] The State presented no evidence suggesprasting that Duragesic abuse rates paralleled or exceeded those of other opioid medications.

b. At trial, Janssen presented extensive additional evidence—beyond DAWN data—that confirms Duragesic has always been less abused than other opioids and that the statements in the Duragesic file card were correct. Data Janssen began receiving in 2006[108] from the Researched Abuse Diversion Addiction-Related Services System ("RADARS") demonstrates

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Test.) at 21:10-24, 22:2-13, 36:13-37:15, 37:18-38:2, 41:4-42:1.

[104] State Ex. 38, 2004 FDA Warning Letter at 2 (*admitted May 30, 2019*).

[105] *Id.* at 2.

[106] *See* Janssen Ex. 802, DURB Meeting Packet (Mar. 11, 2003) at 74, 78 (*admitted June 25, 2019*); Janssen Ex. 882, DURB Meeting Packet (Jan. 11, 2005) at 70 (*admitted June 26, 2019*); Janssen Ex. 3805, DURB Meeting Packet (Oct. 12, 2004) at 20 (*admitted June 26, 2019*); Court Ex. 224 at 25; June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 105:3-6 (stating that the FDA uses DAWN data).

[107] *See* State Ex. 38, 2004 FDA Warning Letter at 2 (*admitted May 30, 2019*).

[108] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 49:9-50:6.

that the rates of abuse, misuse, and diversion of fentanyl were among the lowest of all Schedule II opioids.[109] RADARS derived the rates from five separate surveillance programs it managed, each collecting data through different means and sources.[110]

c. The State has suggested that RADARS data is "biased" because Purdue created this surveillance system,[111] but the State offered no evidence showing how or why RADARS data is unreliable. And the evidence that was offered undercuts the State's theory that Purdue created a "biased" surveillance system, since rates of abuse, misuse, and diversion for oxycodone—the active ingredient in OxyContin—have consistently ranked among the highest of all Schedule II opioids in the RADARS database.[112] Moreover, Purdue's ownership of RADARS was short-lived: it created RADARS in the early 2000s, but transferred it in around 2006 to a non-profit organization, the Denver Health and Hospital Authority.[113]

4. Promoting Duragesic as an alternative to OxyContin—one less prone to abuse—could not have caused the opioid abuse crisis.

46. The trial evidence showed that OxyContin and other oxycodone products—and

[109] *See* Court Ex. 131-135; *see also* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 63:7-78:17.

[110] *See* Court Ex. 130; *see also* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 52:15-56:16.

[111] *See, e.g.*, June 4, 2019 (PM) Trial Tr. (Deem-Eshelman Test.) at 18:13-20, 19:3-8 (Beckworth objection discussing how RADARS was owned by Purdue); *see also* Ponder Depo Tr. at 300:18-20, 300:23-25, 301:01-04 (played June 20, 2019).

[112] *See* Court Ex. 131-135; *see also* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 63:7-78:17.

[113] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 49:9-50:6.

not Duragesic—played a pivotal role in fueling illicit opioid consumption in Oklahoma.

47. In March 2002, the DEA explained that abuse and diversion of OxyContin was a "serious problem" nationwide.[114] It warned that "OxyContin abuse and diversion [would] continue to spread throughout the United States" and continue to "pose a significant problem for law enforcement authorities throughout the United States."[115]

48. The State's Medicaid Drug Utilization Review Board ("DURB") would often review statistics about OxyContin use by Medicaid patients at the same time it examined reports of the drug's misuse, abuse, and diversion.[116] For example, at the July 10, 2001 meeting, the DURB reviewed materials indicating that OxyContin "usage ha[d] nearly doubled every year since its release in 1996."[117] Those same materials summarized reports of national media

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[114] Janssen Ex. 802, March 2002 Drug Intelligence Brief from U.S. DEA, contained in DURB Meeting Packet (Mar. 11, 2003) at 74 (*admitted June 25, 2019*).

[115] *Id.* at 84.

[116] Janssen Ex. 729, DURB Meeting Packet (July 10, 2001) at 71-72 (early review of Oxy Contin utilization showing that utilization had nearly doubled every year since 1996) (*admitted June 25, 2019*); Janssen Ex. 812, DURB Meeting Packet (July 8, 2003) at 66-67, (reviewing OxyContin utilization from April 2002 to March 2003 and reviewing what other state had done to control OxyContin utilization) (*admitted June 25, 2019*); Janssen Ex. 1522, DURB Meeting Packet (Feb. 11, 2003) at 56-58 (reviewing October 2001 to September 2002 OxyContin utilization) (*admitted June 25, 2019*); Janssen Ex. 815, DURB Meeting Packet (Aug. 12, 2003) at 62-64 (re-reviewing April 2002 to March 2003 OxyContin utilization and considering seven potential policy responses for controlling utilization) (*admitted June 25, 2019*); Janssen Ex. 895, DURB Meeting Packet (Apr. 12, 2005) at 38 (explaining that "no quantity limit is currently being applied to this drug [OxyContin]" and recommending a limit of 60 tablets per 30 days, excluding 80mg strength) (*admitted June 25, 2019*); Janssen Ex. 2455, DURB Meeting Packet (May 14, 2002) at 45-46 (discussing how OxyContin was "crushed and ingested, snorted, or injected to circumvent controlled release mechanism and obtain full dose immediately") (*admitted June 25, 2019*); Janssen Ex. 815, DURB Meeting Packet (Aug. 12, 2003) at 65 (reviewing reports of abuse of OxyContin in surrounding states) (*admitted June 25, 2019*); Janssen Ex. 802, March 2002 Drug Intelligence Brief from U.S. DEA, contained in DURB Meeting Packet (Mar. 11, 2003) (*admitted June 25, 2019*).

[117] Janssen Ex. 729, DURB Meeting Packet (July 10, 2001) at 72 (early review of OxyContin utilization showing that utilization had nearly doubled every year since 1996) (*admitted June 26, 2019*).

attention surrounding misuse and abuse of OxyContin, and indicated that some Oklahoma Medicaid "recipients may be potential abusers based on multiple physician and pharmacy usage."[118] Aware that skyrocketing OxyContin prescriptions could be the result of misuse or abuse, DURB reviewed policies enacted by other states—including a prior authorization requirement on more than two tablets a day—to "help reduce the potential for abuse or diversion of OxyContin."[119] The State imposed no restrictions.

49. DURB proceeded to review OxyContin utilization three separate times in 2003.[120] Materials in the July 8, 2003 and August 12, 2003 DURB meeting packets indicated that Medicaid patients were receiving an *average* of 2.9 OxyContin tablets per day.[121] OxyContin, however, "should not be taken more frequently than every 12 hours."[122] The DURB considered a variety of potential policy responses to contain the misuse and abuse of OxyContin.[123] However, despite the alarming number of OxyContin tablets being prescribed to Medicaid patients, the DURB took no action to reign in utilization—either by imposing quantity limits or

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[118] *Id.*

[119] *Id.*

[120] Janssen Ex. 812, DURB Meeting Packet (July 8, 2003) at 66-67 (reviewing OxyContin utilization from April 2002 to March 2003 and reviewing what other state had done to control OxyContin utilization) (*admitted June 25, 2019*); Janssen Ex. 1522, DURB Meeting Packet (Feb. 11, 2003) at 56-58 (reviewing October 2001 to September 2002 OxyContin utilization) (*admitted June 25, 2019*); Janssen Ex. 815 at 62-64, DURB Meeting Packet from August 12, 2003 Meeting (re-reviewing April 2002 to March 2003 OxyContin utilization and considering seven potential policy responses for controlling utilization) (*admitted June 25, 2019*).

[121] Janssen Ex. 815, DURB Meeting Packet (Aug. 12, 2003) at 62 (listing average number of tablets per day) (*admitted June 25, 2019*).

[122] Janssen Ex. 1522, DURB Meeting Packet (Feb. 11, 2003) at 58 ("OxyContin should not be taken more frequently than every 12 hours.") (*admitted June 25, 2019*).

[123] Janssen Ex. 815, DURB Meeting Packet (Aug. 12, 2003) at 62 (re-reviewing April 2002 to March 2003 OxyContin utilization and considering seven potential policy responses for controlling utilization) (*admitted June 25, 2019*).

by requiring prior authorization to obtain OxyContin.[124]

50. At that exact same time, DURB separately assessed Duragesic utilization. Its meeting materials stated that Duragesic utilization "appear[ed] to be within acceptable parameters" and recommended no changes or restrictions.[125] The materials also showed that the overwhelming majority of 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.[126]

51. The DURB specifically declined to require prior authorization for OxyContin in 2003 based on its concern that by restricting access to the medication it would harm Medicaid patients who needed the medication to relieve debilitating chronic pain.[127] At the February 11, 2003 DURB meeting, board member and rural Oklahoma physician Dr. Rick Crenshaw strongly opposed prior authorizing OxyContin. He gave the example of a 22-year-old patient that had been in a motor vehicle accident, had multiple back surgeries, and would "tell you he'd rather die than the live with the pain that he's got."[128] Dr. Crenshaw explained that if Medicaid prior authorized OxyContin, it "wouldn't be a drug in [his] regimen" or that of "a lot of physicians"

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[124] Janssen Ex. 895, DURB Meeting Packet (Apr. 12, 2005) at 38, (explaining that "no quantity limit is currently being applied to this drug [OxyContin]" and recommending a 60 tablet per 30 day limit, excluding 80mg strength) (*admitted June 25, 2019*).

[125] Janssen Ex. 812 at 75, DURB Meeting Packet (Jul. 8, 2003) (*admitted June 25, 2019*)

[126] *Id.*

[127] Janssen Ex. 1522 at 14-16, DURB Meeting Packet for February 11, 2003 Meeting (minutes showing that Dr. Crenshaw, a doctor in rural Oklahoma, explained to DURB that prior authorizing OxyContin would lead him and others not to prescribe it, which would "leave somebody hurting") (*admitted June 25, 2019*).

[128] *Id.* at 14.

because of the extra hassle it creates.[129] Following Dr. Crenshaw's remarks, the DURB voted "not to include Oxy[C]ontin for prior authorization."[130]

52. The State finally imposed a limit of two pills per day in mid-2005, nearly a decade after OxyContin's introduction.[131] But despite later acknowledging that OxyContin used to be "right at the top" of all drugs of abuse prior to its 2010 reformulation,[132] the State did not require Medicaid prior authorization for OxyContin prescriptions until 2008.[133]

53. Notwithstanding the State's efforts to rein in misuse of OxyContin and generic oxycodone products, those drugs have continued to rank just below hydrocodone products as the most abused and diverted prescription opioids.[134] Today, more prescription drug-related

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[129] *Id.* at 15.

[130] *Id.* at 16.

[131] *Id.*

[132] Janssen Ex. 1514, DURB Meeting Transcription (Feb. 13, 2013) at 67:1-19 (*admitted June 26, 2019*).

[133] Janssen Ex. 3914, DURB Meeting Packet (Apr. 9, 2008) at 2, 21 (discussing vote to adopt step therapy tiers and impose prior authorization requirements on certain narcotic analgesics) (*admitted June 26, 2019*); Janssen Ex. 456, DURB Meeting Packet (May 14, 2008) at 15 (stating that vote to prior authorize narcotic analgesics was carried by unanimous approval) (*admitted June 26, 2019*).

[134] Court Ex. 131 at 2 (chart depicting abuse rates for various prescriptions opioids from 2008 to 2014 as reported in J1718); Court Ex. 132 at 2 (chart depicting diversion rates for various prescriptions opioids from 2002 to 2014 as reported in J1718); Court Ex. 134 at 2 (chart depicting misuse rates for various prescriptions opioids from 2003 to 2014 as reported in J1718); Janssen Ex. 1718, RADARS Data on Abuse and Diversion (*admitted June 27, 2019*); Janssen Ex. 624 at 12 ("Opioid pain relievers (e.g., hydrocodone and oxycodone) and benzodiazepines (e.g., alprazolam and diazepam) are the most common prescriptions obtained by fraud or forgery.") (*admitted June 18, 2019*); Janssen Ex. 217, FY 2008-2012 Strategic Plan for OBNDD at 7 ("A persistent problem in Oklahoma is the diversion of legitimate pharmaceutical drugs to illicit use .... Hydrocodone remains the most abused pharmaceutical drug in Oklahoma. OxyContin, Methadone, and other opiates are also frequently abused and commonly result in overdose deaths.") (*admitted June 25, 2019*); Janssen Ex. 1514, DURB Meeting Transcription (Feb. 13, 2013) at 67:1-19, February 13, 2013 (OxyContin seventh most abuse drug in Oklahoma in 2013) (*admitted June 26, 2019*).

overdose deaths are attributable to oxycodone than any other substance.[135]

54. Despite OxyContin's clear record of abuse and diversion, the State accepted a supplemental rebate from Purdue and moved OxyContin to Tier 1 of its Medicaid formulary in 2016, allowing the drug to be prescribe without prior authorization.[136]

55. The robust State data showing substantial diversion and abuse of hydrocodone and oxycodone demonstrates that, far from being misled about the risks of opioid medications, the State was well aware of them. Its decisions to nevertheless pursue policies facilitating access to those medications demonstrate the extent to which the State, like federal regulators and countless Oklahoma physicians, sought to address such risks without restricting access to critically important medications in ways that would cause Oklahoma patients to suffer.[137] Oklahoma doctors share the State's concern that imposing overly stringent restrictions on access to prescription opioids will harm patients in need.[138]

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[135] Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System, Data Update 2007-2017 at 9 (listing number of overdose deaths by substance and year) (*admitted June 6, 2019*).

[136] Janssen Ex. 3757, Email regarding Supplemental Rebates at 4 (explaining that the State "appreciate[d]" Purdue's "effort to offer additional rebates and partner with the state of Oklahoma to better serve our members"); Janssen Ex. 344, August 15, 2016 SoonerCare Bulletin (*admitted June 13, 2019*) (explaining that "brand name Oxycontin will be preferred over generic Oxycodone extended-release (ER) tablets for all tablet strengths" and that 10, 15, and 20mg OxyContin strengths "are Tier-1 and available without prior authorization") (*admitted June 13, 2019*).

[137] Janssen Ex. 1522, DURB Meeting Packet (Feb. 11, 2003) at 14-15 (*admitted June 25, 2019*); State Ex. 1223, CDC MMWR from November 4, 2011 at 4 (noting that "[p]ublic health interventions to reduce prescription drug overdose must strike a balance between reducing misuse and abuse and safeguarding legitimate access to treatment") (*admitted June 3, 2019*); June 14, 2019 (AM) Trial Tr. (Kolodny Test.) at 40:4-41:18 (claiming that the language from S1223 "was the conventional wisdom at the time"); *see also* January 24, 2019 Portenoy Depo. Tr. at 297:14-18 (played May 29, 2019) (noting that for the "right" patient, the risk of addiction to opioid medication can be outweighed by the benefits of taking that medication).

[138] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 13:11-14 ("Q. Do you believe, Doctor, that those patients to whom you prescribe opioids would suffer if you were unable to do so? A. Yeah. They would have an extreme diminution of their quality of life."); June 28, 2019 (PM) Trial Tr.

56. Janssen did not cause the opioid crisis by promoting Duragesic as a superior alternative to OxyContin—a drug that actually did fuel the crisis.

B. Tramadol

1. Background

57. Tramadol is a weak opioid, meaning it is less potent than other opioids.[139]

58. Janssen marketed three medications that contained tramadol: Ultram, a short-acting opioid; Ultracet, a short-acting opioid with acetaminophen; and Ultram ER, a long-acting opioid.[140]

59. The DEA classifies drugs that contain controlled substances into "schedules" under federal law. Five schedules exist, and they classify substances based on currently accepted medical use in the U.S. and abuse potential. Schedule I controlled substances have no accepted medical use, while Schedules II through V controlled substances do but range from a high potential for abuse (Schedule II) to a low potential for abuse (Schedule V).[141]

(Schick Test.) at 191:20-192:9 (explaining that opioids "absolutely" help his patients function and make "a huge difference" in their lives); July 3, 2019 (AM) Trial Tr. (Toal Test.) at 36:21-37:1 ("Q. And why are they necessary? A. For function and for recovery, and it -- also if you eliminate enough complications, you affect mortality. Our mortalities are often low, but if you look at all the complications that kill people, a lot of them are directly related to not having enough pain relief."); July 8, 2019 (PM) Trial Tr. (Halford Test.) at 50:6-16 ("Q. Do you believe they would suffer if those drugs were not available? A. Yeah. I'm very confident they would suffer, many of my patients would suffer tremendously, both -- both in terms of pain but also socially and in terms of the ability to function and carry on with their job, for example, or interact with their family.").

[139] *See* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 38:11-13 (agreeing that tramadol is a "weak opioid," meaning a larger dose is needed for the effect of a more potent opioid); June 28, 2019 (PM) Trial Tr. (Schick Test.) at 181:11-12 (stating that Ultram is a weaker opioid).

[140] June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 21:4-20.

[141] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 57:3-58:25 (providing an overview of how drugs are scheduled and what scheduling means); *see also* July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 56:21-57:2 (explaining types of medications in Schedules I through V).

60. The FDA approved tramadol medications as nonscheduled drugs.[142] The agency recognized that keeping a weak opioid like tramadol nonscheduled would benefit patients.[143] Weak opioids provide physicians an alternative to stronger opioids, like oxycodone or Lortab, a hydrocodone-acetaminophen combination.[144] Janssen received reports from physicians that scheduling tramadol could increase prescriptions of stronger opioids because physicians would no longer have an incentive to prescribe a nonscheduled opioid first.[145]

61. After the FDA approved Ultram, Janssen convened an Independent Steering Committee ("ISC") to implement a post-market surveillance program to monitor for abuse, misuse, and diversion of tramadol.[146] Data gathered by the ISC showed that when tramadol abuse or misuse was detected, it was often short-term.[147] RADARS data going back to 2002 also showed very little abuse, misuse, or diversion of tramadol.[148]

62. In the mid-2000s, Oklahoma and several other states began to consider scheduling tramadol.[149] Janssen sought to provide these states with the surveillance information it had

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[142] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 25:8-13.

[143] *Id.*

[144] *See* June 4, 2019 (PM) Trial Tr. (Deem-Eshelman Test.) at 65:21-66:8.

[145] June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 33:11-20.

[146] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 25:8-24.

[147] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 33:21-34:1.

[148] *See* Janssen Ex. 448, Index to Nucynta IR and ER Safety Surveillance Plans at 822 (showing national abuse rates in the Opioid Treatment Program), 824 (showing diversion rates at a national level in the Drug Diversion Network), 826 (showing national abuse rates based on the Key Informant Network), 828 (showing national intentional exposure rates in the Poison Control Center Network), 832 (showing national abuse rates from the College Survey Program) (*admitted June 28, 2019*).

[149] *See* State Ex. 463, Email chain between B. Moskovitz, G. Vorsanger, et al. (Feb. 20-21, 2008) (*admitted June 3, 2019*).

collected to provide a complete picture of the risks associated with tramadol use.[150] Sometimes, Janssen received only a few days' notice that a state was discussing scheduling tramadol.[151]

63. In an email about Oklahoma's potential scheduling of tramadol, Dr. Moskovitz used the phrase "'SWAT' team" as a metaphor to describe a group of individuals who could mobilize quickly to share surveillance information with states.[152] By quickly sharing surveillance data on tramadol, Janssen hoped to help states make informed scheduling decisions.[153] Ultimately, the company had no say as to whether tramadol would be scheduled.[154]

64. Like Duragesic, Janssen's tramadol products had low market share in Oklahoma. SoonerCare claims data from 1996 to 2017 showed that Ultram, Ultram ER, and Ultracet made up 2.04 percent of opioid reimbursements, BlueCross/BlueShield data from 2008 to 2017 showed a 0.43 percent share, and HealthChoice data from 2004 to 2018 showed a 0.42 percent share.[155]

65. The State never identified a single Oklahoman who developed opioid use disorder due to tramadol. Indeed, only 0.13 percent of Oklahomans diagnosed with opioid use disorder even received a tramadol prescription in the year before their diagnosis.[156]

66. The State attributed few Oklahoma deaths to tramadol. The 2007 to 2016 Fatal

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[150] June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 30:11-34:23.

[151] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 31:13-32:6.

[152] State Ex. 463, Email chain between B. Moskovitz, G. Vorsanger, et al. (Feb. 20-21, 2008) (*admitted June 3, 2019*); June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 32:15-22; June 28, 2019 (PM) Trial Tr. (Moskovitz Test.) at 139:8-20.

[153] June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 32:7-12, 34:13-23.

[154] *Id.* at 32:7-12.

[155] *See* Court Ex. 201 at 4; July 11, 2019 (AM) Trial Tr. (Marais Test.) at 38:5-25.

[156] Court Ex. 207 at 3; July 11, 2019 (AM) Trial Tr. (Marais Test.) at 79:2-81:22.

Unintentional Poisoning Surveillance System ("UPSS") Data Update includes overdose deaths involving tramadol but does not specify whether tramadol was the sole cause of death or whether some or all of the deaths involved multidrug toxicity.[157] A recent update of UPSS data from 2007 to 2017 does not report tramadol deaths and does not explain why tramadol was removed.[158] Tramadol is also absent from the Piercefield[159] report regarding overdose deaths in Oklahoma between 1994 and 2006.[160] Out of the 32 opioid-related medical examiner report narratives that the State presented at trial, only four cite tramadol as the lone cause of death—and the State did not show that any of those four reports involved Janssen's drugs.[161] The detection of tramadol alone does not link the overdose to any particular drug.[162]

2. Promoting Ultracet and Ultram ER as alternatives to more commonly abused hydrocodone products could not have caused the opioid crisis.

67. Janssen marketed Ultracet and Ultram ER as alternatives to hydrocodone products such as Lortab.[163] Janssen's sales representatives encouraged doctors to use Ultracet and Ultram

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[157] *See* State Ex. 2400, Fatal Unintentional Poisoning Surveillance System: Data Update at 7 (*admitted June 6, 2019*).

[158] *See* Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System: Data Update at 9 (*admitted June 6, 2019*).

[159] Dr. Emily Piercefield was an epidemic intelligence service officer assigned to Oklahoma to review unintentional medication-related overdose deaths. June 7, 2019 (PM) Trial Tr. (Nguyen Test.) at 11:18-12:7.

[160] *See* State Ex. 1569, Emily Piercefield et al., Increase in Unintentional Medication Overdose Deaths Oklahoma 1994-2006 (*admitted June 6, 2019*); June 7, 2019 (AM) Trial Tr. (Nguyen Test.) at 70:10-75:2.

[161] Court Ex. 83 at 28 (Case # 602029), 30 (Case # 0710372), 31 (Case # 0900014), 32 (Case # 0900555); June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 86:22-88:11 (discussing Case # 602029, with no mention of Janssen drug), 91:16-93:2 (discussing Case # 0710372, with no mention of Janssen drug), 93:5-94:8 (discussing Case # 0900014, with no mention of Janssen drug), 94:9-95:10 (discussing Case # 0900555, with no mention of Janssen drug).

[162] June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 104:3-8 (if a drug detected in toxicology testing came from a prescription source, OCME cannot discern the brand name of that drug).

[163] State Exs. 2481-2492, Call Notes ("Ultracet b/4 hydros. Nurses talked about they liked ult for

ER to reduce the number of hydrocodone prescriptions they wrote. The State's primary criticism of Janssen's tramadol marketing targeted part of that effort.[164] For one month in the spring of 2005, Janssen's sales representatives used a "spring breaks, sprains, and strains" theme to encourage doctors to consider Ultracet instead of Lortab for acute springtime injuries.[165]

68. State's expert Dr. Danesh Mazloomdoost testified that it was "wrong" to "start[] a patient on an opioid for a spring break, strain, or sprain," and said that physicians would not have done so 30 years ago.[166] Dr. Kolodny also testified that "for sprains and strains we should not be prescribing an opioid."[167]

69. But neither expert provided any analysis or explanation for why tramadol is not an appropriate medication for acute pain associated with breaks, sprains, and strains, nor did they identify any reason why it would be medically inappropriate to consider Ultracet—a weaker opioid—before hydrocodone. Ultracet is indicated for "the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate," and

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pts and hit on comparable to hydro and use b/4 scheduled drug."; "UER-for use before hydro's and pt who has less severe cp and needs to be active, will inc function and less se's.") (*admitted May 30, 2019*).

[164] The State faults Janssen for detailing Dr. Dennis Roberts, an Oklahoma doctor, who was investigated for, among other things, prescribing Ultram to a woman breastfeeding a child with NAS. July 2, 2019 (PM) Trial Tr. (Diesselhorst Test.) 233:6-234:8. But the State offered no evidence suggesting that Janssen's sales representatives influenced Dr. Roberts' prescribing behavior. The State never reported complaints about Dr. Roberts to Janssen, and he is fully licensed to practice today.

[165] *Id.* ("2 ways to reduce Loratab in clinic, Ultracet for spring breaks, strains and sprains [sic] before Loratab bc Ultracet has be[tt]er side effect profile and low abuse potential" (capitalization omitted); "2 ways to reduce lortab business. Use before lortab with proper dosing for comparable efficacy. I closed for strains/sprain pts from spring break. Nice weather, people become more active and skiing trips.").

[166] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 69:17-70:7.

[167] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 41:20-42:10.

is limited to "short-term use of five days or less."[168] As Dr. Terrell Phillips, an Oklahoma City anesthesiologist and pain specialist explained, serious breaks, strains, or sprains can cause such "severe" acute pain—"if the patient comes in on crutches, can't bear weight, has a purple ankle that's swollen up like a basketball."[169] In such cases, Ultracet is an appropriate "place to start with patients because it ... has less risk of abuse [] potential."[170]

70. The State's experts may disagree with such Oklahoma practitioners, but their conclusory assertions that Ultracet is an improper treatment for such painful acute injuries does not establish that Janssen's promotion of Ultracet was misleading.

71. Hydrocodone, the drug Janssen marketed Ultracet as an alternative to, has been the most commonly diverted and abused opioid in Oklahoma since the 1980s.[171] Along with oxycodone, hydrocodone is (and has long been) the most common opioid medication obtained by

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[168] Janssen Ex. J444, Ultracet Label at 136-137 (*admitted June 4, 2019*).

[169] July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 57:13-21.

[170] *Id.* at 57:3-12.

[171] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 60:11-14, 60:19-61:11, 63:12-64:14 (1980s), 71:2-8 (2006); Court Ex. 131 at 2 (chart depicting abuse rates for various prescriptions opioids from 2008 to 2014 as reported in Janssen Ex. 1718); Court Ex. 132 at 2 (chart depicting diversion rates for various prescriptions opioids from 2002 to 2014 as reported in Janssen Ex. 1718); Court Ex. 134 at 2 (chart depicting misuse rates for various prescriptions opioids from 2003 to 2014 as reported in Janssen Ex. 1718); Janssen Ex. 1718, RADARS Data on Abuse and Diversion (*admitted June 27, 2019*); Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment, at 12 ("Opioid pain relievers (e.g., hydrocodone and oxycodone) and benzodiazepines (e.g., alprazolam and diazepam) are the most common prescriptions obtained by fraud or forgery.") (*admitted June 18, 2019*); Janssen Ex. 217, FY 2008-2012 Strategic Plan for OBNDD, at 7 ("A persistent problem in Oklahoma is the diversion of legitimate pharmaceutical drugs to illicit use. . . . Hydrocodone remains the most abused pharmaceutical drug in Oklahoma. OxyContin, Methadone, and other opiates are also frequently abused and commonly result in overdose deaths.") (*admitted June 25, 2019*); Janssen Ex. 1644, DURB Meeting Packet (July 9, 2014) at 29 (involved in more deaths than meth, cocaine, and heroin combined in 2014) (*admitted June 26, 2019*).

fraudulent phone orders or forgery.[172] Before it was rescheduled in October 2014, it was "not uncommon" for Oklahoma doctors "to come in on Monday and find out that [they] had 30 scripts filled on Lortab over the weekend"—all of them "fake call ins."[173] Similarly, hundreds of thousands of hydrocodone tablets were stolen every year from pharmacies.[174]

72. Hydrocodone is associated with a staggering number of OUD diagnoses. Dr. Marais' analysis of Medicaid prescription opioid claims and OUD diagnoses showed that among all Medicaid patients diagnosed with OUD, only .13 percent received any tramadol products manufactured by Janssen within the preceding 365-day period. By contrast, 41.51 percent received a hydrocodone product over the same time period.[175] Hydrocodone is also associated with a substantial number of overdose deaths. The State's unintentional poisoning data shows

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[172] Court Ex. 131 at 2 (chart depicting abuse rates for various prescriptions opioids from 2008 to 2014 as reported in Janssen Ex. 1718); Court Ex. 132 at 2 (chart depicting diversion rates for various prescriptions opioids from 2002 to 2014 as reported in Janssen Ex. 1718); Court Ex. 134 at 2 (chart depicting misuse rates for various prescriptions opioids from 2003 to 2014 as reported in Janssen Ex. 1718); Janssen Ex. 1718, RADARS Data on Abuse and Diversion (*admitted June 27, 2019*); Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment, at 12 ("Opioid pain relievers (e.g., hydrocodone and oxycodone) and benzodiazepines (e.g., alprazolam and diazepam) are the most common prescriptions obtained by fraud or forgery.") (*admitted June 18, 2019*); Janssen Ex. 217, FY 2008-2012 Strategic Plan for OBNDD, at 7 ("A persistent problem in Oklahoma is the diversion of legitimate pharmaceutical drugs to illicit use. . . . Hydrocodone remains the most abused pharmaceutical drug in Oklahoma. OxyContin, Methadone, and other opiates are also frequently abused and commonly result in overdose deaths.") (*admitted June 25, 2019*).

[173] Janssen Ex. 939, March 8, 2006 DURB Meeting Transcription, at 11:19-12:4 (*admitted June 26, 2019*).

[174] *See, e.g.*, LaRue Depo. Tr. at 54:17–55:12 (played on July 8, 2019) (14,000 OxyContin pills stolen from pharmacy), 55:20–58:06 (217,000 doses of OxyContin and hydrocodone were diverted by a pharmacy technician who stole them to allegedly pay off her daughter's debt to a drug dealer), 67:14–69:08 (6,800 units of hydrocodone diverted from Oklahoma State University Medical Center), 76:19–78:8 (399,500 tablets of hydrocodone and 234,000 tablets of alprazolam were diverted from Hillcrest Medical Center by a pharmacy technician who then provided them to her daughter's boyfriend, who was a member of gang that engaged in criminal drug trafficking).

[175] Court Ex. 207 at 3.

that hydrocodone has been involved in more prescription-related overdose deaths than any substance other than oxycodone.[176] The State knew that hydrocodone was the most abused and diverted opioid for decades, yet it encouraged—or at least declined to discourage—the prescribing of hydrocodone and other short-acting opioids by placing them on Tier 1 of its Medicaid formulary and imposing no limit on the number of hydrocodone pills that could be dispensed to a single patient until recently.[177]

73. Oklahoma doctors told the DURB that favoring hydrocodone was problematic for multiple reasons. At the March 8, 2006 meeting, Dr. Michael Schwartz, an Oklahoma pain management doctor, asked the DURB to carefully consider whether its preference for short acting opioids over extended release opioids was appropriate.[178] He explained that pain management patients do "much better with long acting opioids," and that "one of the biggest problems" he faced as an Oklahoma pain management doctor was "our Lortab problem, hydrocodone."[179] Dr. Schwartz recounted patients coming to him taking anywhere from 40 to 90 Lortab a day. While some patients were legitimately using those tablets, Dr. Schwartz explained that "[t]he problem [] with writing that quantity of Lortab" is that they can "be sold because . . .

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[176] Janssen Ex. 1644, DURB Meeting Packet (July 9, 2014) at 29 ("The most common prescription drugs involved in overdose deaths are hydrocodone, oxycodone, and alprazolam. In Oklahoma more overdose deaths involved hydrocodone than methamphetamines heroin and cocaine combined") (*admitted June 26, 2019*); Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System: Data Update, at 9 (*admitted June 6, 2019*).

[177] June 26, 2019 (AM) Trial Tr. (White Test.) at 74:2-15 (immediate-release opioids were placed into Tier 1); Janssen Ex. 1515, DURB Meeting Packet (Feb. 13, 2013), at 29-30 ("Tier-1 products are covered with no prior authorization necessary") (*admitted June 26, 2019*); Janssen Ex. 1816, DURB Meeting Packet (July 12, 2017) at 117 (*admitted June 26, 2019*); Janssen Ex. 3875, OHCA Quality Team Day 2015 Project Application (implementing identifying quantity limits on "short-acting painkillers") (*admitted June 26, 2019*).

[178] Janssen Ex. 939, March 8, 2006 DURB Meeting Transcription at 7:10-8:12 (*admitted June 26, 2019*).

[179] *Id.* at 8:6-21.

you can buy [them] very cheaply . . . [b]ut on the street, a 10 milligram Lortab can go from anywhere from $40 to $100 a tablet."[180]

74. Janssen, which, far from marketing or promoting hydrocodone products, encouraged doctors to prescribe the weaker medication Ultracet as an alternative to hydrocodone, did not cause this widespread criminal diversion of hydrocodone.

75. Despite warnings about abuse and diversion of hydrocodone from Dr. Schwartz and others,[181] the State's Medicaid program did not place quantity limits on hydrocodone products until January 2015.[182] Once the quantity limit was implemented, the State reported that 300,000 fewer pills were prescribed each month to Medicaid patients.[183]

76. The State preferred hydrocodone products, despite their frequent diversion and abuse, because they were cheaper than other opioid medications.[184] Largely thanks to that preference, hydrocodone was the single most reimbursed drug in Oklahoma's Medicaid program from 2001 to 2015.[185] Hydrocodone was also the most prescribed drug—of any kind—outside

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[180] *Id.* at 9:9-25.

[181] Janssen Ex. 1034, February 13, 2008 DURB Meeting Transcription at 13:8-14:2 (*admitted June 26, 2019*); Janssen Ex. 1514, February 13, 2013 DURB Meeting Transcription, at 67:1-68:14 (Vicodin, which is hydrocodone and acetaminophen, number two most abused drug behind marijuana because "[i]t's easier to obtain" and "[e]asier to divert") (*admitted June 26, 2019*).

[182] Janssen Ex. 1816, DURB Meeting Packet (July 12, 2017) at 117 (*admitted June 26, 2019*); Janssen Ex. 3875, OHCA Quality Team Day 2015 Project Application (identifying quantity limits on "short-acting painkillers") (*admitted June 26, 2019*).

[183] Janssen Ex. 3875, OHCA Quality Team Day 2015 Project Application, at 2 (*admitted June 26, 2019*).

[184] *See generally* Janssen Ex. 1514, DURB Meeting Transcription (Feb. 13, 2013) (*admitted June 26, 2019*).

