

STATE OF OKLAHOMA } S.S.

IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

JUL 1 2 2019

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,Case No. CJ-2017-816Plaintiff,Judge Thad Balkmanv.William C. Hetherington
Special Discovery Master

Defendants.

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<u>RENEWED MOTION FOR JUDGMENT OF DEFENDANTS JOHNSON & JOHNSON</u> <u>AND JANSSEN PHARMACEUTICALS INC. AND BRIEF IN SUPPORT</u>

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Defendants Janssen Pharmaceuticals, Inc.¹ and its parent company Johnson & Johnson ("J&J") (collectively, "Janssen Defendants"), having rested their case, renew their July 3, 2019 Motion for Judgment and again move this Court for a judgment in their favor on the State's public-nuisance claim. Janssen hereby incorporates by reference all arguments raised in its prior motion for judgment.

I. <u>INTRODUCTION</u>

As Janssen's July 3, 2019 motion for judgment explained, the State's case-in-chief failed to identify actionable conduct by Janssen, failed to prove that such conduct caused Oklahoma's opioid abuse crisis, failed to apportion the State's contributions to the crisis, failed to justify joint and several liability, and failed to identify a permissible remedy. The evidence presented in Janssen's defense case has only confirmed these defects. Janssen accordingly files this renewed motion for judgment, incorporating its prior arguments by reference and addressing the defense evidence that further underscores its entitlement to judgment.

II. LEGAL STANDARD

A motion for judgment requires the trial court to "weigh the evidence," "determine the sufficiency [of the plaintiff's evidence]," and "render judgment accordingly." *Biggs v. Fed. Land Bank of Wichita*, 1939 OK 328, ¶ 12, 95 P.2d 902, 904. In ruling on such a motion, the court "consider[s] all the evidence submitted, that which is favorable to the plaintiff and to the defendant." *Bridges v. Bridges*, 1975 OK 170, ¶ 4, 544 P.2d 493, 494. "[I]f th[e] evidence [is] insufficient at the conclusion of the plaintiff's evidence" to prove the plaintiff's claim, judgment must be entered for the defendant, because "there is no logical reason for requiring the defendant

¹ Janssen also refers to Janssen Pharmaceuticals, Inc.'s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

to prove a defense to the alleged cause of action which the plaintiff failed to establish." *Biggs*, 1939 OK 328, ¶12, 95 P.2d at 904; *see also Snow v. Winn*, 1980 OK 27, ¶ 3, 607 P.2d 678, 680-81 (judgment for defendant required if evidence "preponderates" in his favor). And where the plaintiff has presented nothing more than "conjecture and speculation" on an element of her claim, judgment must be entered for the defendant. *Gillham v. Lake Country Raceway*, 2001 OK 41, ¶ 8, 24 P.3d 858, 860-61 (collecting cases); *accord Safeway Stores v. Fuller*, 1941 OK 357, ¶ 15, 118 P.2d 649, 651; *Hepner v. Quapaw Gas Co.*, 1923 OK 536, ¶ 18, 217 P. 438, 443.

III. THE STATE HAS IDENTIFIED NO ACTIONABLE CONDUCT

As explained in the Janssen Defendants' prior Motion for Judgment, the State failed to point to any conduct that could give rise to public-nuisance liability. The State failed to prove a public nuisance under Oklahoma law. And its case was built on evidence about legally protected activities such as Noramco's federally authorized active pharmaceutical ingredient ("API") sales, third-party speech about medicine, and lobbying. The State's failure to point to any actionable conduct requires entry of judgment for Janssen.

A. The State Has Failed to Prove a Public Nuisance

As Janssen argued in its prior Motion for Judgment, the State failed to prove that a public nuisance exists. Oklahoma caselaw restricts the State's public-nuisance statute to harmful uses of property, injuries to property, or acts historically recognized as "nuisances per se," such as encroachments on public highways. *See Fairlawn Cemetery Ass'n v. First Presbyterian Church, U.S.A. of Okla. City*, 1972 OK 66, ¶ 14, 496 P.2d 1185, 1187 ("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."); *Briscoe v. Harper Oil Co.*, 1985 OK 43, ¶ 9, 702 P.2d 33, 36 (describing public nuisance as a tort "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"). Here, the State's case is not about property or any recognized "nuisance per se," but about the sale of goods and commercial activity on a national and international scale. The State's nuisance claim therefore fails.

As Janssen's prior motion further explained, applying Oklahoma's nuisance statute to the conduct at issue here would violate the Oklahoma and U.S. Constitutions' due process protections. 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. Here, the State demands billions of dollars under statutory language punishing anything that "injures or endangers the comfort, repose, health, or safety" of "any considerable number of persons." 50 O.S. §§ 1, 2. That statute did not give Janssen notice that its sale of lawful goods on national and international markets could subject it to public nuisance liability at all. And, as explained below, the statute's authorization for the State to "abate" the "public nuisance" did not give Janssen notice it could be asked to pay for decades of government programs to address a statewide social program. If accepted, the State's demands in this case would leave Oklahoma with a statute so capacious that it provides no meaningful notice of the conduct it targets. Imposing massive liability based on such unbounded statutory language would violate Janssen's right to fair warning.