[185] Janssen Ex. 773, DURB Meeting Packet (Mar. 12, 2002) at 84; Janssen Ex. 824, DURB Meeting Packet (Oct. 14, 2003) at 74; Janssen Ex. 925, DURB Meeting Packet (June 14, 2005) at 49; Janssen Ex. 996, DURB Meeting Packet (Sept. 12, 2007) at 44; Janssen Ex. 1038, DURB Meeting Packet (Mar. 12, 2008) at 76; Janssen Ex. 1114, DURB Meeting Packet (Feb. 11, 2009) at 39; Janssen Ex. 1151, DURB Meeting Packet (July 8, 2009) at 22; Janssen Ex. 1171, DURB

of Medicaid.[186]

77. Promoting Ultracet as a preferable alternative to hydrocodone did not cause the opioid crisis.[187]

C. Nucynta

1. Background

78. Janssen began developing Nucynta and Nucynta ER in the early 2000s.[188]

79. The active ingredient in Nucynta and Nucynta ER is tapentadol. Unlike most opioids, tapentadol has a dual mechanism of action that allows a patient to receive pain relief not only through the mu receptor (the mechanism of most opioids), but also through norepinephrine reuptake inhibition.[189]

80. Janssen released Nucynta, a short-acting formulation of tapentadol, in 2009.[190] Nucynta has always been indicated exclusively for acute pain,[191] such as "pain associated with

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Meeting Packet (Sept. 9, 2009) at 45; Janssen Ex. 1274, DURB Meeting Packet (Oct. 13, 2010) at 52; Janssen Ex. 1515, DURB Meeting Packet (Feb. 13, 2013) at 33; Janssen Ex. 1620, DURB Meeting Packet (Apr. 9, 2014) at 24; Janssen Ex. 1644, DURB Meeting Packet (July 9, 2014) at 68-73; Janssen Ex. 1715, DURB Meeting Packet (Apr. 8, 2015) at 45 (*all admitted June 26, 2019*).

[186] State Ex. 1569, Emily Piercefield et al., *Increase in Unintentional Medication Overdose Deaths Oklahoma 1994-2006*, at 1 (*admitted June 7, 2019*).

[187] The State likewise produced no evidence Janssen coordinated with Purdue on any marketing or promotional effort for Janssen's tramadol products. While Janssen engaged in discussions with Purdue over a routine co-promotion agreement involving Ultram SR, the agreement never came to fruition. *See* State Ex. 1069, Business Dealings with Other Manufacturers at 1 (*admitted June 19, 2019*); Mashett Depo. (played June 19, 2019).

[188] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 44:15-23.

[189] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 131:21-133:19 (explaining how tapentadol's dual mechanism of action works).

[190] *See* June 4, 2019 (AM) Trial Tr. (Deem-Eshelman Test.) at 51:20-22.

[191] *See* Janssen Ex. 2777, 2008 Nucynta Label at 1 (*admitted June 4, 2019*); Janssen Ex. 2782, 2016 Nucynta Label at 1 (*admitted June 4, 2019*).

an immediate injury over a short period of time."[192]

81. Janssen did not launch a new opioid in 2009 to expand the opioid market. Rather, Janssen believed that Nucynta, because of tapentadol's dual mechanism, was a unique and innovative medication that would offer equal efficacy and better tolerability compared to other opioids.[193] The data supported this belief: Nucynta's clinical trials showed that patients experienced fewer adverse events than patients taking standard opioids.[194]

82. In 2011, Janssen released Nucynta ER, an extended-release formulation of Nucynta.[195] Like Duragesic, Nucynta ER is indicated for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[196] Nucynta ER is also the first and only opioid to be indicated for "neuropathic pain associated with diabetic peripheral neuropathy."[197]

83. To deter abuse of the product, Janssen launched Nucynta ER with a tamper-resistant coating that made Nucynta ER difficult to crush, chew, snort or inject.[198] Janssen conducted a variety of tests on Nucynta ER's tamper-resistant coating, and the results showed

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[192] June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 6:19-23.

[193] *See* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 135:9-18, 136:10-13.

[194] *See* Janssen Ex. 677, Nucynta ER & Nucynta slide presentation, "Powerful Chronic and Acute Pain Management," at 13, 18, 20 (showing the incidence of treatment-emergent adverse events in each study) (*admitted June 28, 2019*); *see also* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 133:20-134:12 (discussing Janssen's belief that Nucynta may have "a better tolerability profile" than other opioids due to its dual mechanism of action); June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 38:2-16 (testifying that the results of these studies showed that Nucynta was "a better tolerated drug" than other opioids).

[195] *See* June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 51:23-24.

[196] Janssen Ex. 2786, 2014 Nucynta ER Label at 1 (*admitted June 4, 2019*).

[197] *Id.*; June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 11:25-12:2.

[198] *See* June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 12:25-14:16.

that the tamper-resistant formulation "substantially raise[d] the hurdle for tampering."[199] Janssen waited until this formulation was finalized before launching the drug,[200] and Nucynta ER became the first opioid introduced on the market in a tamper-resistant formula.[201]

84. Despite the product's unique characteristics, Nucynta never gained significant market share.[202] In 2015, Janssen sold the Nucynta brand.[203]

85. RADARS surveillance data for tapentadol demonstrated that the rates of abuse, misuse, and diversion of tapentadol were among the lowest for all Schedule II opioids.[204] RADARS data also showed illicit transactions involving tapentadol were rare, with a median "street price" of $0.18 per milligram for tapentadol and $0.10 for tapentadol ER, compared to $1.00 per milligram for other Schedule II drugs.[205] Data from the National Addictions Vigilance Intervention & Prevention Program ("NAVIPPRO"), another drug surveillance program, further confirmed that Nucynta was abused at far lower rates than other opioids.[206]

86. SoonerCare claims data tells a similar story, showing that just 0.04 percent of Medicaid patients diagnosed with OUD received Nucynta or Nucynta ER prescriptions in the

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[199] *See* Janssen Ex. 2713, Nucynta ER Tamper Resistant Formulation Summary at 53-56 (*admitted June 27, 2019*).

[200] *See* June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 14:8-16.

[201] *See id.* at 12:25-13:6.

[202] June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 54:13-55:1.

[203] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 45:6-8.

[204] *See* Court Exs. 131-135; *see also* June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) 63:7-78:17.

[205] *See* Janssen Ex. 2302, Pain Medicine: *Diversion and Illicit Sale of Extended Release of Tapentadol in the United States*, Richard C. Dart et al. at 3-6 (summarizing the median reported street price of tapentadol and tapentadol ER and other schedule II drugs between January 2011 and September 2014) (*admitted June 28, 2019*).

[206] *See, e.g.*, Janssen Ex. 1716, NAVIPPRO Surveillance Report P3 2014 (Sept. 1, 2014 - Dec. 31, 2014) at 9 (showing reported abuse cases and rates for Nucynta and Nucynta ER during the fourth quarter of 2014 as compared to other Schedule II products) (*admitted June 27, 2019*).

year preceding their diagnosis.[207] And Oklahoma's Chief Medical Officer testified that over the last eight years he has "never" seen tapentadol in a post-mortem toxicology screen.[208]

87. Dr. Mazloomdoost criticized Janssen for promoting Nucynta ER for the treatment of chronic non-cancer pain.[209] But as already noted, Nucynta ER's indication is not limited to cancer pain—it has always covered chronic non-cancer pain.[210] And multiple Oklahoma doctors testified that opioids can be appropriately prescribed for the treatment of chronic non-cancer pain.

2. Janssen's detailing practices for Nucynta could not have caused the opioid crisis.

88. The State also criticized Janssen because Nucynta sales representatives visited several doctors who prescribed large amounts of opioids, including doctors who ultimately faced disciplinary proceedings or criminal prosecution. In particular, it criticized Janssen for not training its sales representatives to report doctors who had busy waiting rooms or patients waiting in line outside[211]; patients appearing to be sedated, groggy, or asleep[212]; cash-based practices[213]; or practices where patients received opioid prescriptions after seeing the doctor only briefly[214] or without seeing the doctor at all.[215] But the State offered no evidence of any Janssen sales representative witnessing and failing to report suspicious prescribing practices by an

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[207] Court Ex. 207 at 5; July 11, 2019 (AM) Trial Tr. (Marais Test.) at 81:23-82:25.

[208] June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 149:10-12.

[209] *See* June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 124:15-22.

[210] *See also id.* at 134:12-15.

[211] July 2, 2019 (PM) Trial Tr. (Diesselhorst Test.) at 86:22-87:3, 213:24-214:4.

[212] *Id.* at 87:4-7, 214:15-21.

[213] *Id.* at 87:8-12.

[214] *Id.* at 212:19-24.

[215] *Id.* at 87:16-20.

Oklahoma doctor. Nor did it demonstrate that they had any duty to do so.

89. Janssen sales representatives detailed to prescribers who prescribed long-acting opioid medications in significant quantities because it believed its products were superior to more widely prescribed alternatives,[216] and because doctors with robust prescribing experience would be better suited to appreciate its products' unique attributes[217]—indeed, Duragesic's FDA-approved label instructs that it "should be prescribed only by persons knowledgeable in the continuous administration of potent opioids, in the management of patients receiving potent opioids for treatment of pain, and in the detection and management of hypoventilation including the use of opioids."[218]

90. Janssen's sales representatives, with their average of 9.6 minutes of contact with a prescribing doctor per year, had a limited window into such activity. By contrast, State expert Dr. Jason Beaman testified that, while working at a small-town clinic during his residency, he observed some of the very circumstances the State criticized Janssen for not reporting, such as a busy waiting room and patients lining up outside.[219] He also testified that he was aware of factors that only doctors and staff would have knowledge of, including that many patients were coming in from large cities, and patients regularly saw the clinic's doctor after midnight.[220] Beaman testified that he did not report the doctor because he had "no direct knowledge that he was doing anything illegal" and "no direct knowledge of harm," and he did not believe his

[216] July 2, 2019 (AM) Trial Tr. (Flanary Test.) at 40:22-41:18.

[217] May 30, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 34:2-21.

[218] Janssen Ex. 2769, 2005 Duragesic Label at 11 (*admitted June 4, 2019*).

[219] June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 155:16-24.

[220] *Id.* at 37:7-38:1.

"conjectures and speculations" constituted reportable conduct.[221] He stated, "I don't think the State Medical Boards want us calling every time there's a long line outside in a waiting room, but I felt uncomfortable based on the questions from nurses and patients."[222]

91. The State regulates physicians' prescribing practices in Oklahoma, and it has the authority and tools to do so. But even with the benefit of undercover investigations, a prescription monitoring program ("PMP") and special reports on physician prescribing practices,[223] the State often delayed taking any action against overprescribing doctors.[224] And the State never informed Janssen of any overprescribing doctors under State investigation.[225]

92. For example, in 2007, the State sent an undercover investigator to the office of Dr. Ronald Myers, a suspected pill-mill doctor. The investigator received an opioid prescription

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[221] *Id.* at 156:6-20.

[222] *Id.* at 155:16-24.

[223] Janssen, of course, was privy to none of that information. *See e.g.*, Janssen Ex. 514, Prescription Drug Abuse: Understanding PMP Programs at 4 (noting that "[p]rescription information contained within a PMP is tightly controlled. The unauthorized use or access of prescription records is not tolerated.") (*admitted June 26, 2019*).

[224] *E.g.*, Janssen Ex. 3921-A, October 8, 2013 Report of Investigation for: State of Oklahoma Medicare Part D (3701) (*admitted June 25, 2019*), Dr. George Howell; Janssen Ex. 3921-B, October 27, 2015 Investigation Report, Oklahoma State Insurance Board (2527), Dr. Michael Salrin (*admitted June 26, 2019*); Janssen Ex. 595, April 2, 2015 OBNDD Final Order for Dr. Myers (*admitted June 25, 2019*) (noting undercover operations into the Wellness Clinic and finding that "the Oklahoma and Arkansas PMPs showed a substantial increase in [Dr. Myers's] prescribing, showing that he prescribed a total of 44,850 CDS prescriptions from January 1, 2013 through June 2014, for a total of 4,618,264 dosage units."); Janssen Ex. 298, June 15, 2015 OBNDD Final Order for Dr. Jenkins at 5, 10-14 (describing undercover operations into Dr. Jenkins's practice and noting the use of the PMP to confirm certain unlawful practices) (*admitted June 26, 2019*).

[225] *See* June 25, 2019 (PM) Trial Tr. (White Test.) at 130:7-12 (testifying "I don't know" when asked if Oklahoma ever reported what it had uncovered about Dr. Myers' prescribing practices between 2007-2015 to Janssen); June 26, 2019 (AM) Trial Tr. (White Test.) at 56:9-11 (stating "I don't know" when asked whether the State informed Janssen of complaints it had received about Dr. Roberts in 2010); July 2, 2019 (PM) Trial Tr. (Diesselhorst Test.) at 250:14-18 (testifying she was "never" advised about the State's investigation of doctors).

without an examination or any medical records demonstrating medical necessity, yet the State took no action against Dr. Myers until eight years later in 2015.[226] And in the intervening period, the State failed to inform Janssen of what it knew about Dr. Myers's medical practice.

93. In some cases, the alleged overprescribing physicians are still practicing today.[227]

94. The State also had exclusive control over the PMP (a statewide database containing prescriber and patient-level prescription data on opioids and other medications), and at any time could have required prescribers to check the PMP before writing an opioid prescription to ensure a patient had not received a similar prescription from another physician.[228]

95. But the State did not do so until November 2015.[229] The reduced rate of prescription opioid related deaths in recent years closely tracks the implementation of additional requirements for the prescription monitoring program.[230]

3. Janssen's "unbranded" educational materials and programs could not have caused the opioid-abuse crisis.

96. Finally, the State criticized "unbranded" educational materials or programs that Janssen produced leading up to and following the 2009 launch of Nucynta. Unbranded materials do not mention specific products; they raise awareness about health conditions and treatment

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[226] Janssen Ex. 218, Oklahoma State Board of Medical Licensure and Supervision Report of Investigation, at 6 (*admitted June 25, 2019*); Janssen Ex. 595, *State v. Myers* (April 2, 2015) (*admitted June 25, 2019*).

[227] Carter Depo. Tr. at 68:12-69:2 (played July 10, 2019) (noting that Dr. Dennis Roberts is off probation and is a "full doctor" again).

[228] *See e.g.,* Janssen Ex. 514, Oklahoma Bureau of Narcotics presentation entitled "Prescription Drug Abuse, Understanding PMP Programs" (*admitted June 26, 2019*) at 4 ("Prescription Information Contained Within a PMP is Tightly Controlled. The Unauthorized Use or Access of Prescription Records is not Tolerated.").

[229] June 20 (PM) Trial Tr. (Hawkins Test.) at 104:17-20.

[230] June 17 (PM) Trial Tr. (Beaman Test.) at 158:16-24.

options generally.[231]

97. ***Finding Relief*** was an unbranded educational brochure sponsored by Janssen and released in 2009. The brochure discussed pain management for older adults and was intended for distribution to patients at doctors' offices.[232] The brochure described different types of pain interventions and treatment options, including anti-inflammatory drugs, yoga, meditation, massage, hypnosis, and acupuncture. It also discussed responsible prescription-drug storage and use.[233] Only one page—page 17—of the 36-page brochure discussed opioids.[234] And the statements on that page—discussing opioid "myths" and "facts," including the risk of addiction—are supported by scientific evidence and are identical to statements made by FDA the same year.[235]

98. ***NEO Pathways*** was an unbranded campaign launched by Janssen in 2008 to educate doctors on the different pathways associated with pain management.[236] Education on different pain pathways was relevant to the introduction of tapentadol, which acted through two pathways—norepinephrine reuptake inhibition and the mu opioid receptor.[237]

99. ***Prescribe Responsibly*** was a website Janssen launched in 2010 to promote the appropriate prescribing of opioids and publicize the risks associated with opioid use. The

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[231] *See* June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) 108:21-109:11 (testifying that unbranded programs pertain to a "therapeutic area" or "the managing of a condition" rather than "marketing to a specific product").

[232] State Ex. 1247, Finding Relief Brochure (*admitted June 4, 2019*).

[233] *Id.* at 9-14.

[234] *Id.* at 10.

[235] *See, e.g.*, June 28 (AM) Trial Tr. (Moskovitz Test.) at 55:25–60:10, 62:11–66:19, 67:18–76:12.

[236] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 113:16–114:5.

[237] *Id.*

website compiled resources about safe prescribing for patients and caregivers.[238] These resources included pain assessment and reassessment scales and tools, risk assessment resources, opioid withdrawal assessment tools, and a patient-doctor opioid-agreement checklist.[239] Among those resources, the State focused on two articles written or co-written by Dr. Howard Heit and Dr. Keith Candiotti.[240] The State also introduced a *Pain Resource Guide* created by the American Pain Foundation attached to an email about a *Prescribe Responsibly* "binder."[241]

100. All of the unbranded marketing materials that the State challenged were released in 2008 or later—more than 12 years after the opioid crisis began in Oklahoma, according to testimony from the State's experts.[242] As Dr. Kolodny conceded, any unbranded materials "couldn't have an impact on prescribing behavior prior to 2009 if they were released in 2009."[243]

101. The State focuses in on a handful of allegedly misleading statements in these documents, but all had scientific support.

102. For example, the State criticized Janssen statements describing the risk of addiction for patients treated with opioids as "rare" or "low," in unbranded materials and internal

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[238] *Id.* at 114:9–115:15.

[239] *See* Janssen Ex. 2438, Prescribe Responsibly Overview (*admitted June 5, 2019*); June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 5:20–12:2.

[240] State Ex. 954, H. Heit & D. Gourlay, *What a Prescriber Should Know Before Writing the First Prescription* (*admitted June 10, 2019*); State Ex. 974, K. Candiotti, *Use of Opioid Analgesics in Pain Management* (*admitted June 3, 2019*).

[241] State Ex. 1227, APF's Pain Resource Guide: Getting the Help You Need at (*admitted June 4, 2019*).

[242] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 34:23–35:5 ("The epidemic began in 1996."); June 25, 2019 (AM) Trial Tr. (White Test.) at 71:2–10 ("I think it's really important that people realize that prior to 1996, we did not have an oversupply of opioids in the State of Oklahoma."); June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 70:6–10 ("I would say we would have to aim to return to pre-1996 levels [of opioid use disorder], minimally.")

[243] June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 53:20-54:6.

strategy or training documents. Specifically, the State challenged the *Finding Relief* brochure's assertions that the notion that "Opioid medications are always addictive" is a "myth," and that "Many studies show that opioids are rarely addictive when used properly for the management of chronic pain" is a "fact."[244]

103. These statements were not misleading. Consistent with the current scholarship, the FDA stated in 2009—the same year Janssen sponsored Finding Relief—that "properly managed medical use of opioid analgesic compounds, taken exactly as prescribed [are] safe, can manage pain effectively, and rarely cause[] addiction. "[245]

104. While ethical concerns preclude the use of clinical trials to definitively measure addiction rates, many studies have sought to analyze the rate of addiction in patients on long-term opioid use. Some focus on determining the "prevalence" of addiction, or the number of people who have an opioid addiction at a particular point in time.[246] Others aim to measure the "incidence" of addiction to address the question about the likelihood of a patient developing this

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[244] State Ex. 1247, Finding Relief Brochure at 10 (*admitted June 4, 2019*); *see also* State Ex. 1227, APF's *Pain Resource Guide: Getting the Help You Need* at 18 (*admitted June 4, 2019*) (asserting that opioids are not universally addictive, and that studies show "the chance of addiction is low" when taken as prescribed "[u]nless you have a ... history of substance abuse"); State Ex. 1364, Neo Pathways Training Powerpoint at 15-16 (*admitted May 29, 2019*) (stating that "Although many physicians are reluctant to prescribe controlled substances, the risks (for both patient addiction/misuse and physician disciplinary action) are much smaller than commonly believed." and suggesting that "Many HCP's will find the 2.6% incidence of addiction" in a study authored by Dr. Russell Portenoy "to be extremely low"); State Ex. 1780, Internal Tapentadol Strategic Plan at 4 (*admitted June 11, 2019*) (stating that the "Fear of addiction contributes to the under-use of opioid analgesia" but that the "actual risk of addiction in the supervised pain management setting is low (<2%)"); State Ex. 974, K. Candiotti, *Use of Opioid Analgesics in Pain Management*, at 2 (*admitted June 3, 2019*) (asserting that "According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics therapy.").

[245] Janssen Ex. 3606, FDA Guide to Safe Use of Pain Medicine at 4 (admitted on June 14, 2019).

[246] *See* June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 66:24-67:17; July 1, 2019 (AM) Trial Tr. (Fong Test.) at 64:3-17; July 9, 2019 (AM) Trial Tr. (De La Garza Test.) at 111:17-113:11.

condition, by looking at the number of new cases that emerge over time.[247]

105. Dr. Kolodny, a State expert, testified that there "have never been many studies that show that opioids are rarely addictive when taken long-term for chronic pain."[248] He further referred to studies that have found the prevalence rate of addiction to be 25 percent or higher.[249] A 2010 survey looking at opioid drug dependence in individuals receiving four or more opioid prescriptions over a 12-month period found the prevalence rate to be 25.8 percent.[250] But the survey provides a breakdown of the mental health and psychological characteristics of the patients analyzed, demonstrating that these patients had risk factors that were not necessarily representative of the general U.S. population.[251]

106. Conversely, multiple studies conducted over the last decade focusing on incidence rates reveal that the risk of a patient developing addiction is low. For instance, a 2008 systematic review collecting 24 different studies based on 2,507 chronic non-cancer pain patients found that the incidence rate of abuse and addiction was 3.27 percent for patients with a prior history of substance abuse and 0.19 percent for patients without a history of abuse or addiction.[252] In 2010,

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[247] *See* July 1, 2019 (AM) Trial Tr. (Fong Test.) at 64:18-65:15.

[248] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 104:24-105:7.

[249] *See* June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 72:21-73:17 (testifying that "evidence suggests that patients who take [an opioid] long-term, that more than 25 percent are likely to have -- or likely to be addicted."), 117:24-118:19 (stating that depending on the criteria used, prevalence of opioid use disorder can be up to 40 percent but that 25 percent "is widely accepted by the scientific and medical community.")

[250] *See* State Ex. 467, Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large U.S. Healthcare System at 3 (*admitted June 28, 2019*).

[251] *See id.* at 4 (Table 1 showing the mental health and psychological characteristics of the patients in the study); *see also* July 1, 2019 (AM) Trial Tr. (Fong Test.) at 85:4-95:6 (discussing the table and explaining how the patients had high risk factors and stating that the prevalence rate was "based on [a] very skewed population.").

[252] Janssen Ex. 646, D. Fishbain, "What Percentage of Chronic Nonmalignant Pain Patients Exposed to Chronic Opioid Analgesic Therapy Develop Abuse/Addiction and/or Aberrant Drug-

another systematic review analyzing 26 studies covering 4,893 patients found an opioid addiction rate of 0.27 percent.[253] Two years later, a systematic review of 17 studies involving 88,235 patients with acute or chronic pain who were treated with opioids found that the incidence of opioid dependence in the patients from the various studies ranged from 0 to 24 percent, with a median of 0.5 percent.[254] A retrospective study published in 2014 reviewing data from 2000 to 2005 from 568,640 patients to determine rates of new occurrences (incidence) of opioid use disorder found an overall incidence rate of 0.18 percent.[255] And, just last year, a review of 12 studies including over 300,000 patients treated with opioids concluded that the incidence of iatrogenic opioid dependence was 4.7 percent.[256]

107. As these incidence studies show and the FDA's positions confirm, Janssen's various statements on the low risk of addiction from properly prescribed and taken opioids were not misleading.

108. The State also challenged as false or misleading internal Janssen strategy or training documents suggesting that chronic pain remained undertreated.[257] These statements

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Related Behaviors? A Structured Evidence-Based Review," Pain Medicine at 1 (*admitted July 1,* 2019).

[253] Janssen Ex. 400, Treadwell, et al., Cochrane Library Long-term opioid management for chronic noncancer pain (Review) 3-4 (*admitted June 28, 2019*).

[254] Janssen Ex. 672, S. Minozzi, et al, *The Development of Dependence Following Treatment With Opioid Analgesics for Pain Relief: A Systematic Review* at 1 (*admitted July 9, 2019*).

[255] Court Ex. 138; June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 81:9-89:20; *see also* Janssen Ex. 3938, Edlund, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain: The Role of Opioid Prescription* (*admitted June 28, 2019*).

[256] Janssen Ex. 3948, C. Higgins, et al., *Incidence of Iatrogenic Opioid Dependence of Abuse in Patients With Pain Who Were Exposed to Opioid Analgesic Therapy: A Systematic Review and Meta-Analysis* at 1 (*admitted July 9, 2019*).

[257] *See* State Ex. 1239, Ortho-McNeil "Unbranded Promotion" Slide Deck (*admitted June 3, 2019*) (listing as an objective: "Heighten awareness of the under-treatment of pain and its

were not false or misleading. The evidence establishes that government agencies like the CDC continue to acknowledge the existence of a significant chronic pain problem in the United States.[258] Furthermore, Oklahoma physicians offered unrebutted testimony that the demand for pain treatment in Oklahoma has continued to grow.[259]

109. The State also challenged as false or misleading statements by Janssen in a marketing research document and an unbranded marketing messaging card suggesting that untreated acute pain could lead to chronic pain.[260] These messages were not false or misleading. The Court credits Dr. Moskovitz's testimony that research shows untreated pain can lead to increases in the severity and duration of the pain, as well as Dr. Toal's testimony that the statement was consistent with his clinical experience.[261]

110. Finally, the State challenged statements in publications sponsored or published by Janssen discussing the concept of pseudoaddiction.[262] Dr. Mazloomdoost criticized the concept

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consequences"); State Ex. 1364, Neo Pathways Training Powerpoint (*admitted May 29, 2019*) (instructing sales representatives to "[e]stablish that moderate to severe acute pain continues to be untreated"); State Ex. 1780, Tapentadol Strategic Plan (*admitted June 11, 2019*) (an internal document asserting: "A large proportion of patients with moderate to severe pain do not receive adequate pain management" and "Opioid analgesics are currently underutilized for the management of moderate to severe pain.").

[258] Janssen Ex. 1971, CDC MOrbitiy and Mortality Weekly Report (Sept. 14, 2018) (*admitted June 13, 2019*).

[259] *See* July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 30:16-31:7; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 17:3-12.

[260] *See* State Ex. 1163, *Pain Non-Branded Campaign Market Research* at 16 (*admitted June 4, 2019*) (testing message that "Acute pain not properly treated can lead to chronic"); State Ex. 1365, Neo Pathways messaging cards at 2 (*admitted June 3, 2019*) (stating that "The onset of chronic pain is often related to unresolved acute pain from injury or surgery.").

[261] June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 63:6-25.

[262] *See* State Ex. 954, H. Heit & D. Gourlay, *What a Prescriber Should Know Before Writing the First Prescription* (*admitted June 10, 2019*) (discussing pseudoaddiction and claiming that "[w]hile a diagnosis of addiction is made prospectively over time, a diagnosis of pseudoaddiction is usually made retrospectively."); State Ex. 2354, *Current Concepts in Pain Management*

of pseudoaddiction as lacking scientific foundation.[263] The Court concludes that pseudoaddiction is a common-sense concept that is supported FDA-approved labeling for Janssen's products.[264] The Court also credits the testimony of Dr. Lynn Webster, a noted pain expert, that pseudoaddiction remains a valid concept today, particularly in light of the scope of the chronic pain problems.[265]

111. Nor did the State offer any proof that these materials impacted prescribing by Oklahoma physicians after they were released. The trial record is devoid of evidence that a single Oklahoma doctor or patient even read, let alone relied on any of these materials.

IV. STATE'S ATTEMPT TO EXPAND LIABILITY BEYOND JANSSEN'S DRUGS

A. Noramco and Tasmanian Alkaloids

112. In 1979, Johnson & Johnson formed a subsidiary, Noramco, to provide a reliable, high-quality supply of the active pharmaceutical ingredient (API) for certain opioid products).[266] It subsequently diversified its product portfolio to include other narcotic API.[267] Its customers were Johnson & Johnson affiliates and other FDA- and DEA-regulated pharmaceutical companies.[268] At the time of divestiture, Noramco was a subsidiary of Janssen Pharmaceuticals,

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(*admitted June 11, 2019*) (references "maladaptive behaviors in patients who do not have true addiction (for example, pseudoaddiction).").

[263] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 60:20-25.

[264] *See, e.g.*, Janssen Ex. 2776, 2018 Duragesic Label at 31 (*admitted June 4, 2019*) ("Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.").

[265] Webster Depo Tr. at 403:16-25, 404:3-8, 11-13, 19-24, 405:2-6, 9-11, 14-15 (played July 10, 2019).

[266] State Ex. 1048, Noramco World Wide Narcotics Franchise Presentation at 13 (*admitted May 29, 2019*).

[267] *See* State Ex. 340, Noramco Organizational Alignment Presentation at 3-4 (*admitted May 29. 2019*).

[268] *Id. at 5*; Grubb Depo. Tr. at 55:7-17, 263:9-19 (played July 10, 2019).

Inc.[269]

113. Tasmanian Alkaloids was founded in 1975 as a joint venture between Abbott Laboratories and Ciech Polfa.[270] Johnson & Johnson acquired Tasmanian Alkaloids in 1982.[271] Tasmanian Alkaloids primarily sold concentrate of poppy straw ("CPS") to licensed API suppliers such as Noramco.[272]

114. In 1994, Tony Fist, a scientist at Tasmanian Alkaloids, began developing a strain of poppy—the "Norman" poppy—that contained the alkaloids thebaine and oripavine, but was free of morphine and codeine.[273] The Norman poppy produces approximately the same quantity of alkaloid per hectare as previous varieties of poppies, but as thebaine and oripavine in place of morphine and codeine.[274] Thebaine is used to produce certain opioid APIs, such as oxycodone, buprenorphine, naloxone, and naltrexone.[275] Thebaine is not abusable in its raw state.[276] Unlike previous varieties, the Norman poppy could be grown without risk of diversion for illicit purposes because thebaine and oripavine are not easily converted into morphine or heroin.[277] The first commercial crop of Norman poppies was harvested in 1997.[278]

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[269] *See* Grubb Depo. Tr. at 271:5-8 (played July 10, 2019).

[270] State Ex. 6, A.J. Fist, *The Tasmanian Poppy Industry* at 3 (*admitted May 29, 2019*).

[271] *Id.*

[272] *See* Grubb Depo. Tr. at 26:9-18 (played July 10, 2019); State Ex. 1788, December 1998 Supply Agreement between Noramco and Purdue at 3-4 (*admitted under seal May 29, 2019*).

[273] State Ex. 6, A.J. Fist, *The Tasmanian Poppy Industry* at 6 (*admitted May 29, 2019*).

[274] *Id.* at 7.

[275] *Id.* at 2.

[276] June 11, 2019 (AM) Trial Tr. (Kolodny Test.) at 116:18-22.

[277] State Ex. 6, A.J. Fist, *The Tasmanian Poppy Industry* at 7 (*admitted May 29, 2019*).

[278] *Id.* at 6.

115. Noramco's U.S. market share varied year to year for each API it manufactured.[279] From 2013-2015, Noramco supplied between 40 and 60 percent of the morphine, oxycodone, hydrocodone, and codeine API used in the United States. During those same years, Noramco supplied less than 15 percent of the U.S. market for oxymorphone and hydromorphone.[280]

116. The evidence shows that, among other customers, Noramco sold raw materials to Purdue.[281] Although the State presented that Noramco discussed oxycodone supply requirements with Purdue "for many years,"[282] boasted that its "poppy was a transformational technology that enabled the growth of oxycodone,"[283] and referred to a strategy of "partner[ing]" with pharmaceutical manufacturers in a presentation,[284] none of those facts suggests—much less proves by a preponderance of the evidence—that Noramco's relationship with Purdue went beyond an ordinary buyer-seller relationship. In fact, 1998 and 2008 Supply Agreements between Noramco and Purdue explicitly state the parties are independent contractors and nothing more.[285]

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[279] Grubb Depo. Tr. at 86:6-18 (played July 10, 2019).

[280] State Ex. 1048, Noramco World Wide Narcotics Franchise Presentation at 22 (*admitted May 29, 2019*).

[281] May 29, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 36:12-37:1, 53:14-54:17; State Ex. 494, October 1998 Letter from Michael Kindergan to Ed. Miglarese (*admitted May 29, 2019*); State Ex. 1788, 1998 Supply Agreement between Noramco and Purdue (*admitted under seal May 29, 2019*).

[282] State Ex. 494, October 1998 Letter from Michael Kindergan to Ed. Miglarese (*admitted May 29, 2019*) ("we have been discussing the supply of oxycodone for many years now").

[283] State Ex. 340, Noramco Organizational Alignment Presentation at 7 (*admitted May 29. 2019*).

[284] State Ex. 1048, Noramco World Wide Narcotics Franchise Presentation at 16 (*admitted May 29. 2019*).

[285] Janssen Ex. 343, January 2008 Supply Agreement between Noramco and Purdue at 14 (*admitted with redactions June 26, 2019*); State Ex. 1788, 1998 Supply Agreement between Noramco and Purdue at 8 (*admitted under seal May 29, 2019*)

117. Johnson & Johnson sold Noramco and Tasmanian Alkaloids in 2016.[286]

118. At all times, Tasmanian Alkaloids and Noramco sold their products under strict international and federal regulatory scrutiny.

119. International drug control treaties govern the global manufacture and consumption of narcotic drugs.[287] The United States enacted the Controlled Substances Act ("CSA") and formed the DEA to carry out its obligations under these treaties.[288]

120. The CSA authorizes the importation of "such amounts of crude opium, poppy straw, [or] concentrate of poppy straw . . . as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes."[289] Under the CSA's implementing regulations, American companies wishing to purchase narcotic raw materials from manufacturers such as Tasmanian Alkaloids must receive explicit authorization from the DEA in the form of an import permit.[290]

121. A similar regime governs Noramco's production and sales of API. API producers like Noramco, as well as Noramco's customers, must apply annually for a DEA license. The DEA publishes registrant licenses in the Federal Register.[291] The DEA also performs regular inspections and audits of API producers' security systems and transactions.[292]

122. Under the CSA and its implementing regulations, the DEA must establish annual

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[286] Grubb Depo. Tr. at 23:15-18, 27:8-19 (played July 10, 2019).

[287] *Id.* at 282:23-283:13.

[288] *Id.*

[289] 21 U.S.C. § 952(a)(1).

[290] *See* 21 C.F.R. §§ 1312.11, 1312.12.

[291] Grubb Depo. Tr. at 51:19-52:5 (played July 10, 2019).

[292] *Id.* at 52:11-53:2.

quotas for controlled substance production and sales. The DEA follows that mandate by annually setting three levels of API quotas:

a. Aggregate quotas dictate how much API should be produced nationwide each year.[293]

b. Manufacturing quotas dictate how much an API individual producer, like Noramco, can manufacture each year.[294]

c. Procurement quotas dictate how much API a given manufacturer can purchase from producers such as Noramco each year.[295]

123. The CSA and its regulations explain that these quotas serve to "insure an adequate and uninterrupted supply of … basic classes of controlled substances." 21 C.F.R. § 1303.12(a). In other words, they "provide for the estimated medical … needs of the United States." 21 U.S.C. § 826(a)(1); 21 C.F.R. § 1303.11(a), (b).

124. The State presented no evidence that either Noramco or Tasmanian Alkaloids ever failed to comply with their regulatory obligations.

125. *Noramco was an independent subsidiary.* Noramco paid and trained its own employees, and those employees had Noramco business cards, used Noramco letterhead, and worked out of Noramco-owned facilities.[296] Noramco—not Janssen or Johnson & Johnson—owned its own manufacturing facilities and directed Noramco's day-to-day operations, including developing business plans and product selection criteria.[297]

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[293] *See* 21 U.S.C. § 826(a); 21 C.F.R. §§ 1303.11, 1303.13.

[294] *See* 21 U.S.C. § 826(c); 21 C.F.R. §§ 1303.21-1303.27.

[295] 21 C.F.R. § 1303.12.

[296] Grubb Depo. Tr. at 182:3-9, 271:18-274:2 (played July 10, 2019).

[297] Id. at 274:4-275:6.

126. Noramco and Janssen had minimal overlap. Of 483 global employees between Noramco and Tasmanian Alkaloids, only 28 were shared with Johnson & Johnson.[298]

127. The State presented no evidence that Janssen intended to use its unbranded marketing to increase Noramco's or Tasmanian Alkaloids' sale of raw materials.

128. The State did not introduce a single instance of unbranded marketing by Janssen for the first three decades it owned those companies. The earliest piece of unbranded marketing material identified by the State was the 2008 NEO Pathways sales training.

129. After 2008, internal Janssen documents referring to its unbranded efforts state that the efforts aimed to "[p]ave the way for the tapentadol launch"[299] and "get customers ready for new products."[300] Although it had access to hundreds of thousands of Janssen documents, the State did not present a single one suggesting the campaigns were instead intended to bolster Noramco's and Tasmanian Alkaloids' raw material businesses.

130. Janssen corporate representative Kimberly Deem-Eshleman, who was on the Nucynta brand team beginning in 2008 when Janssen's unbranded marketing began, and was "involved in the marketing of tapentadol,"[301] testified that she had "no knowledge, personal knowledge, of Noramco[.]"[302] Similarly, Noramco Business Development Vice President Bill Grubb testified that Noramco had no role in the marketing of the medicines in which its API was

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[298] State Ex. 1048, Noramco World Wide Narcotics Franchise Presentation at 9 (*admitted May 29. 2019*).

[299] State Ex. 1239, Unbranded Tactical Slide Deck (*admitted June 3, 2019*); *see* June 3, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 67:22-24.

[300] State Ex. 223, Tapentadol Neo-Pathways Overview (*admitted May 31, 2019*); *see* May 31, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 33:19-22.

[301] May 31, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 64:23-24.

[302] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 39:21-23.

used.[303]

131. The State presented no rebuttal to this extensive evidence indicating that Noramco had no connection to *any* opioid marketing efforts, whether branded or unbranded.

B. Professional and Scientific Organizations

132. The United States is home to countless professional and scientific organizations including, among many others, the American Cancer Society, the American Alzheimer's Association, the American Chronic Pain Association, and the American Heart Association. Such groups consist of healthcare providers, patients, and industry members. Pharmaceutical companies like Janssen commonly support such organizations.[304]

133. Despite attempts to connect Janssen with Purdue Pharma based on their shared membership in professional and scientific organizations,[305] the State offered no evidence Janssen coordinated with Purdue on any activity at any time through any such organization.

134. The evidence presented at trial showed that Janssen made financial contributions to professional and scientific organizations and that some of the individuals Janssen retained as key opinion leaders ("KOLs") held active roles in some of these groups. On limited occasions, Janssen worked directly with these organizations to create educational resources. But outside of those specific instances, the evidence does not show Janssen exercised influence or control over those groups' activities. Nor does it indicate that Janssen created any professional or scientific organizations.

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[303] Grubb Depo. at 246:24-247:10, 284:23-25, 285:02-11, 285:13-15 (played July 10, 2019).

[304] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 105:8-25, 107:2-19, 109:22-110:2.

[305] June 11, 2019 (AM) Trial Tr. (Kolodny Test.) (claiming without evidence that J&J and Purdue "funded" materials disseminated by the Joint Commission); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 159:5-16 (claiming the American Pain Foundation received "seed funding" from Purdue and, "by year two," J&J and other opioid manufacturers also began contributing).

135. The State's experts criticized statements by third-party organizations and KOLs and asserted in conclusory terms that such statements influenced opioid prescribing practices. But those criticisms represent differences in medical opinion that often reduce to quarrels with mainstream scientific consensuses that remain in place today. For example, although Dr. Kolodny criticized the American Pain Society's and American Academy of Pain Medicine's 1996 Consensus Statement on the Use of Prescription Opioids for the Treatment of Chronic Pain as a document that led to excessive opioid prescribing, principles from that document are codified in the Oklahoma Administrative Code to this day. *See infra* 66. And the State presented no evidence that statements by any of the associations, doctors, or educational platforms its experts criticized caused a single doctor in Oklahoma to write a prescription that should not have been written—much less that ***Janssen's association*** with such third parties did so.

1. Joint Commission on Accreditation of Healthcare Organizations ("JCAHO")

136. *Background.* JCAHO is a nonprofit professional-accrediting organization that certifies healthcare organizations based on performance standards for safe and effective care.[306] Certification has implications for assessment of clinical excellence, contracting, and reimbursement.[307] Dr. Kolodny testified that JCAHO is not a "front group."[308]

137. Dr. Kolodny insisted that JCAHO "developed materials that it sold or

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[306] State Ex. 1349 at 8 (*admitted June 3, 2019*); *see also* June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 16:22-17:14 (JCAHO is "the main accreditation organization of healthcare organizations" in the U.S.).

[307] State Ex. 1574, The President's Commission Report at 21 (*admitted June 3, 2019*).

[308] *Id.* at 16:25-17:5 ("I would not call the Joint Commission a front group.").

disseminated that were sponsored by Johnson & Johnson."[309] As support, Dr. Kolodny referenced Janssen's contributions to JCAHO: $545,244 from 2001 to 2014, with annual amounts ranging from $10,000 (2015) to $498,791 (2011).[310] But neither Dr. Kolodny nor any other State witness identified any JCAHO materials that J&J or Janssen sponsored, influenced, or otherwise helped create.

138. *Pain as the Fifth Vital Sign.* Dr. Kolodny testified that JCAHO in 2001 mandated that hospitals treat pain as a vital sign.[311] He testified that he "believe[s]" J&J, at some point in time, had a "direct" financial relationship with Dr. June Dahl, a retired pharmacology professor whom he "think[s]" has "taken credit for convincing [JCAHO] to introduce the pain standards and to require that pain be treated like it's a vital sign."[312] Dr. Kolodny cited no evidence of an alleged relationship between J&J and Dr. Dahl,[313] and the record contradicts his speculation.[314] In any case, the State offered no evidence that Janssen played any role in JCAHO's decision.

2. American Pain Society ("APS")

139. *Background.* APS was a professional society for scientists, clinicians, and others, focused on increased knowledge of pain and using public policy and clinical practice to reduce

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[309] *Id.* at 16:25-18:17.

[310] *Id.* at 19:5-8; *see also* State Ex. 1349, Contributions to Advocacy Organizations at 8 (*admitted June 3, 2019*).

[311] June 11, 2019 (AM) Trial Tr. (Kolodny Test.) at 29:13-30:17.

[312] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 5:25-6:9.

[313] *See, e.g., id.*; State Ex. 1350, Key Opinion Leader Payment History (*admitted June 3, 2019*).

[314] State Ex. 624, Trends in Medical Use and Abuse of Opioid Analgesics at 1 (*admitted June 10,* 2019) (*compare* "Mr. Joransan receives honoraria from … Janssen Pharmaceutical" *with* "Dr. Dahl serves on the Speakers Bureau for Purdue Pharma and is a consultant for Knoll Pharmaceuticals.").

pain-related suffering.[315] Janssen made regular contributions to the APS.[316] And an internal Janssen document described the benefits of APS membership as networking with other members, subscriptions to publications and communications, and registration at receptions and meetings.[317]

140. *Consensus Statement.* In 1996, APS and the American Academy of Pain Medicine ("AAPM") issued a Consensus Statement on the Use of Prescription Opioids for the Treatment of Chronic Pain.[318] The Consensus Statement explained the personal and societal costs of pain, the inadequacies of pain management, and the state of policy on the use of opioid analgesics for the relief of chronic pain. It then called for the creation of guidelines for prescribing opioids, outlining five "principles of good medical practice."[319] The substance of the Consensus Statement thus stands in marked contrast to Dr. Kolodny's insistence that it is "really saying" that healthcare providers "under prescrib[e] opioids."[320] Although Dr. Kolodny testified that the Consensus Statement is "one of the single most damaging documents when we look back at the history of our opioid crisis"[321] and without citing evidence asserted that it "changed the culture of prescribing" "more than any other single document,"[322] the State of Oklahoma itself codified the Consensus Statement's principles of good medical practice in the Oklahoma Administrative Code.[323] Those provisions remain in full force today.

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[315] State Ex. 1349, Contributions to Advocacy Organizations at 2 (*admitted June 3, 2019*).

[316] State Ex. 1349, Contributions to Advocacy Organizations at 2 (*admitted June 3, 2019*).

[317] *See* State Ex. 1439, Advocacy Launch Plan, at 39 (*admitted June 7, 2019*).

[318] State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain (*admitted May 30, 2019*).

[319] *See id.*

[320] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 25:4-14.

[321] *Id.* at 27:10-16.

[322] *Id.* at 45:9-17.

[323] *Compare* State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain at 3 (*admitted*

141. The State attempted to connect Janssen to the Consensus Statement. It introduced evidence that three healthcare professionals whom Janssen retained as key opinion leaders, Dr. Portenoy, David Joranson, and Dr. Richard Payne,[324] sat on the committee that prepared the Statement.[325] Dr. Kolodny testified that he "believe[s]" J&J had financial relationships with two additional members on the committee, Dr. Matthew Midcap and Dr. Daniel Carr,[326] but he offered no evidence to support his speculation.[327] Dr. Kolodny also criticized Robert Angarola's membership on the drafting committee[328] because he served as Janssen's outside counsel when offering Congressional testimony six years before the Statement's publication.[329] Angarola, who died before the Statement's release, worked on pain and drug policy issues for decades. He served as legal advisor to the International Narcotics Control Board and held senior service roles in numerous agencies under multiple Presidential administrations including in the White House Special Action Office for Drug Abuse Prevention, White House Office of Drug Abuse Policy, and Interagency Committee on New Therapies for Pain & Discomfort.[330] Because of this relevant experience, the Court finds nothing unusual about Angarola's presence on the drafting

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May 30, 2019), *with* Okl. Admin. Code § 435:10-7-11.

[324] State Ex. 1350, Key Opinion Leader Payment History at 5 (*admitted June 3, 2019*); State Ex. 624.

[325] State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain at 4 (*admitted May 30, 2019*); *see also* Portenoy Depo. Tr. at 201:4-19 (played May 29, 2019).

[326] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 40:15-42:21.

[327] *See id.*; *see also* State Ex. 1350, Key Opinion Leader Payment History (*admitted June 3, 2019*).

[328] State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain at 4 (*admitted May 30, 2019*).

[329] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 40:15-44:24 ("I don't know why he's on that document, but I do know that it's inappropriate.").

[330] *See* June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 110:3-1154:2.

committee. Other than pointing to Janssen's unrelated affiliations with these individuals, the State offered no evidence that Janssen played any role in creating the Statement or otherwise contributing to its content.

142. The State likewise presented no evidence that Janssen disseminated the Consensus Statement. It instead pointed to a "Duragesic Press Kit"[331] document quoting the Statement. While the State's counsel characterized the document as "Duragesic.com,"[332] it actually states only that certain of its contents were derived from www.duragesic.com.[333] And the majority of factual statements in the document—including all discussions of the Consensus Statement—cite to sources other than Duragesic.com.[334] The State presented no evidence on the actual contents of www.duragesic.com.

3. American Academy of Pain Medicine ("AAPM")

143. *Background.* AAPM, which co-authored the 1996 Consensus Statement, is a society of physicians and other medical professionals in the field of pain medicine. It engages in education, training, advocacy, and research about pain.[335] Janssen made regular contributions to

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[331] State Ex. 760, Duragesic: Information on Opioid Dependence, Tolerance and Addiction, at 2 (*admitted June 3, 2019*).

[332] June 11, 2019 (PM) Trial Tr. (Beckworth Comm.) at 39:9-11 ("Mr. Medina, can we pull up [State Ex.] 760, which is in evidence. It's the Duragesic.com document."); *id.* at 159:2-4 ("I handed them a copy of what I called Duragesic.com. It's 0760."); *id.* at 165:6-8 ("Now we saw at the bottom that references were taken from Duragesic.com. Right?").

[333] State Ex. 760, Duragesic: Information on Opioid Dependence, Tolerance and Addiction at 2 (*admitted June 3, 2019*).

[334] *See id.* at 2-3 (citing, *inter alia*, State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain (*admitted May 30, 2019*) and Savage S., et al. *Definitions related to the Use of Opioids for The Treatment of Pain: A Consensus Document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine*, AM. PAIN SOC. Available at: wwww.ampainsoc.org/advocacy/opioids2.htm).

[335] State Ex. 1349, Contributions to Advocacy Organizations at 1 (*admitted June 3, 2019*).

AAPM.[336] And an internal Janssen document stated that the benefits of membership included networking with other members, subscriptions to publications and communications, and registration at receptions and meetings.[337]

144. *Imagine the Possibilities Pain Coalition* ("IPPC"). AAPM was a member of IPPC, a Janssen-sponsored coalition of professional organizations, KOLs, Janssen personnel, and academics from universities including Georgetown, Duke, and the University of Pennsylvania, all brought together to discuss pain-management issues. IPPC disbanded in December 2012 after only four meetings.[338] Professor April Vallerand, Ph.D., of Wayne State University authored the only publication to emerge from IPPC, a peer-reviewed article describing the U.S. military's approach to managing pain in returning veterans.[339] The Journal of Pain Research and Management published the article in 2015.[340]

145. *Finding Relief.* In 2009, Janssen sponsored the APS brochure *Finding Relief,* discussed *supra* 50-53.[341]

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[336] *Id.* at 1-2. Additional data show that between 2012 and 2017, Janssen contributed $83,975 to AAPM. State Ex. 896, Homeland Security & Governmental Affairs Committee Report at 5 (*admitted May 30, 2019*).

[337] *See* State Ex. 1439, Advocacy Launch Plan, at 39 (*admitted June 7, 2019*).

[338] June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 15:22-30:5; *see also* Janssen Ex. 3792, IPPC Totality Closeout (describing IPPC's meetings, agenda items, and discontinuance) (*admitted June 5, 2019*); Janssen Exs. 3793-3796, Compilation of IPPC Meeting Summaries (*admitted June 5, 2019*).

[339] *See* June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 28:14-29:3 (testifying that this article is "the only output [from] the [IPPC]"); Janssen Ex. 3798, Pain Management Strategies and Lessons from the Military (*admitted June 5, 2019*).

[340] *See* Janssen Ex. 3798, Pain Management Strategies and Lessons from the Military (*admitted June 5, 2019*).

[341] All "supra" and "infra" references in these proposed findings refer to the page number of the referenced discussion.

4. Federation of State Medical Boards ("FSMB")

146. *Background.* FSMB is a nonprofit organization representing and supporting state medical and osteopathic regulatory boards.[342] Dr. Kolodny testified that FSMB is not a "front group" and that it "does do some important work," such as administering the U.S. Medical Licensing Examination.[343] The State offered no evidence that Janssen made any financial contribution to the FSMB.[344]

147. *Model Guidelines on Prescribing Opioids for Chronic Pain.* Dr. Kolodny testified that the FSMB's Model Guidelines were "disseminated across the country," encouraged opioid prescribing, and "help[ed] change the way" states regulated opioid prescribing, but the State pointed to no evidence of how, if at all, that occurred in Oklahoma.[345] The State offered no evidence that Janssen helped create or disseminate the Model Guidelines. Rather, Dr. Kolodny testified that the FSMB created the Model Guidelines with funding from the Robert Wood Johnson Foundation ("RWJF"), which he "believe[s] was created with shares of Johnson & Johnson stock …."[346] The insinuation that RWJF's grant to a reputable professional organization was an exercise of influence by Janssen or J&J was rank speculation unsupported by any evidence at all.

148. The RWJF is the nation's largest public-health philanthropic organization.[347] The State offered no evidence that J&J or Janssen exerts any influence or control over it.

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[342] State Ex. 1349, Contributions to Advocacy Organizations at 5-6 (*admitted June 3, 2019*).

[343] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 15:1-16:11.

[344] *See id.*; *see also* State Ex. 1349, Contributions to Advocacy Organizations at 5-6 (*admitted June 3, 2019*).

[345] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 15:1-16:11.

[346] *Id.*

[347] Gilson Depo. Tr. at 176:6-8, 11-13 (played June 7, 10, 2019).

5. *University of Wisconsin Medical School Pain & Policy Studies Group ("UWPPSG")*

149. *Background.* UWPPSG was a research program founded by David Joranson in 1996, focused on improving global pain relief, conducting policy research, and educating healthcare professionals on the state of pain-related policy.[348] Janssen made intermittent donations to the UWPPSG, including for the production of a newsletter that was "not technically a part" of UWPPSG.[349] The State presented no evidence suggesting that newsletter was misleading, nor that it was distributed in Oklahoma.

150. *Pain Policy Report Cards.* UWPPSG developed state-specific "Report Cards" that assigned letter grades to each state based on the relative restrictiveness of their prescribing policies."[350] UWPPSG developed the Report Cards "to help states improve their policies."[351] UWPPSG gave Oklahoma a grade of C+.[352] The State presented an internal Janssen document from 2003 that discussed possible ways to use the scorecards,[353] but the State offered no evidence that Janssen ever actually used them.

6. *American Pain Foundation ("APF")*

151. *Background.* APF was a nonprofit patient group founded to support people with

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[348] *See id.* at 15:3-23; State Ex. 1349, Contributions to Advocacy Organizations at 5 (*admitted June 3, 2019*).

[349] State Ex. 1349, Contributions to Advocacy Organizations at 5, n.2 (*admitted June 3, 2019*).

[350] Gilson Depo. Tr. at 239:1-16 (played June 7 and 10, 2019); Ponder Depo. Tr. at 277:1-278:15 (played June 20, 2019).

[351] Ponder Depo. Tr. at 263:2-16 (played June 20, 2019).

[352] State Ex. 1161, Nucynta: Advocacy and Policy Key Launch Activities, at 21 (*admitted June 3, 2019*).

[353] State Ex. 635, Pain Policy Overview, at 18 (*admitted June 10, 2019*); Gilson Depo. Tr. at 272:16-273:9, 273:14-16, 273:20-274:9, 274:13-15, 275:3-17, 275:21-24, 278:1-2, 278:9-12; Ponder Depo. Tr. at 277:1-278:15 (played June 20, 2019).

pain, primarily through public advocacy to improve access to pain management.[354] Dr. Portenoy described APF as "a voice that provided information to patients and pain advocates."[355] Janssen made annual contributions to the APF, and, as for other organizations, an internal Janssen document described the benefits of APF membership as including networking, periodical subscriptions, and registration for events.[356]

152. *Pain Resource Guide.* First published in 2007 and revised in 2009,[357] APF's Pain Resource Guide was an educational booklet intended to help patients obtain effective treatment.[358] Janssen did not create the Guide or exert any influence or control over its content.[359] In March 2011, Laura Flannery sent an email to Deem-Eshleman and attaching a PDF copy of the Guide, writing, "Please let me know if you would like us to revise in anyway."[360] But the evidence shows Flannery was referring not to the Guide itself but to her *description* of the Guide in the email's body.[361] At the time, Janssen had retained Flannery's marketing agency to help Janssen develop a website, Prescribe Responsibly; Janssen was

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[354] State Ex. 1349, Contributions to Advocacy Organizations at 3 (*admitted June 3, 2019*).

[355] Portenoy Depo. Tr. at 61:8-17 (played May 29, 2019).

[356] *See* State Ex. 1439, Advocacy Launch Plan, at 39 (*admitted June 7, 2019*).

[357] State Ex. 1227, Email from L. Flannery to K. Deem-Eshleman attaching Pain Resource Guide, at 33 (*admitted June 4, 2019*).

[358] *See generally id.*

[359] *See* June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 11:6-21 ("[T]he resources themselves were not created by Janssen."); *cf. id.* at 6:8-8:14 (Janssen did not create the resources it placed on the Prescribe Responsibly website).

[360] State Ex. 1227, Email from L. Flannery to K. Deem-Eshleman attaching Pain Resource Guide, at 1 (*admitted June 4, 2019*).

[361] *See* June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 11:6-21 ("[S]he's asking me to look at that brief introduction or that brief overview of what that resource is that would be [placed] on the [Prescribe Responsibly] site.").

considering adding the Guide to that website.[362] Flannery's description, if approved, would also have been included.[363]

153. Dr. Kolodny criticized various statements in the Guide.[364] But the State offered no evidence that Janssen ever placed the Guide on its Prescribe Responsibly website or otherwise disseminated it.[365]

C. Key Opinion Leaders

154. KOLs are doctors considered by their peers to be thought leaders in their respective fields.[366] The medical community, not pharmaceutical companies, determines which doctors are KOLs.[367]

155. In the pain-management field, KOLs often publish and speak on topics related to treating pain. They write books,[368] publish scholarly articles and studies,[369] and speak at CME programs.[370]

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[362] *See, e.g., id.*; State Ex. 1227, Email from L. Flannery to K. Deem-Eshleman attaching Pain Resource Guide at 1 (*admitted June 4, 2019*).

[363] *See* June 5, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 11:6-21.

[364] *See* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 75:14-77:22, 78:19-80:15; State's Ex. 1227, Email from L. Flannery to K. Deem-Eshleman attaching Pain Resource Guide at 8, 18 (*admitted June 4, 2019*).

[365] *See, e.g.*, June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 73:24-81:17.

[366] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 96:6-24; June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 87:11-17.

[367] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 96:6-16 ("Janssen doesn't determine who the KOLs or the thought leaders are. The community in which they practice medicine does.").

[368] *See* June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 10:12-11:1 (discussing Charles Argoff's book, *Defeat Chronic Pain Now*).

[369] *See, e.g.*, State Ex. 878, Russell Portenoy CV at 12-31 (listing articles published in medical journals) (*admitted May 30, 2019*) .

[370] *See, e.g.*, Portenoy Depo. Tr. at 333:13-18 (played May 29, 2019) (testifying that he and Dr. Richard Payne "put together" a CME program in 2002).

156. Janssen, like other pharmaceutical companies, retains KOLs to provide advice on therapeutic areas within their expertise.[371] KOLs serve on Janssen advisory boards, participate in Janssen speaker trainings and programs, and consult on clinical trials.[372] Janssen compensates KOLs for their time and services.[373]

157. The State's witnesses testified that because Janssen paid KOLs, it was able to exercise "influence" over them.[374] But the KOLs who testified at trial uniformly stated that the funding they received from pharmaceutical companies did not influence their work.[375] Indeed, Dr. Portenoy began publishing books and articles on pain management in the early 1980s, long before Janssen launched Duragesic,[376] and there is no evidence that his views changed when he later received funding from Janssen.

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[371] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 96:6-24.

[372] *See, e.g.*, Portenoy Depo. Tr. at 138:8-15 (played May 29, 2019) (testifying that he was a speaker "related to Duragesic"); June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 91:24-92:19; Janssen Ex. 2342, OMJPS Health Care Compliance Reference Guide (Jan. 2006) at 5 (*admitted June 4, 2019*); *see also* May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 96:6-24;.

[373] *See, e.g.*, Portenoy Depo. Tr. at 49:16-50:16, 50:18-19, 50:21-52:12, 54:3-54:11, 54:13-18, 55:11 (*played May 29, 2019*) (discussing consulting fees and educational grants); June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 85:24-86:5 (discussing speaking fees); 91:22-92:19 (discussing health care compliance policy governing educational grants and agreements with KOLs); Janssen Ex. 2342, OMJPS Health Care Compliance Reference Guide (Jan. 2006) at 5 (*admitted June 4, 2019*).

[374] *See* Portenoy Depo. Tr. at 63:2-5 (played May 29, 2019) (testifying that drug companies paid honoraria and fees "in a way that elevate[d] specific messages"); June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 44:7-45:4 (testifying that KOLS were "influenced by pharmaceutical marketing … purchase power").

[375] Portenoy Depo. Tr. at 40:1-9 (played May 29, 2019) (Portenoy testifying that he "never spoke for anybody except [him]self"); Argoff Depo. Tr. at 223:7-223:20 (*played July 8, 2019*) (Argoff testifying that he "would never say something that [he] didn't feel comfortable saying," and that he did not recall a drug company ever asking him to do so); Webster Depo. Tr. at 301:2-5, 9 (*played July 10, 2019*) (Webster testifying that he could not recall ever saying anything "false or misleading" in any speaker program).

[376] *See* State Ex. 878, Russell Portenoy CV at 10-31 (*admitted May 30, 2019*).

158. The State introduced a document, entitled "Tapentadol Team Status - 6/24/2009 - Acute Pain Publications," that it argued shows Janssen influenced KOLs' speech. The document contains a table listing various projects and the author and status on each.[377] Kolodny claimed that the document "suggest[ed] that Johnson & Johnson was ... ghost writing journal articles" published by KOLs.[378] He testified that "[i]f this is ... in fact[] evidence," it would represent an unethical attempt to influence prescribers.[379] But the State presented no evidence that the articles listed were published, were misleading, or did not reflect the views of the listed authors.

159. The State also presented documents showing that Janssen sometimes analyzed the influence of its KOLs and sought to understand the extent to which KOLs' views aligned with Janssen's. Dr. Kolodny discussed an internal Janssen email referring to a plan to categorize KOLs as "Opponents," "Neutrals," or "Advocates."[380] The State also presented a 2004 PowerPoint presentation provided to Janssen, entitled "Duragesic KOL Mapping Analysis," that discussed how "to maximize DURAGESIC prescribing that is produced by physicians who are influenced by thought leaders."[381] But neither document references any plan to influence KOLs' speech, and the State presented no evidence that Janssen implemented these plans or that a single Oklahoma doctor was influenced by a Janssen-funded KOL. Janssen's internal analyses of KOLs do not make Janssen responsible for KOLs' work product or speech. Nor do these

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[377] *See* State Ex. 972, "Tapentadol Team Status - 6/24/2009 - Acute Pain Publications" (*admitted June 13, 2019*).

[378] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 50:16-51:6.

[379] *Id.* at 52:11-19.

[380] State Ex. 461, 2/18/2002 Email from Heather Thomson to Michele Cole Re: KOL Categorization (*admitted June 12, 2019*); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 54:23-55:2.

[381] State Ex. 1372, Duragesic KOL Mapping Analysis at 4, 7 (*admitted June 12, 2019*).

analyses suggest that Janssen worked only with KOLs with whom it agreed. To the contrary, the evidence shows that Janssen retained KOLs with whom it disagreed.[382]

160. Finally, the State challenged limited instances in which Janssen disseminated, or discussed disseminating, KOLs' research. The State highlighted a PowerPoint presentation related to the Neo Pathways unbranded campaign.[383] The presentation was created for Oklahoma sales representatives attending a November 2008 "District Hub Meeting" and has a slide instructing them to "[u]se Portenoy's study to create dialogue about Opiophobia as a barrier."[384] It notes that "[m]any HCP's will find the 2.6 percent incidence of addiction to be extremely low" and "[i]t's not about the percent, but about the barrier contributing to the undertreatment of pain."[385] Dr. Kolodny testified that Dr. Portenoy's study should not have been used to suggest a low rate of addiction because it had a large patient dropout rate.[386] But the State did not present evidence that Janssen sales representatives actually used the study when visiting physicians; that Janssen or J&J funded, influenced, or controlled the study; or that the study did not represent Dr. Portenoy's independent conclusions.

D. Continuing Medical Education

161. CME seminars are programs that clinicians attend to satisfy state medical board licensing requirements.[387] CMEs are not designed to discuss specific products but to educate

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[382] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 90:14-18 ("Q. Ms. Deem-Eshleman, does Janssen only work with KOLs who it agrees with? A. No, not at all. Q. Does it always agree with its KOL[s]? A. No. Sometimes we agree to disagree[.]").

[383] State Ex. 1364, 2008 Neo Pathways PowerPoint (*admitted May 29, 2019*).

[384] *Id.* at 5, 16.

[385] *Id.* at 16.

[386] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 70:25-71:15.

[387] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 93:25-94:5.

medical professionals in different therapeutic areas.[388]

162. Pharmaceutical companies frequently sponsor CMEs. When they do, they generally retain third parties to independently create the programs.[389] CMEs must be approved by accreditors, who review programs to ensure they are not promotional.[390] CME rules bar pharmaceutical companies from influencing or controlling CME content.[391]

163. Before Janssen sponsored any CME program, its medical affairs committee would evaluate whether the program addressed a needed issue in the relevant therapeutic area.[392] This review process had to comply with rules set by both the accrediting organization and the FDA.[393]

164. Janssen and J&J sponsored several CME programs in the pain-management field. For example, Janssen provided funding to the National Pain Education Council ("NPEC"), a CME platform co-chaired by Drs. Portenoy and Payne.[394] NPEC developed the 2002 CME program "Appropriate Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program," which aimed to "advance the clinical management of pain through education and communication[.]"[395] As another example, J&J funded a CME presentation by Dr. Stephen Colameco called "Responsible Opioid Prescribing."[396]

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[388] June 4, 2019 (PM) Trial Tr. (K. Deem-Eshleman Test.) at 95:4-11 (testifying that CMEs are "purely" educational).

[389] *Id.* at 94:6-13.

[390] *Id.*

[391] *Id.* at 77:10-18 (testifying that CME programs "must be independent of influence in content and conduct").

[392] *Id.* at 95:14-96:2.

[393] *Id.* at 98:5-16.

[394] State Ex. 975, NPEC, "Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program" (June 2002) at 1-3 (*admitted June 4, 2019*).

[395] *Id.* at 8.

[396] State Ex. 2372, Responsible Opioid Prescribing PowerPoint at 1 (*admitted June 13, 2019*).

165. The State and its witnesses criticized certain CMEs funded by grants from Janssen. Specifically, Dr. Kolodny criticized Colameco's "Responsible Opioid Prescribing" PowerPoint presentation, testifying that it improperly de-emphasized opioids' addictive properties and conveyed that tolerance is not a problem with chronic opioid therapy.[397] Dr. Mazloomdoost criticized the brochure associated with the 2002 NPEC CME, testifying that it improperly favored opioids over other treatment options and did not adequately warn about opioid dependence.[398] The State and its witnesses also suggested that Janssen and J&J attempted to influence CME content by choosing which ones to fund.[399]

166. But Janssen did not control or influence CME content.[400] The Accreditation Council for Continuing Medical Education ("ACCME") sets the standards for CME content and helps ensure its independence.[401] ACCME guidelines prohibited pharmaceutical companies from influencing CME content, including dictating who will speak at CME programs.[402] Among

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[397] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 75:19-80:9 (discussing "Responsible Opioid Prescribing" CME slides).

[398] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 51:9-18 (testifying that the brochure "subtly" conveys that "opioid management is the mainstay of pain management"), 61:1-62:5 (testifying that the brochure does not pay enough attention to the dangers of opioid dependence).

[399] *See* June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 56:1-14 (testifying that J&J sponsored CME programs because it believed that the programs would have "a positive financial benefit to [the] company"), 67:16-19 (claiming that State Ex. 2364 showed an interest in funding medical programs to increase profits); *see also* State Ex. 2364, Implementing Segmentation Presentation (Nov. 6, 2001) at 2 (*admitted June 13, 2019*) (presentation provided to Janssen from Health Products Research, Inc. that recommended determining "which medical education programs have the greatest ROI by segment").

[400] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 60:11-25 (Janssen did not "have any role in the content development of [] CME programs").

[401] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 94:6-23.

[402] *Id.* at 95:14-97:16 (describing the numerous rules in place to ensure independence of CME content); Janssen Ex. 490, Accreditation Council for Continuing Medical Education, Standards for Commercial Support, Standards to Ensure the Independence of CME Activities (2004) at 2-3 (*admitted June 4, 2019*) (same).

other things, ACCME standards also required that CME providers ensure that CME program materials were "made free of the control of a commercial interest."[403] The State presented no evidence to suggest Janssen or the third parties that developed Janssen-funded CMEs violated those standards, and its expert witnesses failed to address the stringent control over content mandated by the ACCME.

167. To the contrary, the State's witnesses confirmed that Janssen had no influence over CME content. Dr. Portenoy, who worked on several CME programs funded by Janssen, including NPEC, testified that he was never influenced by a CME sponsor and that a pharmaceutical company has never dictated to him the content of a CME.[404] He stated that he never presented or observed any CME that lacked balanced information about the risks and benefits of opioid therapy.[405]

168. Neither Dr. Mazloomdoost nor Dr. Kolodny could point to any evidence that Janssen controlled or influenced the content of the CME activities that it sponsored. Dr. Mazloomdoost could not identify any part of the 2002 NPEC program brochure that Janssen or J&J wrote and could not point to any evidence that "anyone from Janssen or J&J dictated the [brochure's] content."[406] He did not attend the NPEC program, he did not speak with any doctor who prescribed Duragesic at that time, and he did not speak to anyone who had prescribed

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[403] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 99:11-100:12 (testifying about Standard 1, "Independence" in Janssen Ex. 490); Janssen Ex. 490, Accreditation Council for Continuing Medical Education, Standards for Commercial Support, Standards to Ensure the Independence of CME Activities (2004) at 2 (*admitted June 4, 2019*).

[404] Portenoy Depo. Tr. at 331:6-11, 16-19 (*played May 29, 2019*).

[405] *Id.* at 335:11-336:21 ("I never had that experience of watching a CME program and feeling that it was presenting information that was improper."); *see also id.* at 335:11-22 (testifying that all of the CME programs he created aimed to present a "fair and balanced sense of the science as it relates to … use of opioids in chronic noncancer pain").

[406] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 107:9-108:9.