B. The First Amendment Bars the State's Assault on Speech, Association, And Lobbying By Janssen and Others

As Janssen's prior motion likewise explained, the First Amendment bars a claim that pervasively challenges constitutionally protected speech, association, and lobbying.

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1. The First Amendment Bars the Government's Content-Based Challenge to Speech About Science, Medicine, and Public Health

i. The Commercial Speech Doctrine Does Not Apply

As Janssen explained in its original Motion for Judgment, the First Amendment bars the State's content-based challenge to Janssen's marketing and promotion of prescription opioids. At bottom, the State contends that Janssen—and countless others—got the science of chronic pain wrong,² and Janssen should be punished for advocating a view that the State disagrees with. But the First Amendment's protections extend to speech about "public health," which is "clearly a matter of public consonance," *Magnusson v. New York Times Co.*, 2004 OK 53, ¶ 12, 98 P.3d 1070, as well as "[s]peech in aid of pharmaceutical marketing," such as that at issue here. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). Accordingly, state laws infringing such speech "must be subjected to heightened judicial scrutiny." *Id.* Attempts to impose "content-based burden[s]" on pharmaceutical marketing thus must pass "heightened judicial scrutiny," *id.* at 565, and "are presumptively invalid." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992).

The State cannot avoid heightened scrutiny by categorizing Janssen's speech as commercial. First, the State largely targets speech that is noncommercial, such as medical education and advocacy by doctors, nonprofits, and other third parties. Second, the rationales of the commercial speech doctrine do not apply to the speech at issue here, which concerns complex scientific and policy questions of exceptional public importance that remain actively debated. *See Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S.

² See, e.g., 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 (PM) 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").

748, 771 n.24 (1976) (commercial speech doctrine assumes speech is "more easily verifiable" than other speech); *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796 (1988) (speech that "is inextricably intertwined with ... otherwise fully protected speech" does not "retain[] its commercial character").

ii. The State's Claim Fails Even Under the Commercial Speech Doctrine

But as explained in Janssen's prior Motion for Judgment, the State's claims fail even under the commercial-speech doctrine. The Supreme Court is clear that "the State cannot engage in content-based discrimination to advance its own side of a debate." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 580 (2011). The First Amendment thus allows states to prohibit only "inherently misleading" commercial speech. *Pearson v. Shalala*, 164 F.3d 650, 656-58 (D.C. Cir. 1999) (*Pearson I*). And the State bears the burden of establishing that Janssen's speech was misleading by clear and convincing evidence. *See Bose Corp. v. Consumers Union the United States, Inc.*, 466 U.S. 485, 511 & n.30 (1984). The State has taken issue with various promotional statements by Janssen, plucked from hundreds of thousands of communications over a twenty-year period. But as Janssen's prior motion explained, none of the speech the State challenged was inherently misleading, and so none of it can be punished in tort. The evidence presented during Janssen's case further confirms that the State's potshots at Janssen's commercial speech lack merit.

A centerpiece of the State's case is that Janssen improperly promoted Duragesic as less frequently abused than competing medications like OxyContin. The State has relied on a September 2, 2004 FDA Warning Letter asserting that Janssen's comparisons of Duragesic and OxyContin were "false and misleading" because Drug Abuse Warning Network ("DAWN") data

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did not provide "substantial evidence" for comparative claims.³ That letter never suggested Duragesic was *not* less prone to abuse than OxyContin—only that the DAWN data did not support such a claim.⁴ And as Janssen's defense case has shown, all available evidence confirms that Janssen's comparative claims were correct all along.

Janssen collected information about comparative abuse rates from diverse sources, and *all* confirmed that Duragesic was abused at substantially lower rates than other opioids. A 2004 report by the medical consulting firm Pinney Associates reviewed scientific literature and surveyed drug-abuse experts about the Duragesic fentanyl patched, concluding "the rates of abuse of this system have been relatively low" due to the "slow onset of effect" and the "relative difficulty of extracting and purifying the fentanyl" from the reservoir.⁵ Similarly, Janssen received quarterly reports from the non-profit RADARS surveillance system—which tracks abuse, misuse, and diversion of prescription drugs. As Dr. Bruce Moskowitz explained, those reports showed that "the products that Janssen marketed, Duragesic, Nucynta, and Nucynta Extended Release were consistently among, if not the lowest of the products that were … mentioned."⁶ The system's Key Informant Network,⁷ Law Enforcement Network,⁸ Poison Control Network,⁹ and survey reviews indicated that fentanyl and tapentadol had among the lowest diversion and abuse rates of any opioids.¹⁰

³ S-0038 at 2.

⁴ *Id.* at 104:20-15; S-0038 at 2.

⁵ Id. at 89:1-16; J-862 (admitted June 27) at 21.

⁶ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 78:10-17.

⁷ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 64:1-68:22; see also Court Exhibit 131.

⁸ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 53:23-54:4.