Duragesic based on the information in the brochure.[407] Dr. Mazloomdoost's criticisms of the program stem from a mere difference of opinion: He acknowledged that Dr. Portenoy "has a different view [about] the use of prescription opioids" than he does, and that the NPEC brochure reflects Dr. Portenoy's opinion.[408]

169. That different doctors can hold different opinions about the benefits and risks of opioid medications for their patients is not surprising and says nothing about whether Defendants caused the opioid crisis.

170. The State also presented no evidence that the CMEs Drs. Mazloomdoost and Kolodny criticized were widely viewed in Oklahoma or that any Oklahoma doctor relied on those programs. The State failed to identify a single doctor who claimed to have been influenced by a "Janssen-specific" CME.[409]

E. Lobbying

171. Both independently and through third-party advocacy organizations, J&J lobbied the federal and Oklahoma governments to enact its preferred policies related to pain treatment. The Pain Care Forum ("PCF") lobbied the federal government on behalf of its members, including J&J.[410] And although PCF occasionally lobbied state legislators and regulators,[411] the State presented no evidence PCF conducted any lobbying within Oklahoma. Separately, J&J's

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[407] *Id.* at 103:14-105:16.

[408] *Id.* at 108:10-20.

[409] *See* June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 99:14-20.

[410] State Ex. 304, 2013 National Advocacy Business Planning draft at 6 (*admitted June 19, 2019*); State Ex. 1217, Update & 2013 National Advocacy Business Planning, at 5 (*admitted June 12, 2019*); *see also* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 60:9-63:19 (testifying about State Ex. 1217).

[411] Colligen Depo. Tr. at 55:17-22, 130:1-131:10, 135:4-12 (played June 19, 2019); State Ex. 304, 2013 National Advocacy Business Planning draft, at 6 (*admitted June 19, 2019*).

director of state government affairs, Richard Ponder, occasionally met with Oklahoma officials.[412]

172. The PCF was established in 2005 to provide interested organizations with the opportunity to exchange information and ideas about public policy affecting pain treatment.[413] PCF members include roughly 65 organizations, including the Partnership at DrugFree.org, American Cancer Society, American Pharmacists Association, American Society for Pain Management Nursing, American Society of Anesthesiologists, Amputee Coalition, Hospice and Palliative Nurses Association, St. Jude Medical,[414] and other patient groups, pharmaceutical companies, and stakeholders.[415] The PCF meets once a month for one or two hours.[416]

173. The State sought to characterize the PCF as a pro-opioid organization. Dr. Kolodny referred to the PCF as "the opioid mafia."[417] He testified that he "think[s]" that PCF was "formed and most of its efforts were focused on preserving the status quo, increasing the prescribing of opioids."[418] Although Dr. Kolodny accused the PCF of a lack of transparency, claiming that a "journalist would never be allowed to attend a meeting," he also acknowledged

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[412] Ponder Depo. Tr. at 352:5-15, 17-25 (played June 20, 2019).

[413] *See* Colligen Depo. Tr. at 13:24-14:4, 14:8-24, 48:15-17, 48:19-22, 49:05-18 (played June 19, 2019); State Ex. 1349, Contributions to Advocacy Organizations, at 6 (*admitted June 3, 2019*).

[414] State Ex. 1439, Janssen: Demonstrate Industry Leadership, at 32 (*admitted June 7, 2019*); *see* June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 101:3-102:25, 105:5-106:2.

[415] Colligen Depo. Tr. at 48:15-17, 19-22 (played June 19, 2019); Rosen Depo. Tr. at 55:8-15 (played June 7, 2019).

[416] Rosen Depo. Tr. at 58:3-8 (played June 7, 2019); State Ex. 301, PCF Agenda (*admitted June 19, 2019*).

[417] *See, e.g.*, June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 93:17-94:17, 95:19-25; June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 20:11-13.

[418] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 86:10-24; *see* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 69:4-14, 72:16-73:12 ("And so no, I'm not aware of any evidence that Johnson & Johnson ever had any problem with anything that Purdue Pharma was doing.").

that the PCF not only allowed him to attend a meeting but also permitted him to give a presentation in support of a petition he co-authored urging the FDA to impose quantity and duration restrictions on opioid prescribing and to restrict the indications of long-acting opioids to cancer pain.[419]

174. The State also frequently invoked the PCF in an effort to connect Janssen with Purdue Pharma.[420] The State's attorneys and witnesses repeatedly referenced a single slide from a 2011 "Advocacy Launch Plan" slide deck, which referred to Purdue as a "[p]artner[]" and stated that Janssen and Purdue sat at the "same table" for advocacy-related and other meetings, including those hosted by the PCF.[421] And while Janssen at times participated in the PCF,[422] so did more than 60 other organizations.[423]

175. The PCF engaged in lobbying activity. And contrary to Dr. Kolodny's testimony, the evidence at trial shows the PCF's advocacy focused not only on opioid medications, but on pain management generally.[424] The PCF lobbied the federal government, including members of Congress and a number of federal agencies.[425]

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[419] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 92:12-24, 93:17-94:6.

[420] *See, e.g.*, June 11, 2019 (AM) Trial Tr. (Kolodny Test.) ("Q. And you know that Purdue and Johnson & Johnson were together in the Pain Care Forum, right? A. Yes.").

[421] *See* State Ex. 1439, 2011-2012 Advocacy Launch Plan, at 37 (*admitted June 7, 2019*); *see also* May 29, 2019 Trial Tr. (Beckworth Arg.) at 52:22-53:1; Rosen Depo. at 386:14-394:10; June 26, 2019 (PM) Trial Tr. (White Test.) at 135:6-11.

[422] Rosen Depo. at 38:21-39:24, 393:17-20 (played June 7, 2019).

[423] *See, e.g., id.* at 55:8-15, State Ex. 303, Groups Partnering with Janssen, at 1 (*admitted June 19, 2019*).

[424] Colligen Depo. Tr. at 181:18-182:2 (played June 19, 2019).

[425] State Ex. 304, 2013 National Advocacy Business Planning draft, at 6 (*admitted June 19, 2019*); State Ex. 1217, Update & 2013 National Advocacy Business Planning, at 5 (*admitted June 12, 2019*); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 60:9-63:19.

176. For example, the PCF sought an amendment to the Affordable Care Act requiring the Institute of Medicine ("IOM") to convene a committee to study pain-related issues and draft a report.[426] The PCF also sought enactment of the Military Pain Care Act, a bill that would direct federal agencies to implement a pain-care initiative in military healthcare facilities.[427] And the PCF hosted a briefing on "The Epidemic of Pain in America" at the U.S. House of Representatives.[428]

177. J&J declined to participate in PCF activities with which it disagreed. For instance, although J&J signed PCF letters or comments about federal or state policies "on a couple of occasions," when J&J did not agree with PCF's position—and it frequently did not—it would not sign or participate.[429]

178. Likewise, J&J did not always make the same sponsorship decisions as PCF or PCF members. For example, although PCF and other advocacy groups and pharmaceutical manufacturers sponsored Dr. Scott Fishman's book, *Responsible Opioid Prescribing: A Physician's Guide*, J&J did not.[430]

179. Dr. Kolodny criticized the PCF's lobbying activities, but his broad-brush attacks on those activities did not implicate J&J or Janssen and often lacked any evidentiary support. He claimed that some IOM committee members had "financial relationships" with opioid

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[426] *See* Rosen Depo. Tr. at 279:20-280:14, 280:16-281:1 (played June 7, 2019); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 135:21-138:2.

[427] *See* State Ex. 1429, Email chain between H. Udell, B. Rosen, et al. (*admitted June 11, 2019*); Rosen Depo. Tr. at 269:06-270:22 (played June 7, 2019).

[428] *See generally*, State Ex. 2352, The Epidemic of Pain in America (*admitted June 12, 2019*).

[429] Colligen Depo. Tr. at 55:7-10, 55:12-22, 57:18-21, 57:23-58:5, 95:18-20, 95:22-96:3 (played June 19, 2019).

[430] *See* Gilson Depo. Tr. at 50:15-51:4, 70:12-18, 70:20-72:16 (played June 7, 10, 2019).

manufacturers, impliedly impugning their integrity.[431] Dr. Kolodny stated that although some of the IOM report's language is "actually pretty good," he found other language "problematic."[432] These quixotic aspersions fail to establish facts supporting the State's public nuisance claim.

180. J&J also occasionally lobbied within Oklahoma when Ponder discussed legal and policy issues with Oklahoma lawmakers and regulators. But the State presented no evidence of any action Mr. Ponder took—at a DURB meeting or elsewhere. Nor did the State also offer evidence of any action taken by any Oklahoma official as a result of J&J lobbying activities.[433] In fact, Dr. Muchmore, the Chairman of the DURB, testified that it was "utter nonsense" to suggest that a Janssen representative ever "pushed and marketed and misled" the DURB about "any opioid."[434]

V. THE OPIOID CRISIS

181. All parties to this action agreed at trial that Oklahoma has experienced an opioid crisis that resulted in abuse and misuse of opioid medications, rising incidence of opioid use disorder, and opioid overdose deaths. All parties likewise agreed that these consequences of Oklahoma's opioid crisis are tragic. But the Court finds that Defendants were not a cause of the opioid crisis in Oklahoma.

182. Rather, Oklahoma's opioid crisis has been the product of numerous factors that are an extension of an older, larger, more complex drug-abuse problem that began in the 1960s. It has involved multiple geographically disparate sub-epidemics, each driven by an array of

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[431] *See* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 135:21-138:2.

[432] *See id.*

[433] *See* Ponder Depo Tr. at 320:21-321:2, 325:14-17, 326:18-23, 328:11-14 (played June 20, 2019).

[434] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 16:7-12.

different substances including cocaine, crack cocaine, methamphetamine, heroin, and opioids.[435] Despite the disparate nature of the various sub-epidemics, drug-related overdose deaths have "been inexorably tracking along an exponential growth curve since at least 1979," well before the start of the opioid crisis.[436]

183. All of the sub-epidemics have been driven primarily by illicit international drug trafficking and criminal diversion of prescription drugs in the United States.[437]

A. Illicit drug trafficking by Mexican and Columbian cartels ignited the drug abuse crisis in the 1960s.

184. Illicit drug trafficking began in earnest in the 1960s with Mexican criminal organizations—often referred to as cartels—smuggling marijuana and heroin into the United States.[438] Mexican cartels continued trafficking marijuana and heroin throughout the 1970s and 1980s, and became increasingly adept at avoiding detection by state and federal authorities.[439]

185. Oklahoma was no exception. Former OBNDD agent Dr. John Duncan confirmed that heroin was available and presented an issue in Oklahoma by the 1980s.[440] This is confirmed by the earliest available data on admissions to treatment funded by the Department of Mental Health and Substance Abuse Services, which show that 400 people were admitted to State funded treatment facilities for a heroin addiction.[441] The State contends that prescription opioid

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[435] *See* Janssen Ex. 685, Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016 at 2, (*admitted July 11, 2019*).

[436] *Id.* at 6.

[437] *See* July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 17:9-18:4, 92:21-93:17; Janssen Ex. 685, Figure 1 (Charts A & B), Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016 at 2 (*admitted July 11, 2019*).

[438] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 19:5-20:25.

[439] *Id.*

[440] *Id.* at 86:6-24, 88:13-90:3; Court Ex. 213.

[441] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 88:13-89:9.

abuse led to heroin abuse in Oklahoma, but even in 1999, more people were admitted to treatment for heroin addiction than addiction to prescription opioids.[442]

186. In the 1970s, Columbian cartels began to emerge—including the Medellin cartel with its infamous leader Pablo Escobar.[443] They initially smuggled marijuana and cocaine into the United States. By the 1980s, they had increased production of cocaine and also began cultivating opium poppy for heroin; both were trafficked into the United States.[444] Not to be outdone, Mexican cartels added cocaine to their portfolio of illicit drugs by the 1990s.[445] Cocaine and crack cocaine seizures skyrocketed at the turn of the century,[446] and parts of the United States experienced a crack cocaine epidemic in the 1980s and 1990s.[447]

187. Methamphetamine abuse has posed a serious threat in Oklahoma for decades.[448] Although it was originally produced in small scale local operations, domestic production declined following DEA and OBNDD crackdowns in the early 2000s.[449] Mexican cartels quickly entered the methamphetamine business to fill the supply gap and have since "flooded" Oklahoma with cheap methamphetamine.[450] Today, "methamphetamine poses the most

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[442] Janssen Ex. 494, Email from Mark Reynolds to Claire Nguyen (listing admissions to treatment from 1999 to 2013) at 1 (*admitted July 11, 2019*).

[443] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 22:4-14.

[444] *Id.*

[445] *Id.* at 26:17-27:7.

[446] Janssen Ex. 542, OBN 2003 Annual Report at 23-24 (*admitted June 25, 2019*).

[447] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 24:5-11.

[448] Id. at 24:2-5 ("Domestic production of methamphetamines became pervasive in the United States over the 1980s and into the 1990s, certainly in Oklahoma as well.").

[449] *Id.* at 24:12-16; Janssen Ex. 542, OBN 2003 Annual Report at 21-24 (*admitted June 25, 2019*).

[450] *See* July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 24:12-16; Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment at 7 (*admitted June 18, 2019*).

significant illicit drug threat to the state."[451] More fatal overdoses and admissions to treatment are attributable to methamphetamine than any other substance.[452]

188. At roughly the same time they began methamphetamine production, Mexican cartels established initial contacts with Chinese criminal organizations, often called triads, to establish a network for importation of illicit fentanyl powder into Mexico for ultimate distribution in the United States.[453] By the mid-2000s, and especially after 2010, illicit fentanyl emerged as a serious threat across the United States, including in Oklahoma.[454] Today, illicit fentanyl and fentanyl analogs are found laced into heroin, cocaine, and methamphetamine at alarming rates.[455] Heroin has reemerged as a serious threat.[456] Illicit fentanyl is also laced into counterfeit prescription opioids manufactured primarily in Mexico, but also in clandestine labs in Oklahoma.[457] These drugs look practically identical to commonly abused prescription opioids like Lortab and OxyContin, but are in fact laced with deadly illicit fentanyl.[458]

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[451] Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment at 7 (*admitted June 18, 2019*); *see* Janssen Ex. 2951, OBNDD 2018 Drug Threat Assessment at 6 (*admitted July 11, 2019*).

[452] *See* Janssen Ex. 625, ODMHSAS Admissions to Treatment by Drug of Choice (2012-2018) (*admitted June 24, 2019*); Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System: Data Update (2007-2017) at 9 (*admitted June 6, 2019*).

[453] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 20:17-25.

[454] *Id.* at 24:16-18 ("And by the mid-2000s, we saw illicit fentanyl and fentanyl-laced drugs emerge as a significant problem across the United States and in the State of Oklahoma as well."), 78:10-25 (recounting Dr. Pfeifer's testimony on illicit fentanyl being present in Oklahoma as soon as he began as Chief Medical Examiner in 2011).

[455] *See* Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment at 12-13 (*admitted June 18, 2019*).

[456] *See* Janssen Ex. 2951, OBNDD 2018 Drug Threat Assessment at 18-19 (*admitted July 11, 2019*).

[457] Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment at 13 (*admitted June 18, 2019*).

[458] *See* Janssen Ex. 1774, Email from Pfeifer to the National Association of Medical Examiners Mailing List (discussing presence of counterfeit prescription opioid pills in Oklahoma) at 1

B. Non-medical use, abuse, and diversion, especially of OxyContin and hydrocodone products, fueled the opioid crisis in Oklahoma.

189. Another primary factor that fueled the opioid crisis in Oklahoma, criminal diversion of prescription drugs—primarily hydrocodone and oxycodone—has plagued Oklahoma for decades.[459] In 1990, Governor Henry Bellmon sounded the alarm about diversion in Oklahoma and urged the legislature to stop "professional patients" who "dupe doctors into writing prescriptions."[460] But diversion and abuse continued following the 1996 introduction of OxyContin, which abusers "crushed and ingested, snorted, or injected to circumvent [the] controlled release mechanism and obtain [the] full dose immediately."[461] OxyContin found its

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(*admitted July 18, 2019*); Janssen Ex. 624, OBNDD 2017 Drug Treat Assessment at 13 (*admitted June 18, 2019*).

[459] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 59:13-25, 63:16-64:10 (recounting former Oklahoma Bureau of Narcotics and Dangerous Drugs ("OBNDD") agent Dr. John Duncan's deposition testimony regarding diversion of prescription opioids, primarily hydrocodone, along with other drugs, in the 1980's), 68:8-21 (explaining that Governor Henry Bellmon "sound[ed] the alarm about diversion of pharmaceutical pills as early as 1990" and asked the legislature to stop doctor shoppers); Court Ex. 212 at 36 (Senate Journal entry containing statement from Governor Bellmon that "[w]e must stop professional 'patients' who dupe doctors into writing prescriptions for these drugs and then sell this illegal bonanza on the streets"); July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 71:2-8 (concluding based on Governor Bellmon's statements on diversion and the 2008-2012 OBNDD strategic plan, "that diversion remained a major problem in the State of Oklahoma" into the 2000s); Janssen Ex. 217, FY 2008-2012 Strategic Plan for OBNDD at 7 ("A persistent problem in Oklahoma is the diversion of legitimate pharmaceutical drugs to illicit use. . . . Hydrocodone remains the most abused pharmaceutical drug in Oklahoma. OxyContin, Methadone, and other opiates are also frequently abused and commonly result in overdose deaths.") (*admitted June 25, 2019*); July 11, 2019 (PM) Trial Tr. (Bagley) at 71:9-72:8 (concluding, based on 2018 OBNDD Drug Threat Assessment, that diversion of pharmaceutical drugs, including opioids, remains a significant threat in Oklahoma); Janssen Ex. 2951, 2018 OBNDD Threat Assessment at 15 (*admitted July 11, 2019*); Janssen Ex. 624, 2017 OBNDD Drug Threat Assessment at 11 ("The diversion of pharmaceutical drugs continues to increase in Oklahoma.") (*admitted June 18, 2019*).

[460] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 67:19-69:9; Court Ex. 212.

[461] Janssen Ex. 2455, DURB Meeting Packet (May 14, 2002) at 45-46 DURB Meeting Packet(*admitted June 25, 2019*); *see* Janssen Ex. 802, March 2002 Drug Intelligence Brief from U.S. DEA, contained in DURB Meeting Packet for March 11, 2003 Meeting at 78, 85 DURB Meeting Packet (concluding that "[t]he illegal use and sale of OxyContin is a growing problem

way "right [to] the top" of list of most abused drugs, alongside hydrocodone products.[462] As diversion, misuse, and abuse of prescription opioids increased, opioid-related overdose deaths also increased.[463] For years, rates of nonmedical use of opioid pain relievers in Oklahoma were among the highest—and sometimes the highest—in the nation.[464]

190. That surge in opioid abuse, like the prior abuse cycles involving heroin, methamphetamine, and cocaine, was part of a larger trend: As prescription opioid overdose deaths in Oklahoma increased, so did overdose deaths from alcohol, muscle relaxers, benzodiazepines, cocaine, and methamphetamine.[465] But, at least in Oklahoma, that trend has already begun changing. Methamphetamine deaths have increased 600 percent since 2007 and in

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throughout the nation" and explaining that "[f]rom 1996 to 1999, the number of drug abuse deaths reported to DAWN that involved oxycodone more than quadrupled") (*admitted June 25, 2019*); June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 30:13-18 (Q. In 1996, the rate of opioid use began accelerating rapidly. This acceleration was fueled in large part by the introduction in 1995 of OxyContin, an extended-release formulation of oxycodone manufactured by Purdue Pharma. That's a statement you made in this article. Correct? A. Correct.").

[462]Janssen Ex. 1514, February 13, 2013 DURB Meeting Transcription at 67:1-19 (*admitted June 26, 2019*).

[463] *See* State Ex. 1569, Increase in Unintentional Medication Overdose Deaths, Oklahoma, 1994-2006 at 1-2 (explaining that "[u]nintentional overdose deaths are increasing in Oklahoma and often involve multiple substances" and that "nonmedical use of controlled medications is increasing" too) (*admitted June 7, 2019*); Janssen Ex. 673, 2013 Oklahoma State Board of Pharmacy Drug Diversion Prevention Presentation at 15 (showing that 61% of analyzed opioid overdose victims had no prescription and 18% were doctor-shopping—i.e., had prescriptions for controlled substances from five or more doctors) (*admitted June 26, 2019*).

[464] *See* State Ex. 1223, CDC MMWR for Opioid Pain Reliever Overdose Data from 1999-2008 at 8-10 (listing Oklahoma as having the highest percentage of nonmedical use) (*admitted June 3, 2019*); Janssen Ex. 624, 2017 OBNDD Oklahoma Drug Threat Assessment at 12 ("CDC data from 2009 ranked Oklahoma number one for nonmedical use of opioid pain relievers.") (*admitted June 18, 2019*).

[465] *See* State Ex. 1569,Increase in Unintentional Medication Overdose Deaths, Oklahoma, 1994-2006 at 5 (Table 2 illustrating greater than 4x increase in alcohol overdose deaths, 4.5x increase in cocaine overdose deaths, 5x increase in muscle relaxer carisoprodol [Soma] overdose deaths, approximately 10x increase in methamphetamine overdose deaths, and 27x increase in alprazolam [Xanax] overdose deaths) (*admitted June 7, 2019*).

2017, methamphetamine surpassed prescription opioids as the most common drug involved in unintentional overdose deaths in Oklahoma.[466] Meanwhile, prescription opioid overdose deaths have fallen by 43 percent since 2013.[467]

191. Together, the illegal drug trade and criminal diversion of prescription drugs have driven the broader cycles of drug-abuse crisis in Oklahoma.[468] These factors have created difficult decisions for policymakers, who recognize the risk of diversion and abuse but also know that prescription opioid medications are essential for the treatment of chronic and acute pain in patients in Oklahoma and across the United States.

VI. THE STATE'S PURPORTED ABATEMENT PLAN ABATES NOTHING

A. The State's plan does not seek to abate Janssen's conduct

192. The State's purported abatement plan bears no resemblance to the abatement remedies imposed by Oklahoma courts for more than a century. It does not aim to curtail any of Janssen's conduct.[469] Nor could it: Janssen stopped marketing prescription opioids years ago, leaving no conduct to curtail.[470] And it has nothing to do with Janssen's specific prescription

[466] Janssen Ex. 3929, Winter 2019 IPS Publication "Tracking Overdose Deaths: Meth Surpasses Opioids" at 1 (noting that "[f]rom 2007-2017, the rate of methamphetamine-related overdose death[s] increased by 600 percent.").

[467] *Id.*

[468] July 11, 2019 (PM) Trial Tr. (Bagley Test.) at 17:14-22.

[469] *See* State's Abatement Plan, at 5-75, 97-104 (*admitted June 21, 2019*).

[470] *See* June 4, 2019 (AM) Trial Tr. (Deem-Eshelman Test.) at 45:24-46:3 (Duragesic marketing ended around 2007), 45:6-8 (Janssen divested the Nucynta brand in 2015).

opioid medications or to any conduct by Janssen at all.[471] Much of the plan reaches beyond prescription opioids entirely.[472]

193. The plan seeks payment for the purported cost of providing myriad public health and educational services, essentially all of which are already provided by SoonerCare, State employee health plans, private health plans, grants, or other established resources.[473] To explain why Janssen should pay for these services, the State offers little more than a conclusory aversion to the government paying for services it already provides.[474] The State's plan amounts to a request for money damages or penalties—not abatement. As discussed in Section IX, *infra*, the State's nuisance claim therefore fails as a matter of law.

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[471] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 8:11-16 ("Q. Right. Because as I think we've heard on numerous occasions throughout the trial, the case isn't about Janssen and Johnson & Johnson's drugs. Right? A. The State's abatement plan is to abate the opioid crisis, not to abate the -- the Janssen's Nucynta crisis or Duragesic crisis. It's to abate the opioid crisis.").

[472] *See e.g.*, June 20, 2019 (AM) Trial Tr. (Croff Test.) at 103:21-24 (testifying that the licensed alcohol and drug counselors on campus would treat students for addiction to *any* substance); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 35:4-36:1 (confirming that methamphetamine use can cause NAS, but that neonatal evaluation and assessment in the plan would still cover those births), 57:6-11 (envisioning "the entire population entering into this [health information exchange] system.").

[473] *See* June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 80:22-81:2.

[474] *See* June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 44:6-15 ("A. [T]here's no reduction for [the 62.38% federal Medicaid contribution] in [the pain services portion of the abatement plan], if that's what you're asking .... These are the costs of those services and Johnson & Johnson and Janssen should be responsible to abate the opioid crisis, not the taxpayers."); June 24, 2019 (PM) Trial Tr. (Hawkins) at 37:25-38:6 ("Q [T]hose services that are being provided, is the assumption here than Janssen and Johnson & Johnson will pay for that naloxone distribution and education on a going-forward basis if this plan is implemented? A. Yes. Because those grant funds come from taxpayer dollars and the taxpayers should not have to pay to abate the opioid crisis.").

B. The State has not demonstrated that the plan will remedy or is necessary to remedy its alleged harms

194. Setting aside that legal failure, the State has not shown that its purported abatement plan will remedy anything, let alone that it is necessary to remedy any existing opioid problems.

195. The abatement is a list of services and associated costs. The State has not defined what it means to "abate" the opioid crisis. It has set no tangible goals or evaluated how the services identified will meet those goals. Although the State's witnesses testified in conclusory terms that all of the listed services are necessary,[475] neither they nor the State suggested any objective metrics that could be used to measure the plan's success or failure.[476]

196. To the extent the State seeks to return certain opioid-related indicators to "pre-1996 levels," it has neither defined those levels nor explained why they are the correct ones. Likewise, the State has not assessed how, whether, or when its proposed services will accomplish that undefined goal.[477] The Court cannot determine the necessity of a plan designed

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[475] *See e.g.*, June 21, 2019 (AM) Trial Tr. (Hawkins Test.) at 9:8-19 ("Q. And Ms. Hawkins, based on your experience, skills, and training, do you believe that the addiction treatment supplementary services are necessary to abate the Oklahoma opioid crisis? A. Yes."), 11:2-8 ("Q. And based on your education, training, and experience, do you have an opinion as to whether the addiction and mental health help line is necessary to abate the Oklahoma opioid crisis? A. Yes. Q. And what is that opinion? A. It is necessary."), 16:13-23 ("Q. And let's go back to public medication disposal. Based on your training and qualifications, experience, education, do you have an opinion as to whether public medication disposal is necessary to abate the Oklahoma opioid crisis? A. Yes. It is necessary. Q. And do you have an opinion as to whether the cost that you described for public medication disposal are reasonable and necessary costs to implement this portion of the abatement plan? A. Yes. The costs are reasonable and necessary.").

[476] *See* June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 64:20-23 ("Q. Well, what are -- what are the outcome measures? A. There is not an evaluation plan yet to accompany this abatement plan. We would expect to see outcomes in certain areas, but that plan has not been developed yet."), 68:10-25; June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 89:6-13.

[477] *See* June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 82:2-9 ("[I]f we can get a well-funded abatement plan we should go back to 1996, pre-1996 levels."); June 21, 2019 (PM) Trial Tr.

to achieve unknown goals. And both the FDA and the CDC have warned against a simplistic approach focused solely on reducing opioid prescriptions; they instead recommend striking a balance between the risks of misuse and the benefits of legitimate access to treatment.[478]

197. Similarly, the State has "done nothing to set up the intervals of time by which any process or outcome measures would be assessed."[479] Though several witnesses testified that the plan "will take at least 20 years"[480] to work, the State actually has no idea if the plan will be effective at all, let alone how long it might take. It made no effort to conduct the kind of analysis

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(Hawkins Test.) at 67:16-68:3 ("I have confidence that through this abatement plan at the 30-year interval, that this problem can be abated, at least back to the pre-1996 levels."); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 86:22-87:19 (failing to provide an actual figure for "pre-1996 levels" of high school painkiller misuse, testifying instead that the State still "need[s] to set those baselines, yes."); June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 90:24-91:24 (with respect to pre-1996 levels of opioid use disorder, testifying that "I don't have that number with me" and noting that NSDUH data does not go back to 1996); June 26, 2019 (AM) Trial Tr. (White Test.) at 25:19-26:10 (failing to note exactly how many Duragesic prescriptions is "too many," testifying that "I don't have an exact number memorized of what we had pre-'96 to today .... Can I tell you the exact number that it should be pre-'96? I did not memorize those. I'm sorry, I don't know that here today ...."), 109:2-18 ("I don't believe that Nucynta was measured prior to '96 ....").

[478] FDA, *May 13, 2019 Memorandum re Opioids Regulatory Background, FDA Center for Drug Evaluation and Research* at 10 (May 2019 FDA report, declining to recommend limits on doses for prescription opioid medications, and emphasizing that "[i]nadequately treated chronic pain has consequences" and that "[i]t is important to consider the potential repercussions of well-meaning attempts to address the opioid crisis without adequate scientific evidence to support such actions."), available at *https://www.fda.gov/media/127780/download*; State Ex. 1223, CDC Morbidity and Mortality Weekly Report (Nov. 4, 2011) at 4 (warning that "[p]ublic health interventions to reduce prescription drug overdose must strike a balance between reducing misuse and abuse and safeguarding legitimate access to treatment.") (*admitted June 3, 2019*).

[479] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 65:12-66:1.

[480] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 87:20-88:1.

that would be necessary to determine the amount of time or resources required to abate the opioid crisis.[481]

198. Aside from the lack of any evaluation measures, the plan itself does not appear to be designed to achieve any kind of abatement. The plan assumes that the number of people in need of treatment services and the inflation adjusted costs associated with all services will remain the same for the plan's 30-year duration.[482] In other words, the plan presupposes that the same number of Oklahomans who need treatment today will need treatment in 2049. And the plan's principal architect agreed that the need for these services would not cease even after the plan's 30-year run.[483]

199. With only a few exceptions, the services in the plan are already available in Oklahoma through State agencies or privately funded entities.[484] Because Oklahomans already have access to these services, the State's request that Janssen now pay for them cannot possibly

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[481] *See* June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 91:6-12 (explaining that "once the scope and duration of the plan is known, th[e] implementing plans and evaluation plans will be fully developed").

[482] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 71:10-22.

[483] *See id.*

[484] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 43:24-44:3 (P.3), 105:6-106:11 (P.3), 9:10-16 (M.1), 65:25-66:10(M.2), 70:12-71:13 (M.3), 79:25-80:4 (M.4), 85:20-86:1 (M.5); June 20, 2019 (PM) Trial Tr. (Croff Test.) at 48:10-49:5 (M.4), 56:22-57:7 (M.5); June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 78:8-79:24 (T.8); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 41:16-25 (T.10), 75:15-76:17 (T.11), 85:15-21 (T.11), 31:25-34:22 (N.1), 12:14-18 (N.2), 17:10-18:22 (N.3), 46:8-14 (D.1), 50:1-9 (D.2), 54:25-56:21 (D.4), 59:2-18 (D.5), 68:4-12 (D.6); June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 78:23-79:4 (T.1), 82:13-16 (T.2), 54:12-55:1 (T.3), 18:12-21 (T.4), 57:15-22 (T.5), 64:7-65:3 (T.7), 16:16-20 (T.9), 11:5-9 (T.14), 36:1-3, 37:13-24 (P.1), 41:16-42:8 (P.2); State Ex. 4734, State's Abatement Plan set forth in Expert Report of Christopher Ruhm, Ph.D. (hereinafter "State's Abatement Plan") at 65-70 (C.1) (*admitted June 21, 2019*); Janssen Ex. 3934, Prenatal Continuing Education Program Webpage (N.1) (*admitted June 24, 2019*).

be necessary to remedy the opioid crisis. Rather, by requesting that Janssen fund services already offered, the State makes clear that its plan is a demand for money damages or a penalty.

200. Thus, the State has not carried its burden of demonstrating that the abatement plan is reasonable and necessary to abate any existing opioid problems in Oklahoma.

C. The State has not demonstrated that any of the services in the purported abatement plan are necessary to remedy any alleged harms

201. The State failed to demonstrate that any individual service is reasonable and necessary on its own.

202. *T.1/T.2 - Addiction Treatment Services and Supplemental Addiction Treatment Services*. The State requests $232.95 million a year for addiction treatment services.[485] It also requests $85.96 million in the first year and $30.16 million a year thereafter, to fund supplemental treatment services, such as halfway houses.[486]

203. Oklahomans already have access to these services through private insurance plans, State employee insurance plans, or SoonerCare—and the federal government reimburses the State for 62.38% of SoonerCare's costs.[487] Transferring the cost of these existing, already-funded services to Janssen would constitute a penalty or damages, remedies unavailable to the State under Oklahoma's public-nuisance law.[488] The State offered no reasoned analysis of how requiring Janssen to pay for services that already exist, that are already covered by State and private insurance plans, and that extend far beyond Janssen's opioid medications—even beyond

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[485] State's Abatement Plan at 19 (T.1).

[486] *Id.* at 20 (T.2). Ms. Hawkins testified that her answers with respect to T.1 applied equally to T.2. *See* June 24, 2019 (PM) Trial Tr. (Hawkins) at 82:13-16 ("Q. And by the way, the answers to these questions are the same for the services that are contemplated in Section T.2, supplementary services. Correct? A. Correct.").

[487] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 78:23-79:4.

[488] *See id.* at 77:10-79:4.

prescription opioids generally—is necessary to remedy existing opioid problems.[489] Nor did the State provide any objective criteria to measure the success of these services.[490]

204. The plan's size and scope, and its lack of supporting analysis, demonstrate that it amounts to a hoped-for windfall, not a list of indispensable services. The yearly cost for addiction treatment services alone is more than two-thirds of the entire FY2019 budget for the Oklahoma Department of Mental Health and Substance Abuse Services.[491] And while that department asks for $232 million a year in the abatement plan, it sought only $500,000 for prescription drug abuse prevention in its FY2020 budget request.[492] At the same time, it requested $37.8 million for alcohol dependence treatment and $3.5 million for marijuana treatment and prevention.[493] Those requests, coupled with the fact that only ten percent of all admissions to addiction treatment are for opiates, demonstrate that the State's request is excessive.[494] That would remain true even if the Court were to assume that shifting the costs of services covered by SoonerCare, the State employee health plan, or private insurance to Janssen was an appropriate remedy for the State's public nuisance claim. It is not.

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[489] *See id.* at 77:16-24 (T.1 includes those receiving treatment covered by private insurance), 78:23-25 (T.1 includes those receiving treatment covered by SoonerCar), 81:3-16 (T.1 includes those who never received a prescription for any opioid medication).

[490] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 68:10-25.

[491] June 24, 2019 (PM) Trial Tr. (Hawkins) at 67:8-68:22; *compare* Janssen Ex. 627, FY2020 ODMHSAS Budget Presentation at 16, (FY2019 ODMHSAS budget: $337.11 million) *with* State's Abatement Plan at 19 (yearly cost of addiction treatment: $232.94 million).

[492] Janssen Ex. 627, FY2020 ODMHSAS Budget Presentation at 16 (*admitted June 24, 2019*).

[493] *Id.*

[494] Janssen Ex. 625 at 1, ODMHSAS Admissions to Treatment by Drug of Choice (2012-2018) (indicating that 10.3% of all admissions were for opiates, with the top three admissions categories being methamphetamine, marijuana, and alcohol, respectively) (*admitted June 24, 2019*).

205. In addition, the plan provides addiction treatment services to exactly the same number of OUD patients, at the same approximate cost, every year for the plan's 30-year duration.[495] This demonstrates that the State is simply requesting money to cover the cost of providing public health services that have long existed and, according to the State's own plan, will continue to exist regardless of whether funding for these services is transferred to Janssen.

206. Accordingly, the State has not demonstrated that T.1 and T.2 are reasonable and necessary.

207. *T.3 - Addiction and Mental Health Hotline*. The State seeks $4.09 million a year to fund an addiction and mental health helpline.[496]

208. This service addresses all addiction issues, not just those related to opioid medications, as well as mental health issues; it is not tailored to the nuisance alleged by the State. Oklahomans already have access to numerous free addiction and mental health hotlines, including hotlines offered by the Oklahoma Department of Mental Health and the federal Substance Abuse and Mental Health Services Administration ("SAMHSA").[497] The State offered no explanation for how the service identified in the abatement plan might meaningfully differ from existing services.[498] Nor did the State demonstrate how it would implement the service, failing to specify the number of employees that would be covered by the hotline's $4.09 million annual budget. The State also made no effort to tie the need for this service to any conduct by Janssen.

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[495] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 71:10-22.

[496] State's Abatement Plan at 21 (T.3).

[497] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 54:12-55:1.

[498] *See id.* at 50:23-52:20.

209. The State offered no reasoned analysis of how this service will remedy anything, so T.3 is not reasonable and necessary.[499]

210. *T.4 / T.9 - Public Medication and Pharmacy Disposal*. The State requests $139,883 a year for public medication disposal, plus $10.26 million for the first year and $9.26 million a year thereafter to develop pharmacy-based medication take-back programs.[500]

211. The State has provided public medication disposal through the OBNDD since 2011.[501] None of the State's witnesses explained why Oklahoma needs additional medication disposal boxes, which can be used for any type of medications, given already available options.[502] Likewise, retail pharmacies in Oklahoma already provide the same type of pharmacy-based disposal services called for by the plan.[503]

212. Because these programs already exist, the State has not shown that either T.4 or T.9 is reasonable and necessary.

213. *T.5 - Technical Assistance*. The State seeks $945,806 a year for technical assistance and training for OUD assessment and treatment.[504]

214. The State already provides technical assistance services.[505] Federal grants fund those services.[506] And most Oklahoma Department of Mental Health and Substance Abuse

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[499] *Id.*

[500] State's Abatement Plan at 22, 28 (T.4, T.9).

[501] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 18:16-21.

[502] *See, e.g., id.* at 17:5-18:6.

[503] *Id.* at 16:16-20.

[504] State's Abatement Plan at 23 (T.5).

[505] June 20, 2019 (PM) Trial Tr. (Hawkins Test.) at 79:6-9 ("We take a very active role at the Department of Mental Health and Substance Abuse Services when we contract for services. We are often out in the field of providing guidance and technical assistance.").

[506] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 57:15-22.

Services employees are already "trained in public health and have field experience and provide direct assistance out in the communities."[507] The State provided no analysis of how shifting the expenses associated with these services to Janssen would remedy any alleged harm, nor did it make any showing of necessity.

215. Thus, T.5 is not reasonable and necessary.

216. *T.6 - Specialty Courts*. The State seeks $15.87 million a year to develop family drug courts.[508]

217. These services are already funded—at least in part—by recent grants from the U.S. Department of Justice.[509] The State did not take those grants into account when determining the purported cost of providing specialty courts.[510] Ms. Hawkins, the principal witness who testified about details of the plan, did not know whether the specialty courts would be available only to individuals with OUD or to individuals with other drug addictions.[511] And the State offered no explanation for why these services would cost $15.87 million a year, every year for 30 years, when Commissioner White has repeatedly represented that drug courts actually pay for themselves by returning individuals to working society rather than incarcerating them, in turn generating millions more in tax revenue every year.[512]

218. The State did not establish that T.6 is reasonable and necessary.

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[507] *Id.* at 79:10-13.

[508] State's Abatement Plan at 24 (T.6).

[509] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 60:1-6.

[510] *Id.* at 60:1-20.

[511] *Id.* at 61:4-62:23.

[512] Janssen Ex. 627, FY2020 ODMHSAS Budget Request at 5-6 (explaining that State could expect to be paid $6.1 million in total tax revenue from drug court graduates over the FY2010 to FY2012 period) (*admitted June 24, 2019*).

219. *T.7 - Transportation Services*. The State seeks $6.13 million a year to provide treatment and recovery transportation for those receiving OUD treatment.[513]

220. SoonerCare already covers these services—in fact, the State based T.7's annual cost on the State's existing SoonerRide program.[514] Transferring the cost of existing, funded services to Janssen would constitute a penalty or damages unavailable to the State under Oklahoma's public-nuisance law. The State also failed to provide any analysis of why each of the estimated 35,000 people receiving OUD treatment in Oklahoma,[515] already covered by existing insurance plans, would need transportation services. And, again, the State provided no explanation for why it must require Janssen to pay for services that already exist.

221. Accordingly, the State failed to demonstrate that T.7 is necessary.

222. *T.8 - Universal Screening*. The State seeks between $48.48 million and $89.98 million a year to fund four universal alcohol and substance abuse screenings every year for all SoonerCare beneficiaries.[516]

223. SoonerCare already covers these services, and the federal government reimburses the State for those costs based on Medicaid guidelines.[517] Again, transferring the cost of existing, funded services to Janssen would constitute a penalty or damages unavailable to the State under Oklahoma's public nuisance law. The State did not consider any of the existing funding sources when determining the costs it seeks from Janssen.[518] Nor did the State explain

[513] State's Abatement Plan at 25 (T.7).

[514] *See id.* at 25, n.36; June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 64:7-65:3.

[515] State's Abatement Plan at 25, n.36.

[516] State's Abatement Plan at 26-27 (T.8).

[517] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 78:8-79:22.

[518] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 9:3-6.

how requiring Janssen to pay for services that already exist—and services for patients who have not been exposed to opioids—will remedy any opioid-related harms. Similarly, the State made no effort to explain why it is necessary for Janssen to bear the costs associated with these services, which extend far beyond opioid use and abuse.[519]

224. For all these reasons, T.8 is not reasonable and necessary.

225. *T.10 - Pain Services*. The State seeks $103.28 million a year to fund pain services for 32,178 SoonerCare members who received three or more opioid prescriptions in 2017, regardless of whether Janssen manufactured those opioids.[520]

226. Many of these pain services are already covered or could be covered by SoonerCare, and would benefit from the federal government's 62.38% reimbursement rate.[521] The State again failed to take existing funding sources into account.[522] Transferring the cost of existing, funded services to Janssen would constitute a penalty or damages unavailable under Oklahoma's public nuisance law. The State also made no attempt to explain why all patients receiving three or more opioids would have any medical need for the pain services. Finally, to the extent the State believes remedying the opioid crisis requires reducing the number of opioid prescriptions by transferring patients to alternative pain treatments, it fails to explain why the number of relevant patients and the cost of providing them services remain the same for the duration of the abatement plan.

227. Thus, T.10 is not reasonable and necessary.

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[519] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 80:3-16.

[520] State's Abatement Plan at 29 (T.10); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 42:1-6.

[521] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 43:4-45:11.

[522] *Id.* at 44:6-20.

228. *T.11/T.12 - K-12 Prevention and Supplemental Prevention Services*. The State seeks $55.96 million in year one and $26.61 million a year thereafter to fund K-12 prevention programs in Oklahoma schools.[523] It seeks another $68.16 million a year in discretionary funds to be used for prevention and intervention.[524]

229. Some Oklahoma public schools already offer these exact services, which reach far beyond opioid medications.[525] And all Oklahoma schools already have resources for substance-abuse prevention. The State conducted no analysis that demonstrates additional services are needed to remedy any existing problems. The State also provided no explanation for why it needs more than $68 million a year in "discretionary" funds, let alone how those funds would remedy existing harms.[526]

230. The Court agrees that these services may be desirable for a number of broad policy reasons, but the State has not shown they are reasonable and necessary in this case. Nor has the State offered any reason why requiring Janssen to pay for these already-funded programs would constitute anything other than damages or a penalty, which are unavailable here.

Thus, T.11 and T.12 are not reasonable and necessary.

231. *T.13 - Community Prevention*. The State seeks $18.476 million a year to fund community-based prevention services.[527]

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[523] State's Abatement Plan at 31-33 (T.11)

[524] *Id.* at 34 (T.12).

[525] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 75:15-76:17, 77:17-78:15, 85:7-9, 91:20-92:5.

[526] *Id.* at 85:22-86:21.

[527] State's Abatement Plan at 35-36 (T.13).

232. These services already exist, funded in part by federal block grants.[528] The services would also extend to individuals who never took Janssen opioids or any opioids at all.[529] And, although Ms. Hawkins testified that "[t]his is different" than the community mental health centers that exist "across the state," she made no effort to explain how so, or why existing centers could not provide any new services.[530] The State also offered no reasoned analysis demonstrating how these services, to the extent they are not already offered, would remedy any existing opioid problems.

233. T.13 is not reasonable and necessary.

234. *T.14 - Higher Education Discretionary Prevention Funds.* The State seeks $10.15 million a year to hire health professionals and provide discretionary funds for Oklahoma colleges and universities to develop substance-abuse prevention services.[531]

235. Colleges in the State already have health professionals that focus on substance abuse and provide substance-abuse services.[532] The State has made no effort to demonstrate how additional health professionals would remedy any existing opioid problems.[533] Nor has the State shown that hiring additional health professionals to provide services to patients without any connection to opioids will remedy existing opioid problems.[534] And the State has not

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[528] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 6:7-22.

[529] *Id.* at 6:23-7:7.

[530] *Id.* at 5:12-24 (failing to explain how existing community mental health centers differ from the measures sought in T.13).

[531] State's Abatement Plan at 37 (T.14).

[532] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 11:5-9.

[533] *Id.* at 9:23-10:15.

[534] *Id.* at 10:9-15.

demonstrated how discretionary funds would remedy opioid related problems, let alone shown that those funds are necessary.

236. The State has not met its burden of demonstrating T.14's services, which extend far beyond opioid abuse, are reasonable and necessary.[535]

237. *T.15 - Public Education*. The State seeks between $6.3 million and $26.69 million annually for advertising about the abatement plan itself and about the risks of opioid abuse and addiction.[536]

238. The State's witnesses testified that Oklahoma has been telling doctors and the public about the risks of opioid medications for years.[537] All of the Oklahoma doctors who testified in this case said they knew the risks associated with opioid medications, and had for decades.[538] The State provided no testimony or analysis demonstrating that the public is unaware of the risks of abuse and addiction associated with opioids.

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[535] *Id.* at 10:13-11:4.

[536] State's Abatement Plan at 48 (T.15).

[537] June 25, 2019 (AM) Trial Tr. (White Test.) at 51:17-52:13; June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 45:17-46:14 (Project ECHO), 114:16-117:24 (CMEs), 143:23-144:18 (OSU's services for OUD).

[538] July 12, 2019 (AM) Trial Tr. (Phillips Test.) at 27:6-18 ("Q. Thank you, Doctor. Based on your knowledge, training, and experience, do you understand that opioids have risks associated with their use? A. Yes. Going back to medical school, that -- we are taught basic pharmacology. And I think this is still the same today, in speaking to my son that's just recently finished medical school. Since I'm in the field, we -- I tend to talk to him about that particular area more than others. That has not changed in the last 35 years since I was in medical school. Now, you're taught pharmacology on all medications, and part of that training, when it comes to opioids, are training of the risk that goes along with that, including addiction."); July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 13:7-10 ("Q. And you are aware that these medications that come with FDA-approved labels that indicate what the medicine's for and these various risks and hazards associated with it? A. I'm very aware of that."), 14:8-14 ("Q. Well, I wish I could ask it as well as I asked it the first time to draw that objection again. Doctor, in this -- in this case, the State has maintained that Oklahoma physicians are unaware of the risks and benefits of opioid medications. Do you agree? A. I think that's utter nonsense. I think every physician is aware.");

239. The State did not demonstrate T.15 is reasonable and necessary.

240. *P.1 - Naloxone Distribution*. The State seeks $1.59 million in year one and $1.58 million a year thereafter to fund naloxone distribution and education efforts.[539]

241. The State already provides Naloxone to numerous state agencies and at-risk individuals,[540] and grants from the CDC and SAMHSA cover the State's costs.[541]

242. The State has not shown that requiring Janssen to pay for naloxone is reasonable and necessary.

243. *P.2 - Grief Support Services*. The State seeks $1.22 million a year to fund at least one grief support group, specifically for individuals impacted by overdose death, in each of Oklahoma's 17 community mental health center service regions.[542]

244. Oklahoma already funds community mental health centers, and, in the absence of contrary evidence, grief services would appear to fall within those centers' existing mission.[543] Ms. Hawkins, for example, could not say whether community mental health centers in Oklahoma already provide these services.[544] In addition to services that State might already provide, those suffering from grief can seek assistance from a number of other sources, including private

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see also June 28, 2019 (PM) Trial Tr. (Schick Test.) at 181:13-182:12; July 8, 2019 (PM) Trial Tr. (Halford Test.) at 29:17-30:19; July 3, 2019 (AM) Trial Tr. (Toal Test.) at 2:9-25.

[539] State's Abatement Plan at 39-40 (P.1).

[540] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 36:1-3, 37:13-24.

[541] *Id.* at 36:4-37:9.

[542] State's Abatement Plan at 41 (P.2); June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 40:7-44:11.

[543] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 45:16-19 (testifying about community mental health centers in connection with another service), 55:2-56:7. The State also receives a SAMSHA block grant for community mental health services such as these, but the State failed to take those funds into consideration when calculating costs. *Id.* at 5:25-6:3, 6:7-22.

[544] *Id.* at 41:16-42:2.

counseling and church groups.[545] The State offered no explanation why, given these existing resources, Oklahomans also need government-funded grief support services.

245. The State failed to show that this service is reasonable and necessary.

246. *P.3 - University Behavioral Health*. The State requests $20.27 million in year one, and sequentially less in subsequent years, for licensed alcohol and drug counselors and sober-living opportunities on college campuses.[546]

247. Oklahoma colleges and universities already employ licensed drug and alcohol counselors, including two LADCs at OSU.[547] To the extent some universities do not have licensed drug and alcohol counselors, the State provides no meaningful explanation for why typical university counselors cannot do what licensed alcohol and drug counselors would or why other counselors could not become licensed alcohol and drug counselors.[548] And the State offered no evidence that only specially licensed counselors can remedy any current opioid problems. In addition, these services would stretch well beyond opioids, covering any form of substance abuse.[549]

248. The State has not shown the services in P.3 are reasonable and necessary.

249. *P.4 - Syringe Service Program*. The State requests $30.83 million the first year and $30.68 million thereafter for a needle exchange.[550]

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[545] *Id.* at 41:16-42:8, 42:9-12.

[546] State's Abatement Plan at 42-43 (P.3).

[547] June 20, 2019 (AM) Trial Tr. (Croff Test.) Tr. at 43:24-44:3 ("OSU has two LADCs in one of our counseling centers, so they do exist on university campuses.").

[548] *Id.* at 44:15-22 (testifying in conclusory fashion that "typical counselors can't do the same sort of activities as individuals who are trained specifically in alcohol and drug counseling.")

[549] *Id.* at 103:21-24 (testifying that the licensed alcohol and drug counselors on campus would treat students for addiction to any substance).

[550] State's Abatement Plan at 44-45 (P.4)

250. This service relates to all opioids—both licit and illicit—that are misused intravenously.[551] But Janssen's opioid medications are indicated only for transdermal or oral administration. The State introduced no evidence that Janssen's opioid medications were ever abused by injection. The State has not demonstrated that this service relates to Janssen or even to prescription opioids more generally.

251. In addition, the State presented no evidence that this program—explicitly designed to reduce the transmission of blood-borne pathogens—stands to reduce opioid abuse in Oklahoma. And even as to its stated purposes, the State offered no reliable method by which the Court could judge the success of this service: None of the State's witnesses knew what level of reduction would constitute successful "abatement" of blood borne pathogen transmission.[552]

252. The State failed to demonstrate that this service is reasonable and necessary.

253. *M.1 - Continuing Medical Education*. The State requests $843,446 in year one, and sequentially less in later years, for CME courses.[553]

254. Existing CME courses already touch on the subjects outlined in the plan—e.g., the ASAM fundamentals of addiction medicine, a 40-hour course.[554] The State has not pointed to any evidence that current CME courses are insufficient to teach Oklahoma doctors about pain and opioid management or addiction treatment, and no Oklahoma doctor testified that he or she needed further instruction on those matters. And if the State wishes to offer its own CME

[551] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 45:1-8.

[552] *Id.* at 49:21-50:22.

[553] State's Abatement Plan at 46 (M.1).

[554] June 20, 2019 (PM) Trial Tr. (Croff Test.) at 27:10-16 (confirming existence of an online CME on addiction medicine); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 114:16-117:24.

courses, it can do so with grants from the CDC.[555] Finally, even on direct examination, Ms. Croff failed to offer any persuasive explanation for abatement of the crisis requires 40 trainings per year and 150 providers per training.[556]

255. The State has not shown that the services in M.1 are reasonable and necessary.

256. *M.2 - Addiction Medicine Course*. The State requests $758,725 a year for addiction-medicine courses.[557]

257. Since 2015, the Oklahoma State University Center for Health Sciences has offered courses substantially identical to those in the plan.[558] The State did not explain how or whether these already available courses have failed to apprise Oklahoma doctors about addiction medicine, nor could Dr. Croff discern the effects of these courses in the "real world."[559]

258. The State failed to demonstrate that this service is reasonable necessary.

259. *M.3 - Medical Case Management / Consolidation*. The State requests $3.95 million a year for medical case management and consultation, which the State refers to as Project ECHO.[560]

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[555] June 20, 2019 (PM) Trial Tr. (Croff Test.) at 17:4-25.

[556] June 20, 2019 (AM) Trial Tr. (Croff Test.) at at 60:20-61:3 (expressing a need to reach "every quadrant of the State," but providing no evidentiary or numerical basis for specifically choosing the 40 trainings per year that would be provided at the outset of the plan), 61:4-16 (noting in a conclusory manner that "typically the capacity -- this is just a feasibility issue, capacity is typically around 150 [for providers participating in one session].").

[557] State's Abatement Plan at 47 (M.2).

[558] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 66:5-10; June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 115:22-117:24.

[559] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 66:14-23 (noting a lag time before the medical students who took the course would reach practice).

[560] State's Abatement Plan at 48 (M.3); June 20, 2019 (AM) Trial Tr. (Croff Test.) at 70:6-11 (equating "medical case management/consultation" to Project ECHO).

260. The State has already implemented Project ECHO, with OSU expressly providing "an addiction medicine Project ECHO."[561] Dr. Croff offered conclusory testimony regarding the necessity of Project ECHO.[562] But even indulging that testimony, Project ECHO already exists, and there is no plausible basis for concluding that shifting the cost of providing this service to Janssen is somehow necessary to abate the opioid-abuse crisis.

261. This service is not reasonable and necessary.

262. *M.4 - Residency Training Programs*. The State requests $287,632 a year for an eight-hour training course for all second-year medical residents.[563]

263. OSU already implements this program, with funding from a three-year SAMHSA grant.[564] The State failed to demonstrate why it is necessary for Janssen to cover the cost of this pre-existing program, which the Court cannot conclude is necessary to abate current conditions and which would in any event constitute a penalty or damages unavailable to the State under Oklahoma's public-nuisance law. The State also failed to show whether these programs would have any impact at all. Dr. Croff testified that she has not "seen research studies specifically on doing this in residency," then broadly asserted that this service is "what's necessary."[565] That and other unsubstantiated statements[566] do not demonstrate necessity.

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[561] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 70:6-71:13 ("So the same model has been applied by [OSU], and we have an addiction medicine Project ECHO. And it's on Mondays at noon."); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 45:17-46:19; 117:25-118:11; 143:23-144:7.

[562] *Id.* at 75:11 ("It's reasonable and necessary.").

[563] State's Abatement Plan at 49 (M.4).

[564] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 79:25-80:4 ("We are currently implementing this program [at OSU]."), 80:14-20 (discussing SAMHSA grant).

[565] *Id.* at 78:19-79:1.

[566] *Id.* at 80:21-81:10 (discussing the purported necessity of providing 12 opportunities per year for each residency , but failing to provide any evidence justifying the figure of 12 versus any

264. This service is not reasonable and necessary.

265. *M.5 - Academic Medicine*. The State requests $26.36 million in year one and $12.03 million a year thereafter to establish an academic addiction-medicine department.[567]

266. OSU already has an addiction-medicine department.[568] And the State's settlement with Purdue Pharma L.P. funded "a national center for addiction studies and services" at OSU.[569] Dr. Croff testified that the OSU center for addiction studies funded by the State's settlement "does sound like an academic medicine department," and, when pressed, admitted that that is exactly what the new department is.[570] It cannot be necessary for Janssen to cover the costs of a program that already exists, particularly one funded by a settlement with another defendant in this litigation. In addition, even on direct examination, Dr. Croff could not explain how she calculated the cost for each of the proposed department's endowed faculty positionss.[571]

267. These services are not reasonable and necessary.

268. *M.6 - Counter Detailing*. The State requests $4.09 million per year for a "counter-detailing" program aimed at pharmacy and medical-care professionals.[572]

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other number.), 83:12-84:1 (testifying in conclusory fashion that the cost "is reasonable and necessary").

[567] State's Abatement Plan at 50 (M.5).

[568] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 85:20-86:1; June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 143:23-144:14.

[569] June 20, 2019 (PM) Trial Tr. (Croff Test.) at 56:12-21 (including quoted language above).

[570] *Id.*

[571] June 20, 2019 (AM) Trial Tr. (Croff Test.) at 87:11-18 ("This is a reasonable cost and not trying to ask for our wish list of things. We know that we will have -- that we do have talented personnel at [OSU and OU] that can apply for federal grants and start to ask some of those questions."), 88:17-21.

[572] State's Abatement Plan at 51 (M.6).

269. Existing programs already explain to doctors the need to carefully and safely prescribe opioids.[573] For example, pharmaceutical companies have funded risk evaluation mitigation programs administered by the federal government to that effect.[574] The State offered no evidence suggesting those programs, which were introduced just as opioid overdose deaths began to decrease in Oklahoma, are not sufficient. The purpose of the State's proposed service is to "spread" messages, including the message that "[o]pioids are a dangerous drug that need[s] to be . . . safely and carefully prescribed."[575] Though Mr. Stone claimed that doctors in Oklahoma are unaware of that message,[576] practicing Oklahoma physicians testified that they and their colleagues know all about opioids' risks.[577]

270. The State failed to demonstrate that this service is reasonable and necessary.

271. *M.7 - Behavioral Health Workforce Development*. The State requests $2.64 million a year for a loan-forgiveness and tuition-reimbursement program to incentivize mental health practitioners to work in underserved and high-burden communities.[578]

272. While such incentives may be sound public health policy, the State has made no effort to show how they will remedy any opioid-related problems, let alone that the incentives are necessary to abate the opioid abuse crisis.[579]

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[573] June 10, 2019 (PM) Trial Tr. (Stone Test.) at 130:12-15.

[574] *Id.* at 130:16-21.

[575] *Id.* at 129:15-23.

[576] *Id.* at 130:6-11.

[577] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) at 14:8-14 ("Q. [T]he State has maintained that Oklahoma physicians are unaware of the risks and benefits of opioid mediations. Do you agree? A. ***I think that's utter nonsense. I think every physician is aware.***" (emphasis added)).

[578] State's Abatement Plan at 52 (M.7).

[579] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 6:8-7:10.

273. This service is not reasonable and necessary.

274. *N.1 - NAS Evaluation/Assessment*. The State requests $155,587 in the first year and $102,360 a year for the next nine years, with the cycle repeating every 10 years, for neonatal abstinence syndrome ("NAS") evaluation and assessment, including continuing-education courses.[580]

275. Oklahoma University's Health Sciences Center has an office on perinatal quality improvement that provides CMEs on various topics, and the center hosts a working group titled "Opioid Use Disorder in Pregnancy: Neonatal Abstinence Syndrome."[581] Ms. Hawkins, who is not a medical doctor, testified that "[t]he current training that exists within the State of Oklahoma is not -- is not meeting this need."[582] But she offered no substantive explanation for that belief, citing only the purported opinions of unnamed "professionals."[583] Ms. Hawkins also did not consider whether portions of this service have already been implemented based on a 2015 federal law that required HHS to develop recommendations for the prevention and treatment of NAS.[584]

276. This service is also overbroad, as prescription opioids are not the only drug that causes NAS: Many infants diagnosed with NAS are born to mothers addicted to *illicit* drugs,[585]

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[580] State's Abatement Plan at 53 (N.1).

[581] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 33:8-34:9 (although Hawkins did not admit the CME courses are necessarily on the topic of NAS, she noted that the group does in fact offer CME courses and that the center hosts the above-mentioned working group).

[582] *Id.* at 32:25-33:7.

[583] *Id.* at 33:21-34:22 ("I relied on the professionals at the University of Oklahoma Health Sciences Center to put forth necessary interventions to abate the opioid crisis, and they themselves are saying that this particular service is necessary, and I agree.").

[584] *Id.* at 30:8-33:21 (arguing, without demonstrating knowledge of the substance of the law, that this service would still be different than that mandated by the federal government); 42 U.S.C. § 247b-13 (as amended by P.L. 114-91 (Protecting Our Infants Act)).

[585] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 35:4-6.

including methamphetamine, the most abused drug in the State.[586] And the State concedes that this service would cover births unrelated to prescription opioids.[587]

277. For both of these reasons, the State did not show this service is reasonable or necessary.

278. *N.2 - Prenatal Screening*. The State requests $4.925 million in the first year and $1.23 million in years two through five, with the cycle repeating every five years, for prenatal screening.[588]

279. SoonerCare already provides prenatal screening to its beneficiaries. Shifting this cost to Janssen would not only be unnecessary as part of any "abatement" remedy but would represent a penalty or damages against Janssen.[589] Also, the State receives a 62.38 percent federal reimbursement for those services and has a five-year, $1.65 million SAMHSA grant to increase the number of primary and specialty healthcare patients receiving universal screening and intervention services.[590] The State did not factor those funding sources into the cost of the abatement plan.[591] That aside, merely shifting costs for existing services cannot possibly be

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[586] *Id.* at 35:7-8; Janssen Ex. 625, ODMHSAS Admissions to Treatment by Drug of Choice (2012-2018) at 1 (*admitted June 24, 2019*).

[587] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 35:20-36:1 (conceding that "[w]here a mother who has NAS for another substance may be involved is -- you know, may happen ....").

[588] State's Abatement Plan at 54-55 (N.2).

[589] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 12:4-13 (confirming that SoonerCare already covers prenatal screening, but that the State will simply shift costs to Janssen and J&J).

[590] *Id.* at 12:14-25 (failing to subtract the federal contribution from the cost in the plan); June 24, 2019 AM (Hawkins Test.) at 13:24-14:16 (noting that she wrote those grant applications, and that the State receives a five-year SAMHSA grant for $1.65 million).

[591] *Id.* at 14:17-15:7.

necessary to remedy any existing opioid problems. And, as explained in connection with N.1, these services extend to babies with no exposure to opioids.[592]

280. This service is not reasonable and necessary.

281. *N.3 - Neonatal Treatment*. The State seeks $24.21 million in year one and $20.21 million a year thereafter for treatment.[593]

282. Neonatal treatment, like prenatal screening, is already covered by SoonerCare and extends to newborns with no exposure to opioids.[594] For the same reasons as prenatal screening, shifting the cost of neonatal treatment to Janssen is not necessary or reasonable.

283. Separately, the alleged "abatement costs" for this service are actually the future damages calculation of the State's expert, Dr. James Gibson, who was not called at trial.[595] The abatement plan specifically cites to Dr. Gibson's expert report as the source of the costs.[596] And Ms. Hawkins testified that the 2019 cost figure in the abatement plan matches the 2019 future damages calculation Dr. Gibson provided for NAS treatment.[597] The State's attempt to recover what its own expert labeled future damages underscores the disconnect between the State's alleged abatement plan and any legitimate abatement purpose.

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[592] *Id.* at 35:4-8, 35:20-36:1.

[593] State's Abatement Plan at 56 (N.3).

[594] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 17:10-13 (confirming existing SoonerCare coverage).

[595] State's Abatement Plan at 56, n.123 ("Primary Information Source: Dr. James Gibson Expert Disclosure (and supplementation)."); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 19:15-20.

[596] State's Abatement Plan at 56 n.123 ("Primary Information Source: Dr. James Gibson Expert Disclosure (and supplementation).").

[597] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 20:6-17, 25:24-26:1, 26:23-29:14 (agreeing Dr. Gibson sets forth future NAS treatment damages in Table 4), 63:21-65:25 (agreeing that the yearly total for 2019 and 2020 in Table 4 is the same as the yearly total for N.3).

284. *D.1 - Opioid Overdose Review Board.* The State requests $159,590 a year to fund two full-time professionals to coordinate the Oklahoma Overdose Fatality Review Board.[598]

285. That board already exists,[599] as does the Oklahoma State Department of Health's Fatal Unintentional Poisoning Surveillance System.[600] The State did not explain why shifting these costs to Janssen is necessary. Doing so would constitute damages or a penalty unavailable to the State in a public-nuisance action. The service is also overbroad: More Oklahomans overdose on methamphetamine than on prescription opioids, which means this service reaches much further than could reasonably be necessary under the circumstances.[601]

286. Accordingly, this service is not reasonable and necessary.

287. *D.2 - PMP System/Upgrades.* The State seeks $1.73 million in the first year and $1.645 million a year thereafter to fund and enhance the PMP program.[602]

288. Oklahoma introduced the first version of a PMP in 1990; since then, OBN has maintained the PMP, without interruption, with one full-time administrator leading the charge.[603] The State provided no analysis demonstrating that PMP upgrades or additional funding are necessary or would remedy any existing opioid problems. And Oklahoma's PMP is funded with support from CDC, DOJ, and BJA grants,[604] but the State did not factor those funding sources

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[598] State's Abatement Plan at 57 (D.1).

[599] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 46:8-14 (confirming board has had one meeting).

[600] *See* Janssen Ex. 3928, Fatal Unintentional Poisoning Surveillance System: Data Update (2007-2017) (*admitted June 6, 2019*).

[601] Janssen Ex. 3929 , Winter 2019 OSDH Injury Prevention Service Newsletter at 1 (*admitted June 6, 2019*).

[602] State's Abatement Plan at 58-59 (D.2).

[603] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 50:1-9.

[604] *See id.* at 50:1-51:9 (confirming awareness that Oklahoma's PMP receives funding from the DOJ, BJA, and the CDC), 52:2-12 (unaware of the U.S. Attorney for the Western District of

into the cost of the plan.[605] Finally, the PMP covers *all* drugs on schedules II through V, meaning this service would provide enhancements for tracking many non-opioid medications, which cannot possibly be necessary here.[606]

289. The State failed to show this service is reasonable and necessary.

290. *D.3 - Program Management Monitoring/Evaluation*. The State requests $2.33 million a year for providing program management and evaluation of the purported abatement plan.[607] Because this service necessarily relates to the other services in the plan, and because no evaluation plan even exists, these costs are neither reasonable nor necessary.

291. *D.4 - Health Information Exchange*. The State requests $25.59 million in the first year, $38.9 million in the second and third years, and $30.71 million a year thereafter for a health information exchange.[608]

292. Oklahoma already has at least two health information exchanges.[609] This component of the plan fails to account for information exchanged through MyHealth Access Network, a third-party vendor with which the State contracts.[610] Ms. Hawkins knew neither whether the State would continue using MyHealth Access Network nor whether the State would

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Oklahoma announcing that Oklahoma would receive a $5.9 million grant in 2019, with $750,000 to strengthen the PMP).

[605] *See id.* at 51:22-52:1.

[606] *Id.* at 52:13-20 (confirming that for purposes of this funding, "[t]here are more than opioids entered into the PMP system, yes").

[607] State's Abatement Plan at 60 (D.3).

[608] State's Abatement Plan at 61 (D.4)

[609] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 53:15-19 ("There are at least -- yeah, I think there are two HIEs in the state.").

[610] *Id.* at 55:14-19 ("This represents the development and purchasing of a state centralized HIE. We're not talking about MyHealth specifically, here.")

realize any potential cost savings from potentially switching away from MyHealth Access Network.[611] In other words, the State ignored existing health information exchanges, so the Court cannot find this element of the plan is necessary.

293. More fundamentally, the plan envisions "the entire population entering into this HIE system"[612]—that is, all Oklahomans, including those who never took an opioid, would be pulled into the health information exchange. The State has not sufficiently explained how a new health information exchange would remedy any existing opioid problems, but the overbreadth of the exchange undermines the State's claim of necessity.

294. This service is not reasonable and necessary.

295. *D.5 - Epidemiological Staffing*. The State requests $798,370 a year for epidemiological staffing.[613]

296. The State already employs epidemiologists, and ODMHSAS receives a grant for at least one epidemiologist.[614] Ms. Hawkins's conclusory statements about the need for additional staff and epidemiologists does not speak to the necessity ofstaff increases contemplated here.[615]

297. This component is not reasonable and necessary.

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[611] *Id.* at 56:4-21.

[612] *Id.* at 57:6-11.

[613] State's Abatement Plan at 62 (D.5).

[614] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 59:10-60:8 (testifying that the grant covers one ODMHSAS epidemiologist, but claiming that D.5 would include other separate epidemiologists as well).

[615] *See* June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 32:1-19.

298. *D.6 - Data Collection*. The State requests $832,339 in even numbered years and $423,673 in odd numbered years for a data-collection survey.[616]

299. This funding would go toward the Prevention Needs Assessment Survey, which the State already conducts every two years in Oklahoma's public schools.[617] The State simply wants Janssen to cover the cost of that survey, which would amount to a penalty unavailable under Oklahoma's public nuisance law. In addition, the Prevention Needs Assessment Survey collects information unrelated to opioids. Given the breadth of the assessment and the fact it already exists, shifting the costs associated with the survey cannot be necessary to remedy opioid-related issues.[618] In addition, the State wants Janssen to pay for the cost of adding additional indicators to a national CDC survey.[619] But again, the State made no effort to explain why those indicators are indispensable to abating the opioid crisis.