⁹ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 74:16-76:5; see also Court Exhibit 134.

¹⁰ *Id.* 72:1-74:8; *see also* Court Exhibit 133.

Indeed, multiple studies supported Janssen's comparative claims about Duragesic even at the time of the FDA Warning Letter. The letter challenged reliance on DAWN data because such data does not account for the fact that "Duragesic is not as widely prescribed as other opioid products."¹¹ But a 2003 study by Dr. James Zacny accounted for that issue, analyzing DAWN abuse data from 1995 to 2001 while normalizing based on number prescriptions.¹² It found that the "ratio of illicit use to licit use," a measure of abuse, was "several orders of magnitude lower" for fentanyl "than for hydrocodone and oxycodone."¹³A 2000 retrospective analysis by Dr. Yevgeny Mironer compared different opioids except for methadone.¹⁴ Similarly, a 2000 study by Dr. David Joranson showed that while the medical use of fentanyl increased dramatically during those years, abuse *decreased* by 59 percent, and found that "fentanyl abuse was low when compared to other products such as oxycodone."¹⁵ And an unpublished manuscript by former DEA administrator John Coleman found that Duragesic "was not widely sought by drug abusers nor widely diverted or sold by drug traffickers in the U.S. in the ten years since its introduction."¹⁶

All of this evidence points to the same conclusion: Duragesic was less prone to abuse than OxyContin, just as the file card indicated. In the face of this, the State has provided no contrary evidence, instead relying on a warning letter that took no position regarding Duragesic's

¹¹ S-0038 at 2.

¹² June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 106:22-109:5.

¹³ J-861 at 4; June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 106:25-107:15.

¹⁴ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 109:6-110:15.

¹⁵ J-861

¹⁶ *Id.* 114:2-119:12; J-2643.

propensity for abuse. Janssen's case-in-chief has refuted the notion that any discussion of Duragesic's abuse potential in comparison to drugs like OxyContin was at all misleading.

Similarly, Dr. Kolodny claimed that Finding Relief's statement that it is a "fact" that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain" was "simply a lie."¹⁷ In his view, "[t]here were not and have never been many studies that show that opioids are rarely addictive when taken long-term for chronic pain."¹⁸ Yet a peer-reviewed 2008 article in the Journal of Pain Medicine by Dr. David Fishbain, analyzed 24 prior studies with 2,507 chronic pain patients,¹⁹ calculating a total abuse or addiction percentage of 3.27 percent and an abuse or addiction percentage of 0.19 percent among patients with no history of abuse or addiction.²⁰ Dr. Kolodny had criticized Dr. Fishbain's paper on the ground that "not one of the studies that were included in the Fishbain systematic review was actually designed to answer a question about what is the risk of iatrogenic addiction."²¹ But as Dr. Kolodny himself conceded, ethical constraints make it impossible to conduct a prospective elinical study measuring iatrogenic opioid abuse.²²

A 2010 literature review by the Cochrane Collaboration²³ similarly sought to "summarize the evidence pertaining to the efficacy and safety of long-term opioid therapy for chronic noncancer pain."²⁴ The Cochrane organization is "well recognized" and "respected" for

¹⁷ June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 104:24-105:7.

¹⁸ Id.

¹⁹ *Id.* at 75:3-19; J-398 at 1.

²⁰ Id.

²¹ June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 71:16-72:16;

²² June 11, 2019 (AM) Trial Tr. (Kolodny Test.) at 90:21-91:19; *see* June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 75:22-25.

²³ J-400.

²⁴ June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 69:16-20; J-400 (admitted June 28, 2019) at 5.

conducting such systematic reviews.²⁵ The review found that "proper management of ... opioids, in well-selected patients with no history of substance addiction or abuse can lead to long-term pain relief for some patients with a very small, though not zero, risk of developing addiction, abuse, or other serious side effects."²⁶

And a 2014 peer-reviewed study in the Clinical Journal of Pain analyzed claims data for over 568,000 opioid-naïve patients diagnosed with chronic pain between 2000 and 2005.²⁷ About one-third of those patients—197,000 in total—were prescribed opioids.²⁸ And of the 197,000 receiving an opioid prescription, only 347 were diagnosed with opioid-use disorder over an 18month follow-up period.²⁹ Among individuals prescribed long-term opioid therapy, the rate of opioid use disorder ranged from 0.72 percent for those who received low doses, to 1.2 percent for those who received medium doses, to 6.1 percent for those who received high doses.³⁰ Overall, the study calculated a 1.1 percent rate of opioid use disorder for patients who received long-term opioid therapy for chronic pain.³¹

Consistent with these studies, the FDA wrote in 2009 that "[a]ccording to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, *and rarely causes*

²⁵ June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 68:2-13, 69:4-5.

²⁶ June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 70:13-21; J-400 (admitted June 28, 2019) at 2.

²⁷ J-3938; June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 84:15-17, 87:11.

²⁸ June 28, 2019 (AM) Trial Tr. (Moskovitz Test.) at 87:9-14.