300. The State has not met its burden of proving reasonableness or necessity.

301. *D.7 - NAS Reporting*. The State requests $189,557 for the first year, and between $181,369 and $184,439 a year thereafter for NAS reporting.[620]

302. None of the State's witnesses examined whether federal law[621] already requires NAS reporting.[622] Nor did the State provide any type of analysis suggesting that NAS reporting

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[616] State's Abatement Plan at 63 (D.6).

[617] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 68:7-16.

[618] *Id.* at 69:3-12 ("It's a survey that collects substance use indicators as well as risk and protection for the development of substance use problems," and noting that it includes marijuana use and alcohol use).

[619] *Id.* at 66:5-23.

[620] State's Abatement Plan at 64 (D.7).

[621] 42 U.S.C. 5106a(b)(2)(B)(ii) (as amended by P.L. 114-198 § 504).

[622] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 36:17-38:13 ("Again, I can't speak to that, whether it's federal law or not .... It would not have mattered. Why would it matter?").

would remedy any existing opioid-related harms. And as mentioned earlier, Ms. Hawkins testified that NAS is not an opioid-specific problem.[623]

303. The State has not demonstrated that the service is reasonable or necessary.

304. *C.1 - Enforcement/Regulatory*. The State requests between $10.34 million and $13.28 million a year to fund investigatory and regulatory actions.[624]

305. The State made no effort to determine whether the boards and agencies that would receive additional funding, staff, and other resources in this section of the plan submitted budget requests to the State legislature that would cover these items.[625] Ms. Hawkins's conclusory testimony that these funds would permit the relevant entities to "deeply evaluate each case and make recommendations," does not suggest necessity—particularly that it is necessary to abate opioid related issues.[626] This is perhaps best illustrated by the fact Ms. Hawkins could not identify whether any of the boards could not investigate cases of diversion or illegal use of opioids because they lacked personnel.

306. This component is not reasonable or necessary.

D. Conclusion as to the State's abatement plan

307. In sum, the State's abatement plan falls short of meeting the legal requirements for abatement of a nuisance in Oklahoma. But even if the abatement plan were legally permissible, the State failed to demonstrate that any element of the plan it is necessary to remedy any existing opioid related harms.

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[623] *Id.* at 35:4-8, 35:20-36:1.

[624] State's Abatement Plan at 65-70 (C.1).

[625] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 19:24-20:11.

[626] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 37:24-38:14 (including quoted language).

PROPOSED CONCLUSIONS OF LAW

I. BURDEN OF PROOF

1. An action for nuisance damages requires the plaintiff to prove the existence of a nuisance, causation, and injury by a preponderance of the evidence. *See Summers v. Acme Flour Mills Co.*, 1953 OK 224, ¶¶ 10-12, 263 P.3d 515, 517. By contrast, entitlement to nuisance abatement "must be established in the trial court by clear and convincing evidence." *Sharp v. 251st Street Landfill, Inc.*, 1996 OK 109, ¶ 5, 925 P.2d 546, 549, *overruled on other grounds by DuLaney v. Okla. State Dep't of Health*, 1993 OK 113, ¶¶ 1-4, 868 P.2d 676, 678-79.

2. In addition, the State premises its case on the claim that various statements Janssen made about opioids were misleading. But because the challenged statements address topics of active scientific debate, they are not subject to the commercial speech doctrine so the First Amendment categorically bars the State's claims. Even if the commercial speech doctrine were to apply here, the State would bear the burden of proving Janssen's statements were inherently misleading by clear and convincing evidence. *See Bose Corp. v. Consumers Union*, 466 U.S. 485, 511 & n.30 (1984).

3. For the reasons explained below, the State failed to meet its burden of proof under any standard.

II. THE STATE HAS FAILED TO PROVE A PUBLIC NUISANCE

4. The Oklahoma nuisance statute defines a nuisance as "unlawfully doing an act, or omitting to perform a duty, which act or omission" has one of several listed consequences—e.g., "[a]nnoys, injures or endangers the comfort, repose, health, or safety of others." 50 O.S. § 1. A public nuisance is one "which affects at the same time an entire community or neighborhood, or any significant number of persons." 50 O.S. § 2.

5. The Oklahoma Supreme Court has instructed that the "statutory definition of nuisance ... encompasses the common law's private and public nuisance concepts." *Nichols v. Mid-Continent Pipe Line Co.*, 1996 OK 118, ¶ 8, 933 P.2d 272, 276 (emphasis omitted). Applying common law nuisance principles, the Oklahoma Supreme Court has held that a nuisance under 50 O.S. § 1 "arises from an unreasonable, unwarranted, or unlawful use ... of property ... which works an obstruction or injury to the right of another." *Briscoe v. Harper Oil Co.*, 1985 OK 43, ¶ 9, 702 P.2d 33, 36.

6. The State's trial evidence failed to establish two essential elements of its nuisance claim: it neither identified any unlawful act or omission by Janssen nor proved any misuse of property or interference with the property rights of others. Instead, the State based its claim on a wide range of lawful, constitutionally protected activity, much of it with no relationship to Oklahoma at all, let alone to property use in the State.

A. The State has failed to prove an unlawful act or omission.

7. The State failed to show Janssen or J&J committed any unlawful act or omission, a threshold issue for its nuisance claim. 50 O.S. section 1 defines a nuisance as "unlawfully doing an act" or "omitting to perform a duty." So "[f]or an act or omission to be a nuisance in Oklahoma, it must be unlawful." *Nuncio v. Rock Knoll Townhome Vill., Inc.*, 2016 OK CIV APP 83, ¶ 8, 389 P.3d 370, 374. Lawful conduct cannot form the basis for a nuisance claim. *See Insurance Co. of North Am. v. Sheinbein*, 1971 OK 110, ¶¶ 6-7, 488 P.2d 1273, 1275-76 (allowing fire to spread "was not unlawful" under penal code and thus did not support nuisance liability); *Abraham v. Trail Lanes, Inc.*, 2014 OK CIV APP 107, ¶ 13, 352 P.3d 1256, 1262 (rejecting nuisance liability) ("[Plaintiff] has not shown [defendant] acted unlawfully and we have found no duty it failed to perform.").

8. At trial, the State based its nuisance claim on two categories of conduct: Janssen's promotion of opioid medications and Noramco's and Tasmanian Alkaloids' supply of raw materials to pharmaceutical manufacturers.

9. But Janssen's promotion of opioid medications was truthful and was not misleading: Substantial scientific and clinical evidence supported the statements challenged by the State. *See supra* 8-14, 27-32, 39-41. And the First Amendment fully protects the challenged speech, which addressed matters of ongoing scientific debate and was not inherently misleading. *See infra* 128-133. Noramco's and Tasmanian Alkaloids' raw-material sales violated no Oklahoma law and were authorized by a federal regulatory scheme that comprehensively regulated those subsidiaries' sales. *See infra* 149-56. Such lawful and protected conduct cannot form the basis for nuisance liability. *See, e.g., Sheinbein*, 1971 OK 110, ¶¶ 4-7, 488 P.2d at 1275-76.

B. Oklahoma's nuisance statute regulates property rights—not the marketing and sale of goods.

10. The State likewise failed to present any evidence of harm "aris[ing] 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." *Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 36; *see Laubenstein v. Bode Tower, L.L.C.*, 2016 OK 118, ¶¶ 10-12, 392 P.3d 706, 710 (same); *Morain v. City of Norman*, 1993 OK 149, ¶ 14, 863 P.2d 1246, 1249-50 (same); *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."). As the Oklahoma Supreme Court has made clear, plaintiffs much make such a showing to establish a claim for either private or public nuisance: "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.

11. The Oklahoma Supreme Court's public nuisance cases have adhered to that definition since the nuisance statute's passage in 1887—Oklahoma courts have recognized nuisance liability only in cases implicating the use of real property or in narrow circumstances historically recognized as "nuisances per se." *See, e.g., Mackey v. State ex rel. Harris*, 1972 OK 37, ¶ 14, 495 P.2d 105, 108 (operation of unruly saloon where "the location chosen by the respondent in this case is such that it annoys the neighborhood, a residential area"); *Updegraff v. City of Norman*, 1955 OK 195, ¶ 6, 287 P.2d 909, 911 (landowner's failure to maintain an overgrown hedge obstructing a public alley); *Wood v. City of Chickasha*, 1927 OK 77, ¶ 8, 257 P. 286, 287 (poultry plant emitting "disagreeable odors and noises" that "affected many people living in the immediate neighborhood."); *Cummings v. Lobsitz*, 1914 OK 382, ¶ 1 142 P. 993, 994 (building kept in unsafe condition on "principal street" of city). Outside of those narrow contexts, the Oklahoma nuisance statute has never been applied to regulate routine commercial activity, such as the sale and marketing of lawful products.

12. The State has argued that the nuisance statute has no explicit property requirement. But the Oklahoma Supreme Court has instructed that the statute "encompasses the common law's private and public nuisance as at common law," *Nichols*, 1996 OK 118, ¶ 8, 933 P.2d at 276, and it has held—repeatedly—that nuisance is a property tort. *See supra* 122. To disregard the nuisance statute's common-law underpinnings would lead to absurd outcomes, allowing any act that annoys, injures, or endangers others, and occurs at least in part within Oklahoma territory, to constitute a nuisance. So defined, nearly any conduct could be a

nuisance. The Oklahoma Supreme Court has rejected such a broad reading of the nuisance statute. *See State v. State Capital Co.*, 1909 OK 200, ¶ 10, 103 P. 1021, 1026 (rejecting nuisance claim based on marketing of liquor because accepting that theory "would be tantamount to holding that every crime was a nuisance"); *State ex rel. Fallis v. Mike Kelly Const. Co.*, 1981 OK 158, ¶ 14, 638 P.2d 455, 458 (reaffirming *State Capital Co.*).

13. Here, the State challenges the sales and marketing of goods on national and international markets, not the use of real property in Oklahoma. Much of the conduct the State challenged at trial occurred outside of Oklahoma altogether. Among many other things, the State's evidence targeted the production of raw materials in Tasmania, the production of API in Delaware; the activities of academics in Wisconsin, the work of a key opinion leader in New Hampshire, and lobbying activities in Washington, D.C.[627] The State has also challenged speech about opioids—including the *Prescribe Responsibly* website, online CMEs, consensus statements, training slideshows, and internal strategy documents—intangible informational activity bearing no relationship to property at all, much less property in Oklahoma.[628]

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[627] *See, e.g.*, Gilson Depo. Tr. at 263:9-11, 263:15-16; (played June 10, 2019) (discussing manufacturers' use of the Pain and Policy Studies Group report card); Portenoy Depo. Tr. at 43:22-44:8 (played May 29, 2019) (addressing drug companies' use of his work); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 15:1-16:11 (stating that the Federation of State and Medical Boards released guidelines on prescribing opioids for chronic pain with funding from the Robert Wood Johnson Foundation).

[628] *See, e.g.*, State Ex. 900, The Use of Opioids for the Treatment of Chronic Pain at 3 (*admitted May 30, 2019*), State Ex. 954, H. Heit & D. Gourlay, *What a Prescriber Should Know Before Writing the First Prescription* (*admitted June 10, 2019*); State Ex. 974, K. Candiotti, *Use of Opioid Analgesics in Pain Management* (*admitted June 3, 2019*); State Ex. 975, NPEC, "Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program" (June 2002) (*admitted June 4, 2019*); State Ex. 2358, Duragesic Business Plan (*admitted May 30, 2019*); State Ex. 2376, Nucynta Speaker Training (Oct. 10, 2012) (*admitted May 30, 2019*).

14. Such ordinary commercial activity, lacking any meaningful connection to property use and not resembling any historically recognized nuisances per se, cannot constitute a public nuisance. As the State recognized earlier in this litigation, Oklahoma's nuisance statute derived from the nearly identical statutes of North and South Dakota. *See* N.D. Cent. Code Ann. § 42-01-01 et seq.; S.D. Codified Laws § 21-10-1 et seq. A North Dakota trial court recently rejected a similar public nuisance suit against opioid manufacturers, explaining "[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). Similarly, South Dakota courts have defined public nuisance under that state's statute as regulating "the maintenance of a balance between the right to use property and the right to enjoy property unaffected by others' uses." *Prairie Hills Water & Dev. Co. v. Gross*, 653 N.W.2d 745, 752 (S.D. 2002).

15. Many other courts, applying the common law, have refused to extend public nuisance beyond its grounding in property to the sale and marketing of lawful products. *See, e.g., Texas v. American Tobacco Co.*, 14 F. Supp. 2d 956, 973 (E.D. Tex. 1997) (declining to "accept the State's invitation to expand a claim for public nuisance beyond its grounding in real property" to the "manufacturing, advertising, distributing and selling tobacco products"); *Camden Cnty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001) (highlighting the "boundary between the well-developed body of product liability law and public nuisance law"); *Rhode Island v. Lead Indus. Ass'n*, 951 A.2d 428, 456 (R.I. 2008) (public nuisance law "never before has been applied to products, however harmful").

16. Courts across the country have warned that extending public nuisance to regulate ordinary commercial activity would subject a wide range of lawful businesses to sprawling and

unexpected liability. In a case against gun manufacturers, for example, a New York court warned that a failure to "enforce[ ] the boundary between the well-developed body of product liability law and public nuisance law" could cause public nuisance to "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). A California court described the implications of extending nuisance liability to product sales as "staggering" and called nuisance a "peculiarly blunt and capricious method of regulation." *In re Firearm Cases*, 126 Cal. App. 4th 959, 991 (2005). "Any manufacturer of an arguably dangerous product that finds its way into California [could] be hauled into court in California to defend against a civil action brought by a victim of the criminal use of that product." *Id.*

17. This case illustrates the point. At trial, the State tried to establish a connection to property by eliciting testimony that Janssen sponsored medical education seminars on state property, and that its sales representatives trained in Oklahoma on "Oklahoma dirt" and visited doctors in Oklahoma offices.[629] If activity on "Oklahoma dirt" could suffice to establish a nuisance, *any* commercial activity taking place in the State could also give rise to nuisance liability. Similarly, the State invoked historical nuisances per se by eliciting testimony that police pulled over an unspecified Oklahoman under the influence of opioids.[630] Its suggestion that anecdotal reports of downstream traffic offenses can trigger multibillion-dollar nuisance liability only underscores the limitless liability the State's theory poses to Oklahoma and out-of-state businesses. A century of Oklahoma case law limiting the application of nuisance law to bona fide property disputes and nuisances per se forecloses that untenable outcome.

[629] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 45:19-22, 46:11-17, 61:23-62:22.

[630] June 25, 2019 (AM) Trial Tr. (White Test.) at 107:2-108:3.

C. Extending nuisance liability to the marketing conduct at issue would violate the due process protections in the Oklahoma and U.S. Constitutions.

18. Under the Oklahoma and U.S. Constitutions, due process 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, ¶ 24 & n.55, 37 P.3d 763, 774 & n.55; *see* U.S. Const. amend. XIV; OK Const. art. 2, § 7.

19. The State seeks recovery under sweeping statutory language punishing anything that "[a]nnoys, injures or endangers the comfort, repose, health, or safety" of "any considerable number of persons." 50 O.S. §§ 1, 2. Oklahoma courts' longstanding interpretation confining those statutes to property disputes and nuisances per se has long given concrete meaning to that broad language. Extending that language to reach *any* conduct that annoys or injures a large number of Oklahomans—and imposing massive liability as a result—would violate Janssen's due-process right to fair notice under the Oklahoma and United States constitutions.

20. The State's all-encompassing interpretation would violate the Fourteenth Amendment's void-for-vagueness doctrine because it "fails to provide a person of ordinary intelligence fair notice of what is prohibited" and "is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Papachristou v. City of Jacksonville*, 405 U.S. 156, 162 (1972) (the "rule of law entails various suppositions, one of which is that all persons are entitled to be informed as to what the State commands or forbids."); *see also 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?"). And discarding settled, century-old limitations and attaching massive liability to a novel construction of Oklahoma's statute would deprive Janssen of fair

notice. *See Bouie v. City of Columbia*, 378 U.S. 347, 350-55 (1964) (retroactive application of new construction of statute violated due process); *Fabi Constr. Co. v. Sec'y of Labor*, 508 F.3d 1077, 1088 (D.C. Cir. 2007) ("[A]nnouncing [an interpretation] for the first time in the context of this adjudication deprives Petitioners of fair notice.").

21. Due process requires that "[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." *Samson Resources Co. v. Cloud*, 1991 OK CIV APP 55, ¶ 8, 812 P.2d 1378, 1381. And here, there is far more than fair doubt. Rather, Oklahoma precedents clearly hold that the challenged commercial conduct did *not* violate Oklahoma's nuisance statute. The State's nuisance claim thus contravenes the due process protections of the Oklahoma and U.S. constitutions.

III. THE FIRST AMENDMENT PROTECTS JANSSEN'S STATEMENTS

A. Janssen's speech is fully protected under the First Amendment.

22. The First Amendment shields speech with "serious ... scientific value, regardless of whether the government or a majority of the people approve of the ideas [the speech] represent[s]." *Miller v. California*, 413 U.S. 15, 34 (1973). This includes speech on "public health," which is "clearly a matter of public consonance." *Magnusson v. New York Times Co.*, 2004 OK 53, ¶ 12, 98 P.3d 1070, 1075. 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). These protections extend to "[s]peech in aid of pharmaceutical marketing," so state laws infringing on such speech "must be subjected to heightened judicial scrutiny." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). And "[c]ontent-based regulations" on speech "are presumptively invalid." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992).

23. Here, the State challenged marketing and other speech that involved contested positions on scientific and medical issues of public importance. Specifically, the challenged speech addressed the science of chronic pain and the extent to which opioid medications can be effective for the long-term treatment of chronic non-cancer pain. It covered views on governmental policies for opioid medications. And it involved Janssen's interpretation of the scientific literature about the risk of opioid abuse and addiction. *See supra* 8-57. Speech that "is inextricably intertwined with otherwise fully protected speech" does not "retain[] its commercial character." *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796 (1988). Rather, the entirety must be classified as noncommercial. *Id.* The Court therefore concludes that the entirety of the marketing and speech at issue in this case is of "public consonance," *Magnusson*, 2004 OK 53, ¶ 12, 98 P.3d at 1075, entitling it to the full protection of the First Amendment.

24. The State's experts argue that Janssen took the wrong side of scientific and medical debates. Those experts contend that opioids are generally inappropriate or ineffective for treating chronic non-cancer pain.[631] They suggest that the extent of the chronic pain problem in the United States is overstated.[632] And they disagree with statements about the risk of

[631] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 58:16-17; *see also* June 5, 2019 (PM) Trial Tr. (Mazloomdoost Test.) at 150:17-20; June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 40:15-21.

[632] *See, e.g.*, June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 108:12-21 (describing undertreated pain as a "media hook" that pharmaceutical manufacturers "used to promote opioids"); June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 64:19-65:18 (stating, in response to question about APS and CDC estimates of persons suffering from chronic pain, that "[t]hese were never real numbers").

addiction, specifically that "[t]he chance of addiction is low when ... prescribed properly and taken as directed."[633]

25. Those experts are entitled to their views, but the evidence at trial showed that those views run counter to many scientific and medical studies and analyses,[634] the experience of several Oklahoma physicians who regularly prescribe opioids,[635] the consistent position of the FDA,[636] and the Oklahoma Administrative Code.[637]

26. The First Amendment bars Oklahoma from using its nuisance statute "to advance a preferred message" about science or medicine. *Sorrell*, 564 U.S. at 575; *see Consol. Edison Co. v. Pub. Serv. Comm'n*, 447 U.S. 530, 535 (1980) (restrictions on company's "participat[ion] in the public debate on ... controversial issues of national interest and importance ... strikes at the heart of the freedom to speak").

27. Contrary to the State's assertions, honoring these First Amendment protections do not prevent the State "from being able to protect the public from statements like 'you will not get addicted to opioids' or 'opioids do not cause death'."[638] The First Amendment in no way limits the State's power to police fraud. *See, e.g., United States v. Alvarez*, 567 U.S. 709, 717 (2012).

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[633] *E.g.*, June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 78:19-81:17.

[634] *See supra* 54-55 (studies and analyses establishing rates of opioid addiction and abuse).

[635] *See supra* 26-27 (testimony from Oklahoma physicians that opioids can be an effective long-term remedy for chronic pain).

[636] *See* Janssen Ex. 3606, FDA Guide to Safe Use of Pain Medicine at 4 (*admitted June 14, 2019*) ("[S]tudies 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."); *supra* 10 (FDA's rejection of the PROP petition's request to limit the approved indication for chronic non-cancer pain to therapy not exceeding 90 days).

[637] *See* Okla. Admin. Code § 435:10-7-11 (adopting elements of the AAPM/APS consensus statement in setting forth criteria for evaluating a physician's treatment of pain).

[638] Resp. to Mot. for Judgment (July 7, 2019) at 52-53.

But the State presented no evidence that Janssen committed fraud—on the contrary, it showed that Janssen espoused positions that continue to be accepted by broad swaths of the mainstream medical and scientific community, as well as the FDA. *See supra* 10, 26-30, 50-55. The First Amendment prohibits the State from punishing Janssen for a difference of scientific opinion.

B. Janssen's marketing and other speech remains protected even under the commercial speech doctrine because it was not inherently misleading.

28. In any event, the First Amendment's commercial-speech doctrine protects Janssen's speech. That doctrine allows content-based restrictions only in narrow circumstances. Specifically, states may prohibit "inherently misleading" commercial speech, *Pearson v. Shalala*, 164 F.3d 650, 656-58 (D.C. Cir. 1999)—i.e., statements that are "incapable of being presented in a way that is not deceptive." *Revo v. Disciplinary Bd. of the Supreme Ct. for the State of N.M.*, 106 F.3d 929, 933 (10th Cir. 1997). Proof that commercial speech is misleading requires a showing that recipients of the speech "actually ha[ve] been misled by the statement." *Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 112 (1990) (Marshall, J., concurring); *see also Express Oil Change, L.L.C. v. Mississippi Bd. of Licensure for Prof'l Eng'rs & Surveyors*, 916 F.3d 483, 490 (5th Cir. 2019).

29. The State failed to prove by clear and convincing evidence that any of Janssen's statements were inherently misleading. If anything, the evidence showed those statements to be well-supported and within the scientific mainstream. For example, multiple sources of abuse surveillance evidence corroborated Janssen's claim that Duragesic was less abuse-prone than OxyContin, and the State presented no contrary proof. *See supra* 18-20, 28-29. Similarly, numerous studies corroborate Janssen's 2009 claim that prescription opioids rarely cause addiction when used properly to manage chronic pain, and the FDA made much the same claim that year. *See supra* 54-55. And at trial, testimony from Oklahoma physicians affirmed

Janssen's claim that Duragesic could improve functionality in patients suffering from chronic pain. *See supra* 26-27.

30. The State presented no evidence that any Oklahoma doctor was misled by Janssen's marketing. To the contrary, Oklahoma doctors uniformly testified that Janssen had not misled them.[639]

31. Because Janssen's speech was not inherently misleading, but at most "potentially misleading," the First Amendment requires the State to show that nuisance liability satisfies the three-part test from *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980): (1) that the State's interest in burdening the speech at issue is substantial; (2) that nuisance liability directly advances that interest; and (3) that nuisance liability is not more extensive than necessary in light of that interest. *Id.* at 566.

32. The State has never suggested it can satisfy that test. Nuisance liability, which has traditionally applied to property disputes and historical nuisances per se, is a crude instrument to regulate medical speech, and the multi-billion-dollar liability the State seeks to impose on Janssen represents a severe penalty for speech more extensive than necessary to advance the State's interest in such regulation.

33. The State contends that the commercial speech cases Janssen cited are distinguishable because they involve prior restraints on speech rather than retrospective tort liability.[640] But the U.S. Supreme Court has recognized that the First Amendment's protections

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[639] Argoff Depo. Tr. 337:21-338:12, 338:14 (played July 8, 2019); July 3, 2019 (1st AM) Trial Tr. (Muchmore Test.) at 16:7-21, 48:16-25; July 3, 2019 (2d AM) Trial Tr. (Toal Test.) at 48:17-19; *see also* June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 97:17-22 (sole Oklahoma physician called by the State concedes he has not been visited by a Janssen sales representative promoting an opioid).

[640] Resp. to Mot. for Judgment (July 7, 2019) at 53-54.

apply no less to measures that "seek[] to exact a cost after the speech occurs" than to "outright ban[s]." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 337 (2010). The commercial-speech doctrine thus does not allow the State to impose massive liability on Janssen for content-based disagreement with scientific claims that were not inherently misleading.

IV. THE STATE FAILED TO PROVE JANSSEN WAS A CAUSE OF THE OPIOID ABUSE CRISIS

34. The State's nuisance claim requires it to prove that Janssen proximately caused the State's injuries. *See Atchison, Topeka & Santa Fe Ry. Co.*, 1928 OK 256, ¶6, 266 P. 775, 776 ("this defendant was liable for such injury only as was the direct and proximate result of its wrongful act"). "Proximate cause consists of two elements: cause in fact and legal causation." *McKellips v. St. Francis Hosp., Inc.*, 1987 OK 69, ¶ 9, 741 P.2d 467, 470. The Court finds the State has failed to prove that Janssen was either a cause in fact or a legal cause of the Oklahoma opioid abuse crisis.

A. The State did not show cause-in-fact.

35. "Cause in fact … deals with the 'but for' consequences of an act." *Id.* Under that standard, the State must show that the opioid-abuse crisis would not have occurred "but for" Janssen's conduct. The State argues against this but-for standard by observing that it must prove only that Janssen was "***a*** cause"—not "***the*** cause"—of the opioid abuse crisis.[641] But Oklahoma law requires a showing of but-for causation for a defendant's conduct to be considered "a cause": "The defendant's conduct is ***a cause*** of the event if the event would not have occurred ***but for*** that conduct." *McKellips*, 1987 OK 69, ¶ 9, 741 P.2d at 470 (emphasis added).

[641] July 8, 2019 (AM) Trial Tr. (Beckworth Arg.) at 69:21-70:1.

36. The State also argues against but-for causation by urging this Court to apply the "contributing factor" standard of *Lee v. Volkswagen of America, Inc.*, 1984 OK 48, ¶ 33, 688 P.2d 1283, 1289. But *Lee*'s relaxed causation test applies only in multiple-impact car-crash cases. *See id.* at 27-33. And in a lawsuit attempting to assign blame for a complex social problem, *Lee* provides no basis to discard a "textbook tort law" principle: that "an action 'is not regarded as a cause of an event if the particular event would have occurred without it.'" *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 347 (2013) (emphasis added) (quoting Prosser & Keeton on Law of Torts § 265 (5th ed. 1984)).

37. In any event, the Court concludes that the State has failed to prove Janssen even contributed to—much less caused—Oklahoma's opioid abuse crisis.

38. The State based its case on the causal theory that because pharmaceutical opioid sales rose during a period that also saw increased overdose deaths and addiction admissions, the former must have caused the latter. But, as both parties' experts agreed,[642] it is "a statistical truism that correlation is not causation." *Nelson v. Enid Med. Associates, Inc.*, 2016 OK 69, ¶ 52, 376 P.3d 212, 228. Courts consistently find statistical "correlation evidence" too "simplistic" to prove cause in fact, particularly on complex questions that involve multiple parties and individualized decisions such as the impact of pharmaceutical marketing. *See, e.g.*, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 96 (2d Cir. 2015); *accord Brown v. Entm't Merchs. Ass'n*, 564 U.S. 786, 800 (2011); *Nelson*, 2016 OK 69, ¶ 52, 376 P.3d at 228.

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[642] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 40:4-42:10; June 25, 2019 (PM) Trial Tr. (White Test.) at 86:24-87:3; June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 105:13-17; *cf.* June 7, 2019 (PM) Trial Tr. (Nguyen Test.) at 26:18-27:5 (testifying that overall sales and deaths were correlated, but declining to offer opinion on causation).

39. And even under this flawed theory, the State must still prove that ***Janssen*** caused the increased opioid prescriptions on which the State blames the crisis.

40. To attempt to make that connection, the State's experts relied on a wealth of legally protected conduct, such as the speech of third-party advocacy organizations and Noramco's and Tasmanian Alkaloids' sales of raw materials. They made no efforts to separate the causal effects of such protected conduct from the causal effect of any arguably actionable conduct by Janssen—and they never opined that potentially actionable conduct by Janssen itself was sufficient to cause Oklahoma's crisis of opioid abuse. *See NAACP v. Claiborne Hardware*, 458 U.S. 886, 918 (1982) ("[T]he State ... may not award compensation for the consequences of ... protected activity. Only those losses proximately caused by unlawful conduct may be recovered.").

41. With respect to Janssen's own acts, the State pointed to just three types of conduct: (i) branded marketing of its own products, especially Duragesic; (ii) a handful of unbranded materials released between 2008 and 2011; and (iii) instances where Janssen disseminated statements by advocacy groups or key opinion leaders. For the reasons explained below, the State failed to prove that any of this Janssen conduct contributed to or caused the opioid abuse crisis. Indeed, the targeted conduct amounts to truthful statements and the expression of legitimately held beliefs, some of which were debated by the State's experts at trial, all of which were unconnected to improper or excessive prescribing by Oklahoma doctors.

1. Janssen's Branded Marketing

42. Janssen's "branded marketing" promoted Janssen's own prescription opioid medications. *See supra* 20, 47. Because those medications played no role in Oklahoma's opioid-abuse crisis, Janssen's promotion of those medications could not have caused the crisis. Janssen's Duragesic fentanyl patch, Nucynta tapentadol pills, and tramadol products accounted

for a tiny fraction of Oklahoma's opioids market, *see supra* 18, 36-37, 45, were abused far less frequently than other opioids, and were associated with few cases of opioid use disorder, *see supra* 18-20, 26-28, 35-36, 45-46. Rare instances of addiction or overdose death caused by Janssen's products do not prove that those products caused or contributed to a crisis. Janssen warns that its opioid medications might lead to addiction and overdose; that those known risks occasionally materialized does not establish any connection to a broader crisis of opioid abuse and misuse.

43. The State offered no evidence or expert analysis explaining how Janssen's promotion of these rarely prescribed, rarely abused niche medications could have caused an opioid abuse crisis that the State's own records show correlates with widely prescribed, frequently abused oxycodone and hydrocodone pills. *See supra* 39-43. Effectively conceding that it could not draw a line from Janssen's medications to the opioid abuse crisis, the State repeatedly insisted at trial that its case was not about Janssen's medications.[643]

44. The undisputed trial evidence also showed that Janssen's branded marketing for Duragesic, Nucynta, and Ultracet aimed to capture existing market share from Janssen's competitors—including more highly abused drugs like OxyContin and Lortab, *see supra* 29-30, 38-40—not to grow the overall market for opioids.[644] Janssen did not contribute to the opioid crisis through promotional messages meant to discourage doctors from prescribing the drugs at the heart of that crisis.

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[643] *See, e.g.*, June 3, 2019 (PM) Trial Tr. (Beckworth Arg.) at 53:22-24 ("Now, this case isn't about their drug. It's about opioids and all the ones they supplied....").

[644] *See* May 31, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 43:17-22, 45:16-20, 51:7-19, 54:22-55:1, 56:10-11, 58:8-11, 71:23-72:3, 78:11-17, 88:17-22, 106:21-107:2, 110:23-111:2, 114:25-115:2, 116:10-13, 128:10-12 (describing call notes mentioning sales representatives' discussions with physicians about how Duragesic compared favorably to OxyContin and other oral opioids).

45. The State also challenged two branded materials that made general statements about opioids. *See supra* 67-68. But the State presented no evidence that those documents were distributed in Oklahoma and did not identify a single Oklahoma doctor who even reviewed them, precluding a finding that the documents contributed to the crisis. Absent evidence that Oklahoma physicians actually saw these materials, this Court can only speculate whether the documents had any impact at all on Oklahoma, let alone an impact big enough to contribute materially to the opioid abuse crisis. *See McKellips*, 1987 OK 69, ¶ 11, 741 P.2d at 471 ("mere possibility or speculation" cannot show causation).

46. The same basic failing applies more generally to the State's attack on Janssen's marketing: The State did not present evidence of a single Oklahoman harmed as a rfsesult of any statement in Janssen's branded marketing.

47. None of the State's experts provided concrete testimony explaining how Janssen's promotion of rarely prescribed medications with low rates of abuse and addiction caused Oklahoma's opioid abuse crisis. Although Dr. Kolodny criticized Janssen's branded marketing when stating his causation opinion,[645] he did not explain how that marketing caused the crisis, much less did he provide a reliable and sound method to conclude that it did. *See, e.g., Christian v. Gray*, 2003 OK 10, ¶ 36, 65 P.3d 591, 607 ("[W]hen an expert's opinion relates to causation, reliability of that opinion is provided when the expert's opinion is based upon a reliable method for determining causation and the conclusion is analytically appropriate to that method."). Indeed, Kolodny testified that he did not know of any Oklahoma doctor whose prescribing was influenced by a Janssen sales representative.[646]

[645] June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 22:22-23:13.

[646] June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 94:24-95:3.

48. Similarly, Dr. Beaman believed that "pharmaceutical manufacturers, including Janssen," caused Oklahoma's opioid crisis by "unleash[ing]" a "misinformation campaign."[647] But he conceded that he "ha[d] not done research" to support that opinion; he had only "talked to physicians" and "heard several … tell [him] … their experiences with marketing influence."[648] Dr. Beaman also did not connect his broad opinion about pharmaceutical marketing to Janssen's branded marketing of its medications. These vague and unsourced anecdotes cannot show Janssen caused the State's crisis. *See id.*

49. Finally, while Commissioner White asserted that Janssen's distribution of "false and misleading" marketing caused physicians to overprescribe opioids,[649] she formulated that opinion based only on her observation of the State's case.[650] She did not identify any scientifically sound method supporting her opinion, did not cite any specific marketing as a basis for it, and did not provide any other data or analysis to support it. She failed to identify a single Oklahoma doctor who was influenced by a Janssen communication. A conclusory opinion formulated from attendance at trial cannot serve as the basis for a finding of causation. *See id.*

50. Because the State failed to connect Janssen's medications to Oklahoma's opioid abuse crisis—or even identify a single harmful prescription written as a result of Janssen's

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[647] June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 68:22-71:12, 81:20-23.

[648] *Id.* at 68:22-71:12, 81:20-23, 128:16-129:8, 132:1-21.

[649] *See, e.g.*, June 26, 2019 (PM) Trial Tr. (White Test.) at 30:5-14, 54:19-55:8; June 25, 2019 (AM) Trial Tr. (White Test.) at 55:22-56:25, 62:10-63:5, 66:10-19.