²⁹ *Id.* at 88:14-19.

³⁰ *Id.* at 89:9-13.

³¹ *Id.* at 89:j

addiction.³² That statement remains on the FDA's website to this day.³³ Neither Janssen's claim in *Finding Relief* nor the FDA's claim made the same year was "simply a lie,"³⁴ as the multiple studies presented in Janssen's defense showed.

Finally, the State's case-in-chief also relied on the warning letter to challenge Janssen's reliance on the Simpson, Allan, and Milligan studies. The warning letter found that these did not qualify as "substantial evidence" for effectiveness claims because they were "open-label" rather than controlled studies.³⁵ Janssen's evidence, however, established that its marketing about those studies was truthful, and that Janssen reasonably relied on them to show *effectiveness* prior to receiving the warning letter the warning letter did not say that Simpson, Allan, or Milligan were "bad studies," that they were "incorrect in their conclusions," or that they "shouldn't be made available to the medical community."³⁶ The file card openly disclosed their limitations³⁷ and accurately described their findings.³⁸ Such disclosure is all the First Amendment requires from protected commercial speech. *See Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 15 (D.D.C. 2011).

³² J-3606 at 4 (emphasis added).

³³ See https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine (last accessed July 12, 2019).

³⁴ June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 104:24-105:7.

³⁵ State Trial Ex. 0038 at 2-3.

³⁶ June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 90:13-25.

³⁷ See, e.g., June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 96:7-12 (file card disclosed that Milligan was an open-label, 12-month prospective study); 98:9-13 (file card disclosed that Allan was an open-label crossover comparison)

³⁸ See, e.g., June 27, 2019 (PM) Trial Tr. (Moskovitz Test.) at 96:23-25 (file card "did not misrepresent the observations" in the Milligan study); 98:17-20 (file card "accurately represented" that the Allan study shows "improved patient outcomes").

It is telling that the State has built its case around claims with significant evidentiary support, and the distribution of peer-reviewed studies with valid data. Such claims are not inherently misleading, and cannot serve as the basis for liability under the First Amendment.

2. The First Amendment Bars the State's Attempts to Hold Janssen Liable for Third-Party Speech and Lobbying

The First Amendment also precludes the State from holding Janssen liable for third-party speech and lobbying.

i. The First Amendment Fully Protects Third Parties' Non-Commercial Speech on Medical Questions

As Janssen explained in its first Motion for Judgment, the State cannot hold Janssen liable for statements by third parties, such as doctors, academics, key opinion leaders, and nonprofits groups—regardless whether Janssen supported them financially or associated with them in some other way. These third parties' statements about public-health and medical issues bore none of the hallmarks of commercial speech. *See Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 879 F.3d 101, 108 (4th Cir. 2018). Rather, it consisted of medical textbooks, presentations by doctors to doctors, public advocacy by academics, and advocacy and educational materials produced by nonprofit organizations. Such speech "occupies the highest rung of the hierarchy of First Amendment values and is entitled to special protection" because it relates to matters of public concern. *See, e.g., Connick v. Myers*, 461 U.S. 138, 145 (1983). The State cannot impose liability because it disagrees with such speech, even if it asserts the speech was erroneous. *New York Times Co. v. Sullivan*, 376 U.S. 254, 271 (1964).

The State cannot circumvent these protections by claiming that Janssen controlled key opinion leaders or advocacy organizations, as it has presented no evidence that Janssen did so. Its

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case thus reduces to an impermissible attempt to hold Janssen vicariously liable for others' constitutionally protected speech.

ii. The State's Attempts to Punish Janssen for Third Parties' Conduct Violates its Rights of Association

The State's case also violates the First Amendment because it seeks to impose liability on Janssen for the conduct of third parties merely because Janssen had institutional or financial relationships with them.³⁹ As Janssen has explained in prior briefing, however, under the First Amendment, "[c]ivil liability may not be imposed merely because an individual belonged to a group," *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 920 (1982), or made financial contributions to it, *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1294 (3d Cir. 1994) (Alito, J.) (emphasis added). A defendant can be held liable for a third-party group's wrongful conduct only if 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.

The State could do neither here. It presented no evidence that these organizations, whose speech is protected by the First Amendment, acted with unlawful aims and goals. And the State and its experts offered no concrete evidence (other than a handful of brochures Janssen openly sponsored⁴⁰) that Janssen associated with *any* advocacy groups specifically to further the

³⁹ June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 8:20-25, 14:19-23 (testifying that Janssen retained membership in APS and AAPM); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 112:18-113:23 (testifying that Janssen jointly funded a survey with APS and AAPM); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 10:1-13, 12:12-19 (testifying that Janssen retained some members of APS and AAPM as key opinion leaders).

⁴⁰ For example, the State pointed to Janssen's sponsorship of the APS/AAPM brochure, Finding Relief. See State Ex. 3606 (admitted June 14, 2019). Janssen openly disclosed its sponsorship in

messages the State challenges. The State's attempt to hold Janssen liable for engaging with those groups accordingly violates Janssen's First Amendment freedom of association.

iii. The First Amendment's Petition Clause Protects Third Parties' Lobbying and Janssen Cannot Be Held Liable For Their Petitioning Activities

The State also cannot impose liability for Janssen's protected lobbying activity. Under the "*Noerr-Pennington* Doctrine," those who petition the government for redress are generally immune from liability. *Empress LLC v. City & Cty. of San Francisco*, 419 F.3d 1052, 1056 (9th Cir. 2005). This First Amendment protection bars civil liability for lobbying. *See, e.g., GF Gaming Corp. v. City of Black Hawk*, 405 F.3d 876, 884 (10th Cir. 2005) (*Noerr-Pennington* barred suit premised on defendants' "lobbying of government officials").

Here, the State has presented about constitutionally protected lobbying activities—much of it conducted by other companies. *Noerr-Pennington* doctrine forecloses the State's effort to impose liability based on that evidence.

C. Federal and Oklahoma Law Bar Liability for Noramco's And Tasmanian Alkaloids' Sales of Raw Materials

As Janssen explained at length in its prior Motion for Judgment, it cannot be held liable for the sales of a former J&J subsidiary, Tasmanian Alkaloids, and a former Janssen subsidiary, Noramco, which produced raw materials that other manufacturers used to make their drugs.

First, federal law preempts liability for Noramco's and Tasmanian Alkaloids' federally regulated sales. As part of a comprehensive statutory and regulatory scheme designed to ensure reliable supplies of medically necessary drugs, the DEA carefully authorized what Tasmanian Alkaloids sold, what API Noramco produced, and how much API a manufacturer could buy from

the brochure itself. And the State has offered no evidence that this brochure, which was released in 2009, was ever read by a single Oklahoman.

Noramco. *See* 21 U.S.C. §§ 1303.12(a), 1312.11(a), 1312.13(a)(1). By insisting that those companies should not have supplied their products to opioid manufacturers,⁴¹ the State "effectively challenges" the DEA's judgment that those manufacturers should be able to purchase Noramco's and Tasmanian Alkaloids' raw materials. *See Marenette v. Abbott Labs.*, *Inc.*, 886 F.3d 112, 117 (2d Cir. 2018) (finding obstacle preemption of state-law challenge to federally authorized "organic" label). Liability for those sales would pose an obstacle to the DEA's quota system, and its goal of ensuring that the nation's medical needs are satisfied. Federal law preempts this attempt to countermand federal authority and interfere with the operation of 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).

Second, Oklahoma law also precludes tort liability for suppliers of raw materials. Oklahoma does not recognize tort liability for component suppliers that, like Noramco and Tasmanian Alkaloids here, 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.

Third, the State has not offered any evidence to hold Janssen and J&J liable for their subsidiaries' activities. Corporate veil-piercing principles preclude any parent corporation liability here. *See Gilbert v. Sec. Fin. Corp. of Okla., Inc.*, 2006 OK 58, ¶ 23, 152 P.3d 165, 175 (recognizing that absent extraordinary circumstances, a corporation cannot be held liable for the actions of its independent subsidiaries); *Gulf Oil Corp. v. State*, 1961 OK 71, ¶¶ 10-11, 360 P.2d 933, 936 (to pierce corporate veil, plaintiff must prove subsidiary's "separate corporate existence

⁴¹ See, e.g., June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 31:13-17.

is a design or scheme to perpetrate fraud" or that subsidiary "is so organized and controlled and its affairs so conducted that it is merely an instrumentality or adjunct of" the parent).

D. Federal Law Forecloses the State's Challenge to the Promotion of Opioids for Chronic Non-Cancer Pain

The State's case fails for the additional reason that its core theory challenges Janssen's promotion of opioids for a lawful use—the treatment of chronic non-cancer pain. Federal law bars the State from punishing Janssen for promoting its medications for lawful, FDA-approved uses.

1. The First Amendment Bars the State from Blocking Promotion of Opioids for A Lawful Use

The Supreme Court has held that, under the First Amendment, states cannot ban promotion of lawful activities or products—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). Here, federal and Oklahoma law allow for the use of long-acting opioids to treat chronic pain. The FDA authorized Janssen to sell those medications for that purpose,⁴² and nothing in Oklahoma limited its ability to do so. Holding Janssen liable for promoting opioids for their lawful purpose would therefore infringe its right to free speech.

⁴² See, e.g., Janssen Ex. 2787, Nucynta ER Label (2016) at 7 (*admitted June 4, 2019*) (approving its long-acting opioid medicines for the "the management of pain in opioid-tolerant patients severe enough to require daily, around-the-clock, long-term opioid treatment); *see also* Janssen Ex. J2776, Duragesic Label (Jan. 2018) at 1 (*admitted June 4, 2019*) (same).

2. The State's Theory Is Preempted Because There Is Clear Evidence the FDA Would Not Have Let Janssen Modify Its Medications' Labels

Because the FDA dictates drug labeling, state law 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). As explained in Janssen's prior Motion for Judgment, promotional activities like sales representative visits and brochures qualify as labeling. *See 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)

The State's challenges to Janssen's promotion of opioids for chronic non-cancer pain⁴³ thus boil down to the premise that Janssen should have unilaterally narrowed the FDA-approved indications authorized by its products labels. Yet the State's case has not identified any new information that would warrant a label change. *See* 21 C.F.R. § 314.70(c)(6)(iii) (federal law allows alterations in drug labeling only when there is "newly acquired information" that requires a manufacturer to, among other things, "delete false, misleading, or unsupported indications for use or claims for effectiveness"). And there is "clear evidence" that the FDA would not have permitted such a label change: Its rejection of the PROP petition's request to eliminate an indication for chronic non-cancer pain shows that the FDA would have rejected a similar

⁴³ 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 Janssen sales representative falsely stated "[t]hat long-acting opioids have a role in chronic non-malignant pain, and that they benefit the patients over the long-term").

manufacturer-initiated change to a drug label. *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); *see also North Dakota ex rel. Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-cv-01300, Slip Op. at 14 (N.D. D.Ct. May 10, 2019) (finding challenges to marketing of opioids for chronic non-cancer pain preempted based on FDA's rejection of PROP petition).⁴⁴ Finally, the same preemption principles defeat the State's claim that Janssen falsely implied scientific support for the concept of "pseudoaddiction."⁴⁵ Indeed, the FDA has approved labeling for Janssen's medicines that embodies this concept and continued to do so after Janssen's recent evidentiary review triggered by the PROP petition.⁴⁶

3. The State's Theory Is Preempted Because It Would Pose an Obstacle to the FDA's Regulation of Prescription-Drug Advertising

As Janssen's prior briefing also explained, the State's theory is preempted because it would pose an obstacle to the federal government's comprehensive regulation of the approval and marketing of prescription drugs. *See, e.g.*, 21 U.S.C. § 393 (FDA's mission is 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. § 355(d) (providing that no new drug can be marketed unless and until the FDA determines that the drug

⁴⁴ The same preemption principles preclude the State's claim that Janssen should not have advanced the concept of "pseudoaddiction"—the FDA has approved labeling for Janssen's medicines that set forth this concept and continued to do so after the PROP petition. The State has cited no new evidence suggesting the concept is incorrect.

⁴⁵ See, e.g., June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 139:24-147:25 (describing article written by Howard Heit available on www.prescriberesponsibly.com as misleading for discussing concept of pseudoaddiction); June 10, 2019 (PM) Trial Tr. (Stone Test.) at 86:3-6 (discussing pseudoaddiction vis-à-vis launch of Nucynta).

⁴⁶ Janssen Ex. 2776, Duragesic Label (Jan. 2018) at 31 (*admitted June 4, 2019*); Janssen Ex. 3736, Nucynta ER NDA Approval and Label (Aug. 25, 2011) at 25 (*admitted June 14, 2019*).

is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling" submitted with the drug's FDA application); 21 U.S.C. §§ 352(n), 355(d) (vesting the FDA with the power to both approve new prescription drugs and regulate their marketing and promotion); 21 C.F.R. §§ 201.1-201.58, 202.1 (FDA regulations regarding drug approval, marketing, and promotion); *see Hines*, 312 U.S. at 67. A multi-billion dollar state law judgment against Janssen for promotional statements that tracked its labeling and thus satisfied FDA requirements would upset this extensive federal regulatory system by chilling manufacturers' communication of messages endorsed in their medicines' FDA-approved labels,. Basic preemption principles block states from forbidding what federal law authorizes, and undermining the goals of federal regulatory programs. *See Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996).

E. The Oklahoma Nuisance Statute's Safe Harbor Forecloses Liability for Federally Authorized Activities

The State's targeting of federally authorized conduct also runs afoul of the Oklahoma nuisance statute's safe harbor, which provides 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 State cannot hold Janssen liable for FDCA-authorized promotions of its medicines for their approved indications or Noramco's and Tasmanian Alkaloids' CSA-authorized raw material sales. 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."); *DePriest v. AstraZeneca Pharm., L.P.*, 351 S.W.3d 168, 177 (Ark. 2009) ("advertising ... supported by the FDA-approved labeling" falls within safe harbor for "conduct that is permitted under laws administered by a federal agency").

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IV. <u>THE STATE HAS FAILED TO PROVE JANSSEN CAUSED THE OPIOID</u> <u>CRISIS</u>

Janssen is also entitled to judgment because the State has presented no viable evidence of but-for or proximate causation for the opioid abuse crisis.

A. The State's Evidence Does Not Support a Finding Of Cause-In-Fact

As explained in the July 3, 2019 Motion for Judgment, the State and its experts offered no evidence to support a finding that anything Janssen did caused Oklahoma's injuries.