[650] *See, e.g.*, June 25, 2019 (AM) Trial Tr. (White Test.) at 31:24-32:6 ("They did not tell us … that they were basically unleashing a sales force armed with what I can only diplomatically, after watching this trial, call misleading and dishonest information about the addictive nature of these medications."); *id.* (Whitten Arg.) at 88:4-15 ("She is an expert witness … . She has sat here through this trial … . She's heard the testimony of Dr. Kolodny and Dr. Beaman and Renzi Stone, who she has relied upon.").

branded marketing—this Court concludes that the State failed to meet its burden to prove that Janssen's branded marketing caused or contributed to that crisis.

2. Janssen's Unbranded Marketing

51. All of Janssen unbranded marketing was published between 2008 and 2011, more than a decade after the State asserts the crisis began, at a time when opioid overdoses in Oklahoma were already peaking.[651] *See supra* 50-52.

52. And while the State's evidence about Janssen's unbranded marketing targeted select passages in a handful of promotional documents, the State presented no evidence that any of those documents achieved wide circulation in Oklahoma or that the specific challenged passages influenced Oklahoma physicians. This evidence allows only for speculation whether these materials could have materially influenced prescribing practices in the State and thus cause an opioid abuse crisis. Such speculation cannot support a finding of causation. *McKellips v. Saint Francis Hosp., Inc.*, 1987 OK 69, 741 P.2d at 471.

53. None of the State's experts testified that these unbranded marketing materials were a cause of Oklahoma's opioid abuse crisis. While Dr. Kolodny opined that Janssen caused the crisis through "an unbranded campaign to increase opioid prescribing,"[652] his definition of that "campaign" went far beyond Janssen's own marketing and instead encompassed third-party

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[651] *See, e.g.*, Aug. 30, 2018 Hr'g Tr. at 57:17-58:1 (Oklahoma's opioid crisis "can [be] trace[d] … to a very specific point in time, and that is when OxyContin was brought to market [in 1996] and promoted in an aggressive, concentrated, and targeted way"); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 171:6-12 (Oklahoma's opioid epidemic started in 1996); June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 30:13-18 (acceleration in opioid prescribing fueled in large part by introduction of OxyContin in 1995-1996); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 35:4-5 ("[t]he epidemic began in 1996"); June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 99:3-13, 102:17-23 (opioid prescription-related deaths start rising in 1999 and begin to substantially increase in 2003-2004).

[652] June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 22:4-6.

conduct[653] including CMEs[654] and speech by KOLs[655] and advocacy organizations.[656] Kolodny's opinion on Janssen's "unbranded campaign" also rested on Janssen's lobbying.[657] But the First Amendment protects third-party speech and Janssen's lobbying. *See supra* 146-49. To the extent an expert opinion encompasses such constitutionally protected conduct, it cannot establish causation. *See NAACP v. Claiborne Hardware*, 458 U.S. 886, 918 (1982) ("[T]he State ... may not award compensation for the consequences of ... protected activity. Only those losses proximately caused by unlawful conduct may be recovered."). Moreover, Dr. Kolodny conceded that Janssen's unbranded marketing in the late 2000s could not have caused the surge in opioid addiction and death over the previous decade, which was already nearing its peak.[658]

54. Dr. Beaman testified that the opioid crisis "started in 1996 as a consequence to the ... aggressive unbranded marketing campaign by the pharmaceutical manufacturers."[659] But the State identified no unbranded marketing by Janssen from that time, and it could not have: Janssen's unbranded marketing did not begin until the late 2000s when it prepared to introduce Nucynta. Dr. Beaman's opinion about "unbranded marketing" by "pharmaceutical

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[653] *See generally* June 11, 2019 (PM) at 159:7-11 ("unbranded marketing in the form of KOLs and third parties").

[654] *See* June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 99:11-13 (CMEs).

[655] *See, e.g.*, June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 95:4-7 (KOLs); June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 22:14-21 ("front groups," "patient groups," and "professional groups").

[656] *See, e.g.*, June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 99:23-25; *see also* June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 22:14-21 (defining "unbranded campaign" to include "front groups," "patient groups," and "professional groups").

[657] June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 21:14-23:13.

[658] June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 51:3-16, 52:5-55:2.

[659] June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 171:9-12.

manufacturers" a decade earlier cannot amount to evidence that Janssen caused or contributed to the crisis.

55. The State therefore failed to present evidence that Janssen's unbranded marketing materials from the late 2000s had any influence in Oklahoma, and none of its experts explained how materials with such limited exposure could have caused a crisis that began more than a decade before the materials existed. This Court accordingly finds that the State failed to meet its burden to prove causation from Janssen's unbranded marketing.

3. Janssen's Dissemination Of Third-Party Materials

56. The Court additionally finds no proof that Janssen's limited dissemination of third-party materials caused Oklahoma's opioid abuse crisis.

57. The State identified only scattered occasions over the course of a decade where Janssen may have disseminated third-party statements about opioids. *See supra* 63-73.

58. But it presented no evidence about the extent to which Janssen distributed any of those statements in Oklahoma. This evidence allows only for speculation about whether Janssen's distribution of third-party statements was sufficiently widespread to materially influence prescribing practices in the State and thus cause an opioid abuse crisis. Such "mere possibility or speculation" is insufficient to prove causation. *See McKellips*, 1987 OK 69, ¶ 11, 741 P.2d at 471.

B. The State did not establish legal cause.

59. The Court concludes that Janssen was not a legal cause of Oklahoma's opioid abuse crisis.

60. "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.

61. No "natural and continuous sequence" connects Janssen's branded promotions to the Oklahoma opioid crisis. Janssen promoted the Duragesic fentanyl patch, Nucynta tapentadol pills, and various tramadol products. But internal documents from the State's drug-enforcement and regulatory agencies consistently explain that widespread diversion and abuse of oxycodone and hydrocodone pills—not the products Janssen promoted—fueled the State's crisis. Any relationship between, on one hand, Janssen's promotion of fentanyl patches, tapentadol pills, and tramadol and, on the other, the widespread abuse and diversion of oxycodone and hydrocodone manufactured and promoted by other companies must, as a matter of law, be too indirect and attenuated to justify liability. *See, e.g., Norman v. Scrivner-Stevens Co.*, 1949 OK 48, ¶ 12, 204 P.2d 277, 280 (no legal cause where defendant's "acts were remote in relation to the act which caused his death").

62. Likewise, no "natural and continuous sequence" connects unbranded promotions in the late 2000s and a crisis that began more than a decade earlier and was already nearing its peak. *See, e.g., Woodward v. Kinchen*, 1968 OK 152, ¶ 13, 446 P.2d 375, 378 ("The proximate cause of any injury must be the efficient cause which sets in motion the chain of circumstances leading to the injury....").

63. The Court also finds an array of independent causes that weaken or break any causal chain between Janssen's conduct and the State's injuries.

64. The medical community's increased emphasis on treating chronic pain, including with opioids, began in the 1970s, long before Duragesic was approved by the FDA in 1990. That new emphasis represents an independent cause of increased opioid prescribing.[660] The trend was

[660] May 30, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 60:9-61:4 ("more chronic pain ... was being diagnosed and treated" from 1988 to 1999); *see also* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 102:22-103:2; State Ex. 1574, "The Interagency Committee on New

reflected in documents like the APS/AAPM 1997 Consensus Statement, which the State's own expert, Dr. Kolodny, said "blew a hole through the dam of narcotic conservatism," was "one of the single most damaging documents when we look back at the history of our opioid crisis," and "more than any other document … changed the culture of prescribing in the United States."[661] That one of the document's drafters had done legal work for Janssen years earlier does not make Janssen responsible for the document. *See supra* 65-67. The Consensus Statement and the shifting medical trend it represented constitute an independent cause of increased opioid prescribing, disrupting any link between Janssen's promotions and the Oklahoma opioid abuse crisis.

65. The independent choices of Oklahoma prescribers represent another independent cause of increased prescriptions. Oklahoma law assumes that if a medication's label adequately warns of its risks, prescribing physicians are "assume[d]" to "exercise the informed judgment thereby gained" as part of their own "independent judgment." *Edwards v. Basel Pharm.*, 1997 OK 22, ¶ 8, 933 P.2d 298, 300. The State's experts conceded that the labels accompanying Janssen's medications adequately warned of their risks.[662] Although the State argued that Janssen's marketing undercut these warnings, it did not identify a single physician who disregarded the warnings because of Janssen's influence. *In re Vioxx Prod. Liab. Litig.*, 2010 WL 11570867, at *7 (E.D. La. Mar. 31, 2010) ("[I]t is not sufficient for Plaintiff to generally

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Therapies for Pain and Discomfort: Report to the White House" at I-1 (May 1979) (*admitted June 3, 2019*).

[661] June 11 (PM) Trial Tr. (Kolodny Test.) 27:11-16, 45:9-17.

[662] *See, e.g.*, June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 105:1-107:21 (conceding Duragesic's label, Janssen Ex. 2769, adequately communicates risks of abuse, fatal overdose, and diversion associated with Duragesic); June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 31:5-33:9 (conceding Nucynta ER's label, Janssen Ex. 2785, warns about the risks associated with misusing or abusing Nucynta ER, including overdose and death).

assert that Merck's misrepresentations led to the prescription of Vioxx. Each decision by each doctor and each patient was different."). To the contrary, multiple Oklahoma physicians testified at trial that they knew of opioids' risks and independently prescribed them based on their patients' individualized medical needs.[663] *See supra* 13-14, 20-21, 23-25. They did so, they explained, because they believed that opioids were and continue to be valuable treatment options for chronic pain. *See supra* 8-14. The FDA still agrees with that conclusion to the present day, and the State has repeatedly insisted that it does not intend for this lawsuit to block pain patients' access to opioid therapy.[664] The informed choices of countless Oklahoma physicians who—like the FDA and the State—knew the risks of addiction and abuse represent an intervening cause breaking any causal link between Janssen's marketing and increased opioid prescriptions.

66. As the State has recognized, the FDA's approval of novel opioid medications, notably its 1996 approval of OxyContin and the pervasive diversion and non-medical use of oxycodone and hydrocodone that followed, also catalyzed abuse and misuse by the early to mid-2000s.[665] OxyContin's release fed into long-term social and economic trends that drove

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[663] July 8, 2019 (AM) Trial Tr. (Halford Test.) at 48:20-49:7; June 28, 2019 (PM) Trial Tr. (Schick Test.) at 242:5-23; July 3, 2019 (AM) Trial Tr. (Toal Test.) at 48:14-19

[664] *See, e.g.*, Janssen Ex. 1576, FDA Response to PROP Petition (*admitted June 13, 2019*); July 15, 2019 (AM Pt. 2) Trial Tr. (Beckworth Arg.) at 37:11-38:1 ("No one [is] trying to take [chronic pain patients'] treatment away.").

[665] *See, e.g.*, Janssen Ex. 729, DURB Meeting Packet (July 5, 2001 (*admitted June 25, 2019*) (OxyContin was released in 1996); Janssen Ex. 734, DURB Meeting Packet (Aug. 14, 2001) at 1, 34-35 (*admitted June 25, 2019*) (letter from Purdue Pharma describing "[r]eports of illegal misuse, abuse, and diversion of Oxycontin"); Janssen Ex. 939, DURB Meeting Transcription (Mar. 8, 2006) at 29 (*admitted June 26, 2019*) (Board member Dr. Bell and Dr. Vorse acknowledging OxyContin diversion was serious problem in Oklahoma); Janssen Ex. 456, DURB Meeting Packet (May 14, 2008) at 8 (*admitted June 7, 2019*) (Woodward of Oklahoma Bureau of Narcotics stating "the problem is obviously the early '90's to the late '90's, the number one drug became hydrocodone"); June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 32:24-33:21 ("[H]ad FDA strictly enforced the law when Purdue was going to introduce

increased overdose rates for benzodiazepines, muscle relaxants, methamphetamine, and cocaine[666] over the same period. *See supra* 64-87, 89-90. Rogue doctors operating "pill mills" fueled the crisis by prescribing opioid medications—primarily hydrocodone and oxycodone—to patients without any legitimate medical need.[667] Criminal diversion and improper prescription of hydrocodone and oxycodone in the late 1990s and early 2000s were not foreseeable consequences of Janssen's branded promotion of Duragesic over that same time period, representing yet another intervening cause defeating legal causation. *See, e.g., Lefthand v. City of Okmulgee*, 1998 OK 97, ¶ 8, 968 P.2d 1224, 1226 ("act of a third person in committing an intentional tort or crime is a supervening cause" that "relieves the initial … actor from liability"). Criminal networks that have flooded the United States with illicit and counterfeit opioids further disrupt the causal chain.[668]

67. The opioid-abuse crisis is a complex social problem driven by countless independent forces, ones Janssen did not control and could not have controlled. Because of those independent causes, Janssen's branded promotion of its products and its unbranded promotions in the late 2000s could not have caused the crisis.

OxyContin and had limited OxyContin's promotion of … we might not have an epidemic today.").

[666] *See, e.g.*, State Ex. 1569, Piercefield, *et al.*, *Increase in Unintentional Medication Overdose Deaths Oklahoma, 1994-2006*, 39 Am. J. Prev. Med. 357, 1 (2010) (admitted June 7, 2019).

[667] Janssen Ex. 624, OBNDD 2017 Drug Threat Assessment at 12 (*admitted June 18, 2019*); Janssen Ex. 832, DURB Meeting Packet for March 9, 2004 Meeting at 46 (discussing rogue pharmacies and pill mills) (*admitted June 25, 2019*); Carter Depo. Tr. at 39:4-40:12 (*played July 10, 2019*).

[668] *See, e.g.*, June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 107:3-17; Portenoy Depo. Tr. at 383:10-384:16 (played May 29, 2019).

C. Due process precludes imposing liability on Janssen for harms its conduct did not cause.

68. The due-process clauses of the Fourteenth Amendment and Oklahoma Constitution prevent this Court from holding Janssen liable to remedy harms that its conduct did not cause. *See* U.S. Const. amend. XIV; OK Const. art. 2, § 7.

69. Due process bars a state from imposing tort liability without the traditional "common-law protection[s]" essential to guard against "arbitrary deprivations of property." *Honda Motor Co. v. Oberg*, 512 U.S. 415, 430-32 (1994). These bedrock safeguards against arbitrary judgments include both actual and legal cause. The U.S. Supreme Court has explained that, as a matter of "textbook tort law," "an action is not regarded as a cause of an event if the particular event would have occurred without it." *Nassar*, 570 U.S. at 347 (quotation omitted). Similarly, legal cause is the "necessary" means of foreclosing liability where "the link has become too tenuous." *Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 838 (1996) (quotation omitted). The State requests that this Court impose massive liability for a crisis that would have occurred without any action by Janssen no connection, proximate or otherwise, to Janssen's conduct. Granting that request would impermissibly contravene these fundamental due process protections. This Court will not do so.

V. THE STATE CANNOT HOLD JANSSEN LIABLE FOR THIRD-PARTY SPEECH OR JANSSEN'S GOVERNMENT LOBBYING

70. The State's trial evidence focused extensively on speech by third parties, including advocacy groups like the American Pain Society and various KOLs. But the First Amendment bars the State from punishing both those third parties' non-commercial speech about scientific issues and Janssen's association with them. It similarly forecloses the State's attacks on lobbying Janssen participated in through the Pain Care Forum.

A. The First Amendment protects third parties' speech on medical issues.

71. The State's witnesses criticized a range of statements by third-party groups, from JCAHO's endorsement of "Pain as a Fifth Vital Sign" to the APS and AAPM Consensus Statement. They also attacked research and public statements by prominent doctors Janssen hired as consultants.

72. But statements by advocacy organizations, doctors, and scientists about public-health questions are not commercial speech. *See 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"). Rather, as speech on public issues, they "occup[y] … the highest rung of the hierarchy of First Amendment values, and [are] entitled to special protection." *Connick v. Myers*, 461 U.S. 138, 145 (1983). And as constitutionally protected speech, they cannot form the basis for liability under state tort law. *See, e.g., Snyder v. Phelps*, 562 U.S. 443, 451-52 (2011).

73. The same is true for CME seminars that Janssen sponsored through unrestricted educational grants. As the undisputed testimony of multiple trial witnesses made clear, Janssen lacked control over the contents of those educational seminars and the doctors who developed them maintained total independence over their contents. *See supra* 76-80. Doctors' educational presentations to other doctors about medical issues represent pure First Amendment speech, even if Janssen sponsored them: "[S]peech does not lose its First Amendment protection because money is spent to project it." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 761 (1976). Janssen accordingly cannot be held liable for the contents of medical presentations its unrestricted grants funded.

74. The State's bid to hold Janssen liable for the conduct of third parties with which it affiliated would also violate Janssen's First Amendment right of association. Under the First

Amendment, "[c]ivil liability may not be imposed merely because an individual belonged to a group." *NAACP*, 458 U.S. at 920. That remains the law even if the defendant made financial contributions. "Joining organizations that participate in public debate, ***making contributions to them***, and attending their meetings are activities that enjoy substantial First Amendment protection." *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1294 (3d Cir. 1994) (Alito, J.) (emphasis added).

75. A defendant thus cannot be held liable for a third-party group's wrongful conduct unless the defendant "specifically intended to further such wrongful conduct." *Id.* at 1290. "The government has the burden of establishing" not only "a knowing affiliation with an organization possessing unlawful aims and goals," but also "a specific intent to further those illegal aims." *NAACP*, 458 U.S. at 919-20. Here, the State neither established that any third party engaged in unlawful conduct nor that Janssen funded or associated with any third party specifically to further unlawful conduct. For that reason, too, the State cannot secure liability against Janssen based on those third parties' actions.

B. The First Amendment's Petition Clause protects Janssen's lobbying activities.

76. The State's witnesses also criticized Janssen's own lobbying of state officials over tramadol scheduling, *see supra* 34-38, as well as federal and state lobbying Janssen participated in through the Pain Care Forum, *see supra* 80-84.

77. The First Amendment protects the "right of the people … to petition the Government." U.S. Const. amend. I. The U.S. Supreme Court has held that the Petition Clause protects citizens' and companies' efforts to inform and influence policy by lobbying the government. *See, e.g., E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("*Noerr*"); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)

("*Pennington*"). Under the *Noerr-Pennington* doctrine, bona fide government lobbying is immune from civil liability. *See, e.g., Empress LLC v. City & Cty. of San Francisco*, 419 F.3d 1052, 1056 (9th Cir. 2005).

78. The State asserts that "[i]t is not that [J&J] petitioned the government; it is that [J&J] spread their false and deceptive message into government channels, seeking to influence doctors from all angles."[669] But under the *Noerr-Pennington* doctrine, it makes no difference what kind of government action Janssen pursued—"*Noerr-Pennington* immunity applies to any concerted effort to sway public officials regardless of the private citizen's intent." *Bayou Fleet, Inc. v. Alexander*, 234 F.3d 852, 859 (5th Cir. 2000). The State presented no evidence that Janssen's lobbying efforts were not bona fide "effort[s] to sway public officials." *Id.* The *Noerr-Pennington* doctrine therefore bars liability for Janssen's lobbying.

VI. FEDERAL AND OKLAHOMA LAW BAR LIABILITY FOR NORAMCO'S AND TASMANIAN ALKALOIDS' SALES OF RAW MATERIALS

79. The State took shifting positions on the significance of Noramco's and Tasmanian Alkaloids' raw-material sales. At times, it asserted those sales made Janssen and J&J liable for Oklahoma's opioid-abuse crisis; at others, it asserted they merely furnished the motive for Janssen's unbranded promotions. Neither position supports liability against Janssen. As explained above, the State's assertion that Noramco and Tasmanian Alkaloids motivated Janssen's unbranded promotions lacked any shred of evidentiary support. *See supra* 61-62. Meanwhile, multiple state and federal doctrines prohibit the State from imposing liability for those subsidiaries' sales.

[669] Resp. to Mot. for Judgment (July 7, 2019) at 55.

A. Federal law preempts liability for Noramco's and Tasmanian Alkaloids' sales of raw materials.

80. Tasmanian Alkaloids and Noramco sold narcotic raw materials under a comprehensive federal regulatory scheme designed to ensure reliable supplies of medically necessary medications. In accordance with that framework, the DEA issued quotas affirmatively authorizing each of those companies' customers to procure the raw materials they purchased, in the amounts they purchased, based on the agency's determination that those sales were necessary to meet the nation's medical needs. *See* 21 C.F.R. § 1312.13(a)(1) (requiring DEA finding that importation of concentrated poppy straw is "necessary to provide for medical, scientific, or other legitimate purposes"); 21 C.F.R. § 1303.12(a) (requiring DEA to allocate API quotas to "insure an adequate and uninterrupted supply of … basic classes of controlled substances").

81. A federal statute impliedly preempts state law if the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012). The CSA preempts liability for Noramco's and Tasmanian Alkaloids' DEA-authorized sales because such liability would directly countermand the agency's decision to permit the sales and would "effectively challenge[]" the DEA's judgment that those sales were necessary to meet the nation's medical needs. *See Marentette v. Abbott Labs., Inc.*, 886 F.3d 112, 117 (2d Cir. 2018); *see also, e.g., Barnett Bank of Marion Cty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996) (finding obstacle preemption of state law prohibiting federally authorized insurance sales). In addition, such liability would discourage the very sales the DEA deemed necessary, undermining the agency's ability to "insure an adequate and uninterrupted supply of … basic classes of controlled substances." 21 C.F.R. § 1303.12(a). Basic obstacle preemption principles bar such state-law interference with federal programs. *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).

B. Oklahoma law precludes tort liability for Noramco's and Tasmanian Alkaloids' sales.

82. Oklahoma law likewise precludes liability for Noramco's and Tasmanian Alkaloids' activities.

83. The Oklahoma nuisance statute includes a safe harbor provision instructing that "[n]othing which is done or maintained under the express authority of a statute can be deemed a nuisance." 50 O.S. § 4. The DEA, under the federal CSA, issued quotas permitting all of Noramco's and Tasmanian Alkaloids' sales. *See supra* 59-61. That explicit authorization brings their sales within the Oklahoma nuisance statute's safe harbor, foreclosing nuisance liability.

84. To avoid that conclusion, the State argued that the safe harbor provision does not authorize a business to operate in any manner it chooses. *See Reaves v. Territory*, 1903 OK 92, ¶¶ 8, 27, 74 P. 951, 954. But the activities the State challenged are the *very acts* federal law authorized: The DEA's quotas authorized Noramco and Tasmanian Alkaloids to sell the precise amounts of raw material and API that they sold, and authorized their purchasers to buy the exact amount of raw materials and API that they bought. It did so under a scheme designed to ensure reliable supplies of medically necessary pharmaceuticals. *See supra* 59-61 . The outcome of those transactions—the sale of opioid medications by Noramco's customers—accordingly was precise result contemplated by the CSA and DEA. The safe harbor's applicability could not be clearer.

85. The Oklahoma safe harbor provides an essential due process protection, as punishing Janssen for the very conduct federal law affirmatively authorized would violate its Fourteenth Amendment due process rights. Imposing liability for such affirmatively authorized

conduct would violate Janssen's due process rights under the federal and Oklahoma constitutions. *See, e.g.*, *Bordenkircher v. Hayes*, 434 U.S. 357, 363 (1978) ("To punish a person because he has done what the law plainly allows him to do is a due process violation of the most basic sort.").

86. Oklahoma also does not recognize tort liability for component suppliers that have no role in making the finished product at issue. *Swift v. Serv. Chem., Inc.*, 2013 OK CIV APP 88, ¶¶ 21-22, 310 P.3d 1127, 1132-33; *Thompson v. TCI Prods. Co.*, 81 F. Supp. 3d 1257, 1263-65 (N.D. Okla. 2015) (Oklahoma law). A component supplier can be held liable only "when [it] substantially participates in the design of the final integrated product." *Swift*, 2013 OK CIV APP 88, ¶¶ 21-22, 310 P.3d at 1132-33. As *Swift* recognizes, "[i]nappropriate decisions regarding the use of raw materials are not attributable to the supplier of the raw materials but rather to the fabricator that puts them to improper use." 2013 OK CIV APP 88, ¶ 22, 310 P.3d at 1133 (quoting Restatement (Third) of Torts, § 5 cmt. c (alteration omitted)). That principle's logic controls the State's public nuisance claim no less than a traditional product-liability action. The State's claim that Noramco's and Tasmanian Alkaloids' customers misleadingly promoted their own finished products is a commonplace product-liability theory. The State's choice to package that theory as a public nuisance claim does not change the conclusion that the purchasers' "[i]nappropriate decisions … are not attributable to the supplier of the raw materials." *Id.*

87. The trial evidence showed that Noramco and Tasmanian Alkaloids did not participate in designing, manufacturing, marketing, or distributing pharmaceutical manufacturers' finished products. —they sold "an active ingredient … formulated further into a

drug product" by their purchasers.[670] Instead, those manufacturers (including Purdue) bought API from Noramco and Tasmanian Alkaloids, and "made a substantial change in the way the [API was] packaged and distributed, and in instructing how [it] should be used." *Swift*, 2013 OK CIV APP 88, ¶ 22, 310 P.3d at 1133. Under *Swift*, any misleading statements the manufacturers made in promoting their finished product are attributable to them—not their raw material suppliers. [671]

C. The State did not produce evidence to pierce the corporate veil.

88. Finally, Janssen and J&J cannot be held liable for their subsidiaries' raw material sales because the State failed to prevent evidence sufficient to pierce the corporate veil.

89. The rule that a parent corporation "is not liable for the acts of its subsidiaries" is a "general principle of corporate law deeply ingrained in our economic and legal systems." *United States v. Best Foods*, 524 U.S. 51, 61 (1998) (quotation omitted). In Oklahoma, "[o]ne corporation may be held liable for the acts of another under the theory of alter-ego liability if (1) the separate existence is a design or scheme to perpetuate a fraud *or* (2) one corporation is merely an instrumentality or agent of the other." *Canal Ins. Co. v. Montello, Inc.*, 822 F. Supp. 2d 1177, 1181-82 (N.D. Okla. 2011) (citing *Gilbert v. Sec. Fin. Corp. of Okla.*, 2006 OK 58, ¶¶ 22-23, 152, P.3d 165, 175) (emphasis in original). "Piercing the corporate veil is "an

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[670] *See, e.g.*, Grubb Depo. Tr. at 268:1-11 (played July 10, 2019); *id.* at 270:7-12 (testifying that "we do not prescribe and we do not make the actual dosage form, we're making an ingredient"), 284:11-285:15 (Noramco has "no involvement" in "deciding what opioid products are made by its customers from the opioid API that Noramco sells" or in the "marketing or promotion" of those products").

[671] he U.S. Supreme Court's recent decision in *Air & Liquid Sys. Corp. v. Devries*, 139 S. Ct. 986 (2019), does not undermine these settled common law principles. *Devries* addressed the circumstances under which a "product manufacturer"—the maker of pumps, blowers, and turbines for naval vessels—must warn of the risks posed when a necessary part is added to its product. *Id.* at 991. It did not address the liability of component-part or raw material suppliers.

extraordinary remedy that should be used sparingly." *Phoenix Energy Marketing, Inc. v. Chase Oil Corp.*, 2017 WL 6397492, at *4 (N.D. Okla. Dec. 14, 2017) (citing *Puckett v. Cornelson*, 1995 OK CIV APP 72, ¶ 6, 897 P.2d 1154, 1156).

90. Oklahoma courts consider nine factors when determining whether one corporation can be held liable for its subsidiaries' conduct under an "alter ego" theory. All of those factors "hinge[ ] primarily on control." *Oliver v. Farmers Ins. Group of Cos.*, 1997 OK 71, ¶ 8, 941 P.2d 985, 987. They include:

> (1) whether the dominant corporation owns or subscribes to all the subservient corporation's stock, (2) whether the dominant and subservient corporations have common directors and officers, (3) whether the dominant corporation provides financing to the subservient corporation, (4) whether the subservient corporation is grossly undercapitalized, (5) whether the dominant corporation pays the salaries, expenses, or losses of the subservient corporation, (6) whether most of the subservient corporation's business is with the dominant corporation or the subservient corporation's assets were conveyed from the dominant corporation, (7) whether the dominant corporation refers to the subservient corporation as a division or department, (8) whether the subservient corporation's officers or directors follow the dominant corporation's directions, and (9) whether the corporations observe the legal formalities for keeping the entities separate.

Gilbert, 2006 OK 58, ¶ 23, 152 P.3d at 175, *overruled on other grounds by Montgomery v. Airbus Helicopters, Inc.*, 2018 OK 17, 414 P.3d 824.

91. The State bore the burden to prove that the corporate veil should be pierced. *See, e.g., Sproles v. Gulfcor, Inc.*, 1999 OK CIV APP 81, ¶ 12, 987 P.2d 454, 457. It tried to make that showing mainly through rebuttal evidence from Matthew Martin, a former Noramco employee. He testified that he worked at Janssen's Titusville campus for part of his Noramco tenure,[672] that he did not believe that Noramco kept separate bank accounts, and that J&J's credo applied to Noramco and appeared on Noramco's website.[673]

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[672] Martin Depo. Tr. at 8:20-9:1 (played July 12, 2019).

[673] *Id.* at 101:10-20; 104:5-105:14.

92. As a matter of law, the State's evidence was insufficient to establish that Noramco was Janssen's alter ego. At most, the State presented evidence on two of the nine factors. Although Janssen's ownership of Noramco satisfies the first factor for alter ego liability, the mere "fact that a corporation owns all or a majority of the stock of another corporation does not destroy the identity of the latter as a distinct legal entity." *See Rea v. An-Son Corp.*, 79 F.R.D. 25, 29 (W.D. Okla. 1978). Similarly, to the extent Noramco might have lacked separate bank accounts, that suggests only that "[l]egal formalities for keeping the entities separate" were not always observed. *Gilbert*, 2006 OK 58, ¶ 23, 152 P.3d at 175.

93. The weight of the other factors compels a finding of corporate independence. Noramco executive William Grubb testified that Noramco owned its own manufacturing facilities, and operated independently from Janssen day to day, developing its own business plans and selecting its own product lines.[674] Noramco—not Janssen—"pa[id] the salaries" of its employees.[675] And Noramco trained its own employees, who had Noramco business cards, used Noramco letterhead, and generally worked at Noramco-owned facilities.[676] The State presented no evidence of common directors or officers, no evidence that Janssen financed Noramco's operations, no evidence that Noramco was undercapitalized, no evidence that the bulk of Noramco's business was with Janssen, no evidence that Noramco's assets were conveyed from Janssen, no evidence that Janssen referred to Noramco as a division or department, and no evidence that Noramco officers followed directions from Janssen. *See id.*

[674] Grubb Depo. Tr. at 271:18-274:2 (played July 10, 2019).

[675] *Id.*

[676] *Id.* at 182:3-9, 271:18-274:2.

94. And the State provided no evidence that Tasmanian Alkaloids was an alter ego of J&J.

95. The State's failure to carry its proof to pierce the corporate veil precludes holding Janssen and Johnson & Johnson liable for their subsidiaries' activities.

VII. FEDERAL AND OKLAHOMA LAW FORECLOSE THE STATE'S CHALLENGE TO THE PROMOTION OF OPIOIDS FOR CHRONIC NON-CANCER PAIN

96. Despite taking aim at a multitude of statements by Janssen or third parties throughout this trial, State experts[677] and counsel[678] have repeatedly reaffirmed that the State's *core* challenge is to Janssen's promotion of opioids as safe and effective for the treatment of chronic non-cancer pain. This challenge runs headfirst into the FDA-approved indications for Duragesic and Nucynta ER, which at all times included the long-term treatment of chronic non-cancer pain. Federal law bars the State from punishing Janssen for promoting its medications for their FDA-approved indications.

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[677] *See, e.g.*, June 11, 2019 (AM) Trial Tr. (Kolodny Test.) at 76:24-77:13 (criticizing J&J's "brilliant multifaceted campaign" in which it stated that "these drugs are the way to improve the quality of life in your patients who might suffer with chronic pain"); June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 124:15-22 ("I believe during the dinner program that I attended, I was in disagreement with the utilization of long-acting opioids, including Nucynta which they were advocating is an appropriate treatment for chronic non-malignant pain."); 126:3-6 (claiming a Janssen sales representativefalsely stated "[t]hat long-acting opioids have a role in chronic non-malignant pain, and that they benefit the patients over the long-term"); June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 58:16-17 ("For the vast majority of people that might suffer with chronic pain, opioids are not appropriate."); June 5, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 150:17-20 ("Q. Do people actually improve on chronic opioid therapy? A. If they have, I haven't seen it in my tenure of 15 years of practice."); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 40:15-21 (opioids are valuable for "acute short-term pain," "chronic cancer pain, malignancy pain, [and] end-of-life care")

[678] *See* May 28, 2019 (AM) Trial Tr. (Beckworth Arg.) at 28:1-20 ("But something happened … What [J&J and Janssen] started doing was using Duragesic as something that should be marketed broadly and widely for everyday chronic pain."); *cf.* July 3, 2019 (AM) Trial Tr. (Whitten Quest.) at 70:24-25 ("Q: And you understand the State in this case is not attacking the use of opioids for acute care?").

97. As an initial matter, the First Amendment prohibits states from banning the promotion of lawful products for their lawful purposes. A state can outlaw a product or limit its legal uses. But when it declines to do so, it cannot use speech restrictions as a way to vicariously target lawful conduct. *See, e.g., Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367-77 (2002) (statute that forbade advertising of certain drugs, but not their sale, violated First Amendment); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 700 (1977) (invalidating statute prohibiting advertisements of legally available contraceptive products).

98. Because the FDA dictates drug labeling, state law also cannot impose a duty to alter labeling where there is "clear evidence" the FDA would disallow the change. *See, e.g., Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676-78 (2019); *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). That restriction extends to promotional statements no less than to the physical labels affixed to drugs because FDA regulations define "labeling" to encompass "virtually all communication with medical professionals" about a medication, including advertising and contacts with doctors. *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); *accord Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014).

99. Here, Janssen presented clear evidence that the FDA would have rejected a change to the labeling of Janssen's long-acting opioids to preclude use for chronic non-cancer pain. In 2012, Physicians for Responsible Opioid Prescribing ("PROP")—a group spearheaded by Dr. Kolodny—filed a citizen petition with the FDA, requesting that the approved indication in the labeling for long-acting prescription opioids be revised to "[a]dd a maximum daily dose,

equivalent to 100 milligrams of morphine for non-cancer pain" and "[a]dd a maximum duration of 90-days for continuous (daily) use for non-cancer pain." The FDA explicitly rejected those portions of the petition in 2013, explaining that "PROP ha[d] not provided scientific support for why labeling should recommend different treatment for such patients," and emphasized that it "kn[ew] of no physiological or pharmacological basis upon which to differentiate the treatment of chronic pain in a cancer setting or patient from the treatment of chronic pain in the absence of cancer." That rejection offers clear evidence that the FDA would have rejected a similar manufacturer-initiated change to a drug label, and thus precludes liability for Janssen's promotions of its products for chronic non-cancer pain. *See, e.g., Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017); *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385-86 (6th Cir. 2017).