First, the State has not offered evidence on the impact of Janssen's alleged conduct. Indeed, the State has not firmly decided what the relevant conduct even is. After presenting a case-in-chief focused pervasively on contributions to third-party groups, relationships with key opinion leaders, lobbying activity, and Noramco's and Tasmanian Alkaloids' raw material sales, the State's opposition to Janssen's motion for judgment suggested the State only seeks to target Janssen's own speech, including its dissemination of third-party statements. It later appeared to retreat from that position in oral argument. Regardless where it ends up, the State lacks proof of causation because its experts made no attempt to measure the impact of *any* of Janssen's alleged conduct.

The State has not offered a speck of evidence that Janssen's own speech caused the opioid abuse crisis. None of its experts ever suggested that Janssen's speech alone sufficed to cause that crisis, and if they had, their opinion would have been scarcely credible. For example, although the State spent hours dissecting Janssen's branded promotion of Duragesic, it offered no evidence that the drug was widely used, much less abused in Oklahoma. Quite the contrary, its own star witness said Duragesic was "hardly prescribed,"⁴⁷ and a wealth of evidence shows

⁴⁷ June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 170:8.

that it was abused and diverted at far lower rates than other opioids.⁴⁸ No evidence explains how the promotion of a drug that was rarely prescribed and even more rarely abused could have caused an opioid abuse crisis.

The State's reliance on unbranded marketing gets it no further. The State has pointed to only a handful of unbranded materials created by Janssen—and even fewer instances of Janssen disseminating statements by third-party groups. The unbranded promotions it points to were all released in 2008 or later—when the opioid crisis was already well under way. Those promotions were, by all appearances, obscure—the State has not identified a single Oklahoma doctor who saw them, much less relied on them. And it has made no effort whatsoever to evaluate whether these documents, released at least *twelve years* after the State claims the opioid crisis began, had any impact at all on physician attitudes in Oklahoma, nor whether they caused harm to a single Oklahoma patient.⁴⁹

In short, the State offered no credible explanation for how branded promotion of the seldom-prescribed Duragesic patch caused an abuse crisis fueled by other manufacturers' pills. Nor did it establish how a handful of unbranded promotions in the late 2000s influenced Oklahoma prescribers. Unable to measure the effects of Janssen's conduct, the State can only ask this Court to speculate on these key causation questions. But while "[a]bsolute certainty [of causation] is not required, however, mere possibility or speculation is insufficient." *See McKellips v. Saint Francis Hosp., Inc.*, 1987 OK 69, 741 P.2d 467, 471.

⁴⁸ *See* supra at 6-7.

⁴⁹ That failure extends to Dr. Russell Portenoy's testimony that "some of the actions taken by" Purdue, Teva, and Janssen "including the way they used [his] work" "create[d] an opioid crisis." Portenoy Depo. Tr. at 44:11-46:02 (played May 29, 2019). The State did not show Dr. Portenoy and he did not identify a single Janssen representation supporting his statement that Janssen had misused his work, much less did it have him rationally explain how any such misrepresentation caused the opioid crisis.

The same defects afflict the State's broader, more sweeping theories, based on contributions to advocacy groups, relationships with key opinion leaders, lobbying activities, and sales of raw materials by Janssen subsidiaries. As Janssen's prior motion explained, the State's experts identified no method to determine the impact of *any* of these activities on prescriptions or the broader opioid crisis. Their opinions instead rely on anecdote and narrative, making no attempt to measure the consequences of Janssen's conduct or account for any other factor that may have caused Oklahoma's opioid crisis (including the activities of several other API and raw material manufacturers). Such unscientific narratives are legally insufficient to establish the causes of a problem as complex and multifaceted as the opioid abuse crisis. See 12 O.S. § 2702 (expert testimony must be "the product of reliable principles and methods"); Christian v. Gray, 2003 OK 10, ¶ 36, 65 P.3d 591, 607 ("An expert's opinion on causation must be more than ipse *dixit.*"). What is more, as explained above and in Janssen's prior motion, the State's broader theories target extensive protected conduct and so cannot support a finding of causation. See, e.g., NAACP v. Claiborne Hardware, 58 U.S. 886, 918 (1982) ("While the State legitimately may impose damages for the consequences of violent conduct, it may not award compensation for the consequences of nonviolent, protected activity. Only those losses proximately caused by unlawful conduct may be recovered.").

Second, as Janssen's prior motion also explained, the State's reliance on a correlation between opioid prescriptions and opioid overdose deaths is statistically unsound and cannot establish the opioid crisis's causes. Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP, 806 F.3d 71, 96 (2d Cir. 2015) (noting that "simplistic" statistical evidence such as "correlation evidence" cannot establish causation on a question as complex as the effects of allegedly unlawful pharmaceutical marketing).

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It also fails because the State has offered no evidence to establish that actionable conduct by Janssen contributed to those rising prescription rates. The fact that Janssen promoted Duragesic over the relevant time period does not establish that it drove the increased prescriptions on which the State premises its case. The State's experts have offered no method to measure any such impact. Indeed, the State has not introduced evidence of a single Oklahoman physician who relied on a single statement by Janssen.

But multiple Oklahoma doctors testified that their prescribing decisions did not and do not turn on pharmaceutical marketing in general, or Janssen's in particular.

Dr. Jeffrey Halford, who practices in Tulsa, testified that he never made a decision to prescribe a medication based on information from pharmaceutical sales representatives.⁵⁰ Instead, "the decision is always based on [his] medical knowledge; [his] judgment about the use of a medication, the appropriate use of a medication; and more specifically, the individual situation that's going on with the patient in front of [him]."⁵¹ In Halford's experience working and training with hundreds of doctors in the past 20 years, most doctors are "super diligent in terms of doing their research and being very careful and cautious about any treatment plan that they make for a patient."⁵² He could not even "imagine a doctor solely relying on the information received from a salesperson" to decide "whether to prescribe a drug or not."⁵³

Dr. Gary Schick, who practices in Oklahoma City, similarly testified that, regardless of pharmaceutical marketing, it was "his role to decide" what medication "was best for [his]

⁵⁰ July 8, 2019 (AM) Trial Tr. (Halford Test.) at 48:20-23; *see also id.* at 57:1-9 ("Q. So you feeling that going in, you're not easily influenced by a sales rep trying to sell you on anything. Right? A. I don't think I'm influenced at all.").

⁵¹ July 8, 2019 (AM) Trial Tr. (Halford Test.) at 48:20-49:7.

⁵² *Id.* at 60:14-23.

⁵³ *Id.* at 48:20-49:7.

patients."⁵⁴ He explained that sales representatives may have made him "more comfortable with [a particular medication],"⁵⁵ but what to prescribe "was always all [his] decision" because he "was the one that had to write the prescription."⁵⁶ He testified that he makes prescribing decisions based on the individual patient—"[e]very patient is an individual person with different circumstances."⁵⁷ Dr. Schick believes he attended multiple speaker programs about Duragesic⁵⁸ and was visited by Janssen sales representatives 157 times over 11.5 years.⁵⁹ Yet he estimates that he prescribes fentanyl patches to only two out of the approximately 1,000 patients he treats,⁶⁰ and did not prescribe Duragesic frequently in the past because he "just didn't get to the point where that drug was appropriate for most of" his patients.⁶¹ And he does not prescribe Nucynta to a single one of his patients.⁶²

Dr. Kyle Toal, a thoracic surgeon in Norman, testified that sales representatives never influenced his prescribing of opioids or any other medication.⁶³ He is not aware of any doctor in

⁵⁶ Id.

⁵⁸ Id. at 176:14-25.

⁶² Id. at 189:18-20.

63 July 3, 2019 (AM) Trial Tr. (Toal Test.) at 48:14-19.

⁵⁴ June 28, 2019 (PM) Trial Tr. (Schick Test.) at 242:5-23.

⁵⁵ Id. at 179:4-13.

⁵⁷ *Id.* at 174:23-175:9 ("Every patient is an individual person with different circumstances. You know, you have to take every patient that comes in and determine what you think is going on with them, what you think the circumstances are around them, who's going to be around to help them, who is not going to be around to help them, who might be, you know, around that might be more problematic versus not, and which of these various treatment modalities that are available to you going to be most appropriate for that individual.")

⁵⁹ Id. at 189:1-12.

⁶⁰ *Id.* at 189:7-17

⁶¹ *Id.* at 177:1-7; *see also id.* at 189:7-17 (testifying that out of "probably" 1,000 patients, only two are on either Duragesic or a generic fentanyl patch).

his "network of doctors that has ever had his or her prescribing decisions regarding opioids impacted by a sales representative."⁶⁴ In fact, he claimed that doctors laugh when he asks them if they are "influenced by pharmacy reps."⁶⁵ According to Dr. Toal, the "doctor with the patient," makes the final decision about the risks and benefits of a medication.⁶⁶

This testimony by Oklahoma doctors accords with the legal principle that when, as here, a pharmaceutical is "properly labeled and carries the necessary instructions and warnings," Oklahoma physicians are presumed to exercise their "independent judgment" based on those warnings in prescribing medicines to their patients, *Edwards v. Basel Pharms.*, 1997 OK 22, ¶ 8, 933 P.2d 298, 300. As the United States Court of Appeals for the Second Circuit explained in rejecting similar aggregate causation evidence in a pharmaceutical marketing, "[t]he nature of prescriptions, ... means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010).

Third, the State's experts did not address any factor other than marketing that could have caused increased opioid prescribing or Oklahoma's opioid abuse crisis, including those described in Janssen's prior Motion for Judgment and below. They did not account for the effects of other companies' marketing of more widely prescribed products, for social factors driving rising overdoses for all drugs over the same period, for reimbursement practices favoring prescription drugs over more expensive therapies, for state policies making hydrocodone and oxycodone widely available to SoonerCare patients, or for illegal diversion and overprescribing by pill mills.

⁶⁴ *Id.* at 49:20-23.

⁶⁵ *Id.* at 49:11-19.

⁶⁶ Id. at 49:5-7.

Anecdotal and narrative evidence that fails to account for *any* other potential cause of the opioidabuse crisis cannot show that Janssen's marketing was a cause of the opioid epidemic. *See Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1193 (W.D. Okla