100. Federal obstacle-preemption rules also preclude holding Janssen liable for promotional statements about opioid medications consistent with their FDA-approved labeling. The Federal Food, Drug, and Cosmetic Act ("FDCA") makes it the FDA's mission to "promote the public health" not only by "ensuring that … human … drugs are safe and effective" but also by "taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393. Congress accordingly vested the FDA with the power to both approve new prescription drugs and regulate their marketing and promotion. *See, e.g., id.* §§ 352(n), 355(d). And under Congress's direction, the FDA has promulgated a comprehensive regulatory regime—establishing a labeling approval process, regulating the content and presentation of drug labeling and advertising, and authorizing enforcement actions for false or misleading marketing. *See, e.g.*, 21 C.F.R. §§ 201.1-201.58, 202.1.

101. This comprehensive regulatory scheme aims to give doctors and the public access to information that the FDA has found to be accurate. Imposing state-law liability on Janssen for promotion consistent with FDA-approved labeling would cast uncertainty on the legal viability of such promotions, chill their dissemination, and impede health care professionals' and the public's access to complete information necessary for those medications' safe and effective use. *See* 71 Fed. Reg. at 3,961 ("The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use."). For this reason as well, the Court concludes that the State's core challenge is preempted.

102. Finally, just as preemption forbids the State from penalizing marketing consistent with an FDA-approved indication, so does the Oklahoma nuisance statute's safe-harbor provision. *See* 50 O.S. § 4. The Court concludes that marketing opioids for the long-term treatment of chronic pain is conduct "maintained under the express authority" of the FDA and its governing statutes, and is therefore immune from liability.

VIII. THE STATE'S CONTRIBUTIONS TO THE OPIOID CRISIS ENTITLE JANSSEN TO JUDGMENT

103. Under Oklahoma law, a plaintiff who contributes to a harm resulting from a nuisance must produce evidence that will enable the court to separate the amount of damage inflicted by the defendants from the amount of damage resulting from the plaintiff's acts. *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, ¶ 6, 204 P. 906, 908. Without such evidence, "the plaintiff will not be entitled to recover from the defendants sued." *Id.*[679] This requirement serves to preclude plaintiffs from recovering "not only for [defendants'] own acts, but for the

[679] Contrary to the State's assertion, *Walters* is a nuisance case. *See* July 8, 2019 (AM) Trial Tr. (Beckworth Arg.) at 81:14-15 ("The case they cite is a negligence case. We do not have a negligence claim."),.

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]") (quotation omitted).

104. However well-intentioned the State may have been in addressing the balance between supplying medically necessary medications and preventing abuse and diversion, the State repeatedly took actions favoring access to widely abused opioids at the risk of abuse and diversion: In administering its Medicaid program, it gave preferential reimbursement treatment to widely abused hydrocodone and oxycodone drugs while removing duration limits, rejecting quantity limits, and declining to impose prior authorization requirements for widely prescribed and abused opioids. Immediately following those decisions, which the State made for both budgetary and medical reasons, the number of Medicaid prescriptions for commonly abused opioid medications increased dramatically.

105. The evidence also shows that the State waited for years to address "doctor shopping." The State knew as early as 2008 that its prescription monitoring program ("PMP") revealed "very alarming" rates of doctor shopping[680]: Between July and September 2007, 1,930 Oklahomans obtained prescriptions for controlled substances from five or more doctors. Yet the State did not require Oklahoma physicians to consult the PMP before writing prescriptions until seven years later. And when confronted with evidence of Oklahoma doctors committing egregious prescription violations, it frequently waited years to take action against them.

106. The State has argued that any responsibility it bears for the opioid crisis should be mitigated by the alleged influence of pharmaceutical lobbyists.[681] But it has not identified a

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[680] Janssen Ex. 637, September 29, 2008 Email from Charlie Price to Emily Lang at 1, 10 (*admitted June 26, 2018*).

[681] Resp. to Mot. for Judgment (July 7, 2019) at 55-56.

single one of its decisions that lobbyists influenced. By all appearances, the State made the choices it did to save money and ensure patient access to pain treatments. Under *Walters*, it cannot compel Janssen to pay for the consequences of those decisions.

107. *Walters* requires a nuisance plaintiff to provide evidence separating the harms it caused from those caused by the defendant. The State offered no such evidence. That failure precludes it from recovering against Janssen. *Walters*, 1922 OK 52, ¶ 6, 204 P. at 908. At a minimum, the logic of *Walters*—that a defendant should not have to pay for a plaintiff's contribution to a nuisance, *see id.*—precludes the State from holding Janssen jointly and severally liable for the entire opioid abuse crisis in Oklahoma.

IX. OKLAHOMA LAW BARS THE STATE'S PROPOSED REMEDY

108. The State's public nuisance claim also fails because the only remedy it seeks contravenes Oklahoma law and is unsupported by the trial evidence. The State's proposed "abatement plan" demands a multi-billion dollar payment by Janssen to fund—for decades—dozens of government programs that the State contends are necessary to remedy Oklahoma's opioid abuse problems. But that remedy is unavailable under Oklahoma's nuisance statute, violates Janssen's jury-trial rights, tramples basic separation of powers principles, lacks support in the trial evidence, and would amount to an unconstitutional excessive fine.

A. The State's Proposed Remedy Constitutes Damages Rather than Abatement of a Nuisance.

109. Oklahoma public nuisance law gives the State only one civil remedy: to "abate" a "public nuisance." 50 O.S. § 11. And as earlier explained, the nuisance statute defines a "public nuisance" as "unlawfully doing an act, or omitting to perform a duty." 50 O.S. § 1. Under that statutory definition, the State's power to abate a "public nuisance" authorizes it to enjoin the defendant's act or omission constituting the nuisance. *See Magnolia Petroleum Co. v. Wright*,

1926 OK 196, ¶ 3, 254 P. 41, 42 (power "to abate and remove" "a nuisance" is "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").

110. Because the power to abate a nuisance is the power to enjoin or mandate conduct, no Oklahoma court has ever awarded cash damages to abate a nuisance.

111. The State's proposed "abatement" remedy, however, does not seek to stop any act or omission by Janssen. In fact, there is no continuing conduct by Janssen for the State to abate: Janssen no longer actively promotes any opioid medications, *see supra* 18, 45, and it divested Noramco and Tasmanian Alkaloids in 2016, *see supra* 59.

112. The State admits that the abatement plan it outlined at trial does not seek to put a stop to any act or omission by Janssen.[682] It instead aims to "abate the opioid epidemic"—that is, to address the harms the State alleges resulted in part from Janssen's actions.[683] Indeed, the State has described the relief it seeks as intended to "clean up" the alleged consequences of pharmaceutical manufacturers' actions.[684]

113. Oklahoma law, however, makes clear that the ***consequences*** of a defendant's conduct are damages—not a nuisance: "Nuisance is a wrong, and damage is the result."

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[682] *See, e.g.*, June 10, 2019 (PM) Trial Tr. (Stone Test.) at 144:25-145:2 ("Q. But the plan doesn't require Janssen or Johnson and Johnson to stop doing anything, does it? A. No.").

[683] *See, e.g.*, May 28, 2019 (AM) Trial Tr. (Hunter Arg.) at 10:9-11 (arguing that the State's abatement plan aims to "bring an end to the opioid epidemic in Oklahoma"), 70:19-23 ("[t]his case is about ... [an] epidemic … and then how to abate it"); June 20, 2019 (AM) Trial Tr. (Croff Test.) at 37:22-38:2 (acknowledging that the plan aims to "abate the crisis"); June 21, 2019 (AM) Trial Tr. (Hawkins Test.) at 33:11-34:20 (describing proposed abatement program as "essential to abating the crisis"); June 26, 2019 (PM) Trial Tr. (White Test.) at 129:19-130:1 (testifying that the State's abatement plan is "need[ed] … to abate the epidemic that [Defendants] caused," and asserting that the plan "can and will abate the opioid crisis").

[684] May 28, 2019 (AM) Trial Tr. (Hunter Arg.) at 11:17-20; May 28, 2019 (AM) Trial Tr. (Beckworth Arg.) at 44:1-2; May 28, 2019 (AM) Trial Tr. (Burrage Arg.) at 76:19-20.

Oklahoma City v. Page, 1931 OK 764, ¶ 10, 6 P.2d 1033, 1036; *see Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 36 ("damage" or "injury" is "the ***result*** of the nuisance"). Because the nuisance statute only allows abatement of conduct, Oklahoma cases have held that "clean-up" costs are damages, not abatement: "***Damages*** adjudged in an action predicated on a nuisance theory may include clean-up costs … and for temporary and permanent injury to the land." *Tenneco Oil Co. v. Allen*, 1973 OK 129, syl. ¶ 2, 515 P.2d 1391, 1392 (emphasis added); *see Burlington N. and Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1029 ("one aspect of ***damages*** the 'victim' of a temporary nuisance can recover is the cost of restoring the land to its former condition") (quotation mark omitted). Because the State's demand that Janssen pay to remedy the opioid abuse crisis does not seek to abate any conduct cognizable as a nuisance under 50 O.S. § 1, it exceeds the State's authority under Oklahoma law.

B. Janssen's jury trial rights preclude this court from granting the State its proposed remedy in a bench trial.

114. For similar reasons, this Court cannot award the State's proposed remedy in a bench trial. Oklahoma law requires that "[i]ssues of fact arising in actions for the recovery of money … be tried by a jury." 12 O.S. § 556; *see also* Okla. Const. art. II, § 19 ("The right of trial by jury shall be and remain inviolate, except in civil cases wherein the amount in controversy does not exceed One Thousand Five Hundred Dollars…."); U.S. Const. amen. VII. The State's demand for billions of dollars from Janssen unmistakably makes this an "action[] for the recovery of money," 12 O.S. § 556, triggering Janssen's jury-trial rights.

115. Although no jury is required where a monetary recovery is "incidental to and dependent upon [an] equitable issue," *Russell v. Freeman*, 1949 OK 256 ¶ 6, 214 P.2d 443, 444, no dominant equitable issue exists here. Rather, as just explained, the ***only*** thing the State seeks from Janssen is monetary payment. Moreover, as just explained, it seeks that payment for

"clean-up costs"—addressing injuries, not conduct—that constitute damages under Oklahoma law. *See supra* 161-163.

116. The details of the State's "abatement" plan confirm the conclusion that its demand for a monetary payout sounds in damages. That plan asks Janssen to pay for many services the State already provides. *See supra* 95-119. Shifting those costs to Janssen would entail no change in the status quo, but only compensate the State for expenses it claims it must incur due to Janssen's conduct. That is not equitable relief, but damages. *See* Frank Gahan, *The Law of Damages* 1 (1936) ("Damages are the sum of money which a person wronged is entitled to receive from the wrongdoer as compensation for the wrong."). Indeed, the State calculated the dollar figures for one of those items—treatment costs for neo-natal abstinence syndrome, *see supra* 114—as part of the "future damages" it claimed before limiting its case to public nuisance.[685] The State's apparent belief that such expenses can be readily pursued as damages only underscores that its "abatement" plan is a thinly veiled attempt to secure damages from Janssen.

117. That conclusion is strengthened by the fact that Oklahoma law does not authorize the Attorney General to seek monetary recoveries dedicated to nuisance abatement. The statute authorizing the Attorney General to bring suit on the State's behalf directs him to pay "into the State Treasury, immediately upon its receipt, all monies [he] receive[s] ... belonging to the State." 74 O.S. § 18(b)(A)(11). Once in the Treasury, neither the Attorney General nor this Court has authority to direct how that money should be spent. Indeed, even the legislature, which must appropriate funds one year at a time and cannot bind future legislatures, lacks

[685] June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 27:2-28:2, 64:6-65:25; State Ex. 4734, at 56, n.123.

authority to implement a decades-long abatement plan. An unconditional cash transfer—the ***only*** monetary recover the Attorney General is authorized to pursue—is not an equitable abatement remedy. This Court therefore cannot award it without violating Janssen's jury-trial rights. *See supra* 163.

C. The separation of powers bars courts from ordering decades of funding for dozens of state government programs.

118. Oklahoma's Constitution commands that "the Legislative, Executive, and Judicial departments of government shall be separate and distinct," and that none of those branches "shall exercise the powers properly belonging to either of the others." Okla. Const. art. IV, § 1.

119. Within that scheme, the power to authorize and fund government spending programs resides exclusively with the legislature. The "state's policy-making power is vested exclusively in the Legislature." *Okla. Educ. Ass'n v. State ex rel. Okla. Legislature*, 2007 OK 30, ¶20, 158 P.3d 1058, 1065. That authority extends to "all rightful subjects of legislation," Okla. Const. art. V, § 36, including programs "to protect and serve the public health," *Cryan v. State*, 1978 OK CR 91, ¶ 15, 583 P.2d 1122, 1125. It also includes the authority to set "fiscal policy," which "is exclusively within the Legislature's power." *Okla. Educ. Ass'n*, 2007 OK 30, ¶ 23, 158 P.3d at 1066. The separation of powers doctrine commits these powers to the legislature, and not the courts, as Oklahoma courts have consistently affirmed. *See, e.g., id.*; *Calvey v. Daxon*, 2000 OK 17, ¶¶ 20-21, 997 P.2d 164, 171-72; *Dixon v. Shaw*, 1927 OK 24, ¶¶ 1-2, 253 P. 500, 501.

120. The State's abatement plan asks this Court to disregard those limitations and do something no American court has ever done: Legislate a solution to a daunting social problem by authorizing decades of government spending programs costing billions of dollars and determining how they will be funded. This Court lacks the power to do so. The wisdom of

massive statewide policy initiatives of the sort the State proposes are committed to the legislature, *see Okla. Educ. Ass'n*, 2007 OK 30, ¶ 20-23, 158 P.3d at 1065-66, which has the constitutional authority and expertise to formulate the State's response to complex policy challenges.

121. That institutional competence is all the more critical in response to a vexing social problem like the opioid crisis. For instance, just this May, the FDA cautioned that the opioid presents difficult policy tradeoffs that require deliberate and well-considered solutions rather than hasty improvised responses:

> It is important to consider the potential repercussions of well-meaning attempts to address the opioid crisis without adequate scientific evidence to support such actions.... Robust evidence supports that chronic pain itself, regardless of type, is an important independent risk factor for suicidality, as chronic pain patients are at least twice as likely to report suicidal behaviors or to complete suicide. In a national sample of Veterans Health Administration [patients], among patients discontinued from long-term opioid therapy for chronic pain, nearly 12 percent had documented suicidal ideation and suicidal self-directed violence in the year following discontinuation....
>
> The idea behind [the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain] was that 'improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse or overdose from these drugs.' However, the guidelines were misinterpreted and misapplied, contributing to substantial harms to patients, particularly patients with chronic pain who were forced to taper their previously stable opioid doses to lower doses, or who were forced to discontinue their opioids through forced tapers or patient.[686]

[686] FDA, *May 13, 2019 Memorandum re Opioids Regulatory Background, FDA Center for Drug Evaluation and Research* at 10 (declining to recommend limits on doses for prescription opioid medications), available at https://www.fda.gov/media/127780/download.

The State acknowledges these difficult tradeoffs, insisting that "No one [is] trying to take [chronic pain patients'] treatment away."[687] But the stated goal of its proposed abatement plan is to return opioid prescribing to pre-1996 rates—an 82 percent reduction from present levels.[688]

122. The wisdom of such goals—and of the massive policy platform the State proposes to achieve them—is a question the Oklahoma Constitution commits to the legislature. The State, however, would have this Court bypass the Oklahoma House and Senate and legislate the State's response to opioid abuse, enacting, with the stroke of a pen, a vast array of long-term statewide government programs regulating everything from K-12 education to pain therapies for Medicaid beneficiaries. Under basic separation of powers principles, this Court lacks authority to make state policy in this way. *Okla. Educ. Ass'n*, 2007 OK 30, ¶¶ 25, 27, 158 P.3d at 1066 (courts are "constitutionally prohibited" from "invad[ing] the Legislature's power to determine policy" and "override the constitutional restrictions placed on … judicial authority").

D. The State failed to demonstrate its plan's necessity or effectiveness.

123. Finally, the State has failed to prove the necessity or effectiveness of its plan.

124. Abatement means "[t]he act of eliminating or nullifying." Black's Law Dictionary (11th ed. 2019). It is accomplished "by way of injunctive decree or order." Keeton & Prosser, *Prosser and Keeton on the Law of Torts* § 90 at 643 (5th ed. 1984). Consistent with those principles, an unbroken line of Oklahoma nuisance-abatement cases awards only injunctive relief that "elimina[tes] or nullif[ies]" the entirety of the offending conduct. *See, e.g.*, *See, e.g.*, *State ex rel. Field v. Hess*, 1975 OK 123, ¶¶ 1-3, 540 P.2d 1165, 1167, 1171 (injunction barring bookstore from displaying obscene materials); *Curlee v. State ex rel. Edmondson*, 1957 OK 72,

[687] July 15, 2019 (AM Pt. 2) Trial Tr. (Beckworth Arg.) at 37:11-38:1.

[688] Court Ex. 41 at 2.

¶¶ 1-4, 309 P.2d 1064, 1064-65 (injunction barring hotel tenants from violating liquor laws on premises); *State ex rel. King v. McCurdy*, 1935 OK 412, ¶¶ 1-2, 43 P.2d 124, 124-25 (injunction barring defendant from operating gas station on a public highway).

125. In addition, under Oklahoma law an abatement remedy can authorize "no more than is necessary" to end the nuisance. *Oklahoma City v. Hoke*, 1919 OK 244, syl. ¶ 4, 75 Okla. 211, 182 P. 692, 692.

126. As explained above, the State has not proved that the dozens of programs it seeks to make Janssen fund are necessary to abate the opioid abuse crisis, nor that they will be effective in doing so. *See supra* 92-119. It has therefore failed to prove that its plan is a proper abatement remedy under 50 O.S. § 11.

E. The State's proposed remedy violates the Excessive Fines Clause.

127. Finally, the Court cannot grant the State's requested remedy because doing so would violate the Excessive Fines Clauses of the United States and Oklahoma Constitution. *See* U.S. Const. Amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."); *Timbs v. Indiana*, 139 S. Ct. 682, 686 (2019) ("[T]he Eighth Amendment's Excessive Fines Clause [is] an 'incorporated' protection applicable to the States under the Fourteenth Amendment's Due Process Clause."). In both criminal and civil cases the "Excessive Fines Clause limits the government's power to extract payments" that are intended "as punishment for some offense," *Austin v. United States*, 509 U.S. 602, 609-10 (1993), and are "grossly disproportionate" to the defendant's fault, *Timbs v. Indiana*, 139 S. Ct. 682, 686 (2019); *see United States v. Halper*, 490 U.S. 435, 447 (1989) ("It is commonly understood that civil proceedings may advance punitive as well as remedial goals.").

128. Here, the State demands a multi-billion dollar payment from Janssen and has made no effort to hide its punitive intent. One of its lead experts—the government administrator

who would control the funds the State demands—testified that Janssen is "[implying] that because we can only show they killed some of those Oklahomans … they should get to walk away scot-free. That's not right."[689] Its lead counsel likewise demanded that "somebody build[] a wall around Princeton, New Jersey, that shuts this company down, … makes them come in and account and say, 'We did it, we know we did it, opioids were really bad and we oversold them and … we deceived the public and doctors.'"[690] And the massive recovery the State seeks dwarfs any conceivable fault attributable to Janssen, whose drugs held miniscule market share and were rarely abused. Such disproportionate punitive liability violates the Excessive Fines Clause, and represents another reason why the State cannot impose billions of dollars in "abatement" liability on Janssen.

X. THE STATE HAS FAILED TO PROVE ENTITLEMENT TO JOINT AND SEVERAL LIABILITY

129. The Court concludes that the State has not proved that Janssen, whose products represented a small fraction of the Oklahoma prescription opioids market, should be held jointly and severally liable for the full cost of all government programs addressing the opioid abuse crisis.

130. The State has suggested it is entitled to joint and several liability under 23 O.S. § 15, which eliminates joint and several liability for private plaintiffs but exempts the State from that rule. But the statute does not purport to automatically entitle the State to joint and several liability—on the contrary, it states that it "shall not apply to actions brought by … the State." 23 O.S. § 15(B). So because the statute does not apply here, the Court must determine the

[689] *See* June 25, 2019 (AM) Trial Tr. (White Test.) at 86:13-87:18.

[690] July 8, 2019 (AM) Trial Tr. (Beckworth Arg.) at 62:11-17.

availability of joint and several liability by reference to the Oklahoma common law cases that governed joint and several liability before the statute's enactment.

131. Those cases allow joint liability in only two circumstances: (1) where multiple parties' concert of action causes a defendant's injuries; and (2) where the injury is single and indivisible. *Kirkpatrick v. Chrysler Corp.*, 1996 OK 136, ¶ 10, 920 P.2d 122, 126. The State bore the burden of proof but made neither showing here.

A. The State has failed to establish concert of action.

132. To justify joint and several liability on a concerted-action theory, the State must show that Janssen and other tortfeasors engaged in "some concerted action … causing [the] injury" and did so as part of "some common purpose or design." *Id.* That standard requires proof of injurious conduct committed as part of "an agreement" or "a common design or plan" akin to a "conspiracy." Restatement (Second) Torts § 876 & cmts. a, b (emphasis added). The State has offered no proof of any such injurious agreement or plan between Janssen and any other party, much less all of the tortfeasors who caused the opioid crisis, which, even on the State's own theory, must include not only all of the prescription opioid manufacturers, but also negligent and willfully dangerous prescribers, those who diverted prescription opioids, and criminal syndicates.

133. Even if the only two potential tortfeasors were Janssen and Purdue, the State's evidence fails. Noramco's and Tasmanian Alkaloids' sales to Purdue do not make Janssen liable for Purdue's conduct. As this Court earlier concluded, the State's evidence about those sales depicts a conventional buyer-seller relationship. *See supra* 57-59. Such a relationship is not "concerted action": "[C]onspiracy law has long recognized that [a buyer-seller] relationship does not, without more, establish the parties' intent to aid each other in some other objective." *Craigslist Inc. v. 3Taps Inc.*, 942 F. Supp. 2d 962, 982 (N.D. Cal. 2013) (C. Breyer, J.); *see*

United States v. Gee, 226 F.3d 885, 893 (7th Cir. 2000) ("A conspiracy is more than a buyer-seller agreement."). The State's evidence showed only an agreement to sell raw materials, not an agreement to engage in the marketing conduct on which the State blames its injuries. And the State presented no evidence that either Noramco or Tasmanian Alkaloids promoted any medications. Even setting aside veil-piercing issues, *see supra* 153-156, those subsidiaries' sales to Purdue do not justify holding Janssen jointly and severally liable for Purdue's conduct.

134. This Court likewise concludes that Janssen's and Purdue's membership in the same advocacy groups does not establish concerted action between those two parties. As the U.S. Supreme Court has explained, "[c]ivil liability may not be imposed merely because an individual belonged to a group, some members of which committed [wrongful] acts." *NAACP*, 458 U.S. at 920; *accord In re Asbestos Sch. Litig.*, 46 F.3d at 1294. With the exception of limited lobbying activities, *see infra* 8-83, the State offered no evidence that Janssen and Purdue coordinated any conduct or entered into any agreement through advocacy groups. Their "mere participation in trade organization meetings where information is exchanged and strategies are advocated does not suggest an illegal agreement." *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1196 (9th Cir. 2015). The State interprets an ambiguous slide from an internal Janssen presentation as referring to Purdue as a "partner" in advocacy groups, *see supra* 82, but even if that interpretation were correct, it would not establish an agreement to engage in injurious conduct.

135. The State presented limited evidence that Janssen and Purdue occasionally coordinated lobbying efforts. But the First Amendment strictly protects lobbying activities, *see supra* at 148-149, so those activities therefore cannot serve as the basis for imposing joint and several liability. *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 an activity that is lawful and shielded by fundamental law cannot be deemed tortious.").

136. Finally, the Court notes that concerted action would not make Janssen liable for the ***entire opioid crisis***—only for the "result or damage done" by ***other tortfeasors*** "in pursuit of a common design." *Kirkpatrick*, 1996 OK 136, ¶ 10, 920 P.2d at 126. The State did not present evidence identifying the scope of any "agreement" or "common design." It has therefore failed to carry its burden to impose joint and several liability on a concerted-action theory.

B. The State has failed to establish an indivisible injury.

137. The State's evidence similarly failed to prove a single, indivisible injury.

138. Joint and several liability applies only where "the separate and independent acts or negligence of several [tortfeasors] combine to produce directly a single injury." *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, ¶ 4, 204 P. 906, 908 (1924); *Delaney v. Morris*, 1944 OK 51, ¶ 6, 145 P.2d at 938.

139. Oklahoma courts have recognized just four kinds of single injuries warranting joint and several liability: (1) a single personal injury caused by multiple events occurring close in time[691]; (2) property damage caused by concurrent negligence[692]; (3) commingled water pollution[693]; and (4) cattle that die from drinking commingled water pollution.[694]

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[691] *See, e.g., Boyles v. Oklahoma Nat. Gas Co.*, 1980 OK 163, ¶¶ 3-4, 7-11, 619 P.2d 613, 615-17.

[692] *See, e.g., Meyer v. Moore*, 1958 OK 165, ¶ 16, 329 P.2d 676, 681.

[693] *See, e.g., Delaney v. Morris*, 1944 OK 51, ¶¶ 6-8, 145 P.2d 936, 938-39.

[694] *See, e.g., Selby Oil & Gas Co. v. Rogers*, 1923 OK 1003, ¶¶ 2-4, 7, 221 P. 1012, 1012-13.

140. Each of those categories involves a "***single*** injury," *Delaney v. Morris*, 1944 OK 51, ¶ 6, 145 P.2d 936, 938 (emphasis added)—they are not "theoretically 'capable of apportionment.'" *United States v. NCR Corp.*, 688 F.3d 833, 838 (7th Cir. 2012).

141. By contrast, the State's trial evidence demonstrated that the opioid abuse crisis is a collection of smaller, separate harms: some involving individual physicians who engaged in improper prescribing, some involving intentional diversion, some involving criminal activity. *See, e.g.*, *supra* 41-43, 48-49. As a matter of law, such "distinct harms" are divisible and joint and several liability cannot apply. *See* Restatement (Second) of Torts § 433A(1) ("Damages for harm are to be apportioned among two or more causes where … there are distinct harms."); *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, 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").

142. Testimony from the State's impact witnesses demonstrated the individualized factors that have contributed to opioid addiction in Oklahoma and elsewhere. For example, while Kristi Hoos's path to addiction began with a physician who failed to advise her of the risks of the Lortab he prescribed,[695] Gary Mendell's son had abused marijuana and Xanax before moving on to Vicodin and OxyContin.[696]

143. Likewise, the testimony of Oklahoma physicians showed that pharmaceutical marketing was just one of many information sources Oklahoma physicians considered. For

[695] June 14, 2019 (AM) Trial Tr. (Hoos Test.) at 93:21-25.

[696] June 18, 2019 (AM) Trial Tr. (Mendell Test.) at 11:24-12:10, 55:15-19.

instance, Dr. Muchmore testified that he rarely saw sales representatives,[697] while Dr. Toal explained that information from pharmaceutical companies was merely one source of information, which he would "verify[]" before adopting.[698]

144. Indeed, courts routinely treat these sorts of distinct injuries distinctly. Case-by-case, patient-by-patient causation analysis is the norm in such actions. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010) ("[T]he nature of prescriptions ... thwarts any attempt to show proximate cause through generalized proof."). And misleading pharmaceutical marketing is assuredly not the only potential cause of the entire opioid crisis.

145. Before summary judgment, the State pledged to provide a statistical model proving "how many doctors bought into" Janssen's marketing messages,[699] a promise that confirms the State itself understood its injury to be divisible. The State's ultimate failure to provide that analysis does not alter the conclusion that its case rests on "distinct harms" capable of apportionment. Restatement (Second) of Torts § 433A(1). Accordingly, even if the State had succeeded in proving that actionable conduct by Janssen contributed to its injuries, it would be entitled to recover only for those of its injuries fairly attributable to Janssen. *See* Restatement (Second) of Torts § 433A(1)(b) ("There may be difficulty in the apportionment of some elements of damages ... but this does not mean that one defendant must be liable for the distinct harm inflicted by the other. It is possible to make a rough estimate which will fairly apportion the damages.").

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[697] July 3, 2019 (AM) Trial Tr. (Muchmore Test.) 40:22-25.

[698] July 3, 2019 (AM) Trial Tr. (Toal Test.) at 95:21-96:3.

[699] Dec. 5, 2017 Hr'g Tr. at 136-37.

C. Imposing joint and several liability would violate the Due Process and Excessive Fines Clauses.

146. The Fourteenth Amendment's Due Process Clause "prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor." *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003); *see also* U.S. Const. Amend XIV; Okla. Const. Art. II § 7. Liability should reflect only "the consequences of [a defendant's] own acts," *Holmes*, 503 U.S. at 268, and should not be "wholly disproportioned to the offense," *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 (2015).

147. As noted, Janssen did not act in concert with any other manufacturer, and the State alleges diverse and separate injuries. If Janssen is required to pay the billions of dollars purportedly needed to address the opioid abuse crisis over the next three decades, its liability will be massively disproportionate to its alleged fault. This outcome would run afoul of the Due Process Clauses of both the United States and Oklahoma Constitutions.

148. Similarly, as explained, such disproportionate punitive liability also violates the Eighth Amendment's Excessive Fines Clause. *Timbs*, 139 S. Ct. at 686; *Halper*, 490 U.S. at 447.

D. The market share of Janssen's opioid medications would provide a reasonable basis for apportionment.

149. Even in the case of a single injury, to avoid joint and several liability, "a defendant need only show a reasonable basis for ... apportionment, which is a low burden." *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 643 F. Supp. 2d 461, 469-70 (S.D.N.Y. 2009). Janssen presented unchallenged trial evidence about its opioid medications' low market share. If the Court finds that joint and several liability on the part of only the manufacturers is otherwise appropriate, this evidence would provide a reasonable basis for apportionment among those alleged tortfeasors.

150. "Reasonableness in law is generally assessed in light of the totality of the circumstances." *Waller ex rel. Estate of Hunt v. Danville, VA*, 556 F.3d 171, 175 (4th Cir. 2009). The circumstances here would make Janssen's prescription opioid market share a reasonable basis to apportion damages. The State's challenge to Janssen's marketing has focused on Janssen's branded promotion of Duragesic and unbranded promotions in the late 2000s intended to help launch Nucynta. *See supra* 25-27, 50-53. Those medications' market shares serve as reasonable estimates of the reach and effect of the marketing efforts intended to promote them. *Cf. In re MTBE Litig.*, 379 F. Supp. 2d at 376 (market share provides reasonable basis to "approximate the [environmental] harm caused" by gasoline manufacturers). The Court also notes that the State opposed Janssen's efforts to secure individualized claims data that would have allowed Janssen to analyze causation at the individual patient level[700]; and failed to deliver its promised statistical model for measuring the effects of the challenged marketing.[701] The State's avoidance of those alternative measurements strengthens the conclusion that the Court can reasonably rely on market share to apportion liability.

151. The State has argued that Duragesic's and Nucynta's market shares would not reasonably apportion liability because Janssen sponsored a handful of "unbranded" promotional materials addressing opioids as a class. As earlier explained, those promotions occurred in the late 2000s and the State has not provided any evidence on their reach or impact. *See supra* 57. Although the State asserted that these unbranded promotions were meant to bolster Noramco's and Tasmanian Alkaloids' raw material businesses, the State provided no evidence supporting that speculative claim. On the contrary, the State's own evidence indicated that Janssen's limited

[700] *See* Def's Mot. to Compel Discovery Regarding Claims Data (Sept. 7, 2018) at 1-4.

[701] Dec. 5, 2017 Hr'g Tr. at 136-37.

unbranded promotions were designed to lay the groundwork for Nucynta's launch. *See supra* 62. This Court thus concludes that Nucynta's market share provides a reasonable measure of their impact.

152. The undisputed trial evidence showed that Duragesic and the Nucynta products accounted for less than 1 percent of opioid prescriptions in Oklahoma: 0.82 percent of Medicaid opioid prescriptions between 1996 and 2017[702]; 0.36 percent of HealthChoice opioid prescriptions between 2004 and 2018[703]; and 0.20 percent of BlueCross BlueShield opioid prescriptions between 2008 and 2017.[704]

153. Accordingly, even if this Court were to conclude that $ [ ][705] of the State's proposed abatement plan would be appropriate to resolve Oklahoma's opioid abuse crisis, and conclude that this crisis is the result of concerted action, or is a single injury, caused only by prescription drug manufacturers, it would not hold Janssen jointly and severally liable for the entire amount. Rather, it would first conclude that pharmaceutical manufacturers should be liable for [ ] percent of that total, or $ [ ]. The range of Duragesic's and Nucynta's market share during this time period was between .20 and .82 percent. Using a midpoint of that market share, Janssen's liability would be 0.51 percent[706] of the true and appropriate cost of abatement. As a

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[702] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 34:6-36:3, 36:21-24, 37:4-15; Court Ex. 201 at 1-2.

[703] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 36:12-18; Court Ex. 201 at 1.

[704] July 11, 2019 (AM) Trial Tr. (Marais Test.) at 36:19-20; Court Ex. 201 at 1.

[705] By providing a space for the court to fill in an amount should it deem it appropriate to Janssen does not waive its position that the State is not entitled to any recovery from Janssen.

[706] At trial, Janssen made an offer of proof of an analysis of nonpublic data from the DEA's Automation of Reports and Consolidated Orders System ("ARCOS"), a comprehensive drug reporting system that tracks shipments of scheduled narcotics, which showed a market share of precisely 0.51 percent. *See* Offer of Proof for Evidence Related to Nonpublic ARCOS Data in the Examination of Dr. Laurentius Marais (July 12, 2019). The State opposed the introduction of this evidence, which would have showed that Duragesic, Nucynta, and Nucynta ER's share of

percentage of the amounts calculated by the State for its 20-, 25- and 30-year plans (which themselves are not credible measures of abatement), 0.51 percent equals $[ ], [ ], or $ [ ].

154. If any of the foregoing conclusions of law are deemed to be findings of fact, they shall be incorporated as factual findings as though fully set forth as such.

Dated: July 31, 2019

Respectfully submitted,

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ARCOS prescription-equivalents for the entire Oklahoma market from 2006 to 2014 was 0.51 percent. *See id.* Ex. A (Janssen Ex. 3767). The State's opposition to the introduction of this data reinforces the reasonableness of relying on the available Medicaid, HealthChoice, and BlueCross BlueShield data to establish market share.

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CERTIFICATE OF MAILING

Pursuant to OKLA. STAT. tit. 12, § 2005(D), this is to certify on July 31, 2019, a true and correct copy of the above and foregoing has been served via email to the following:

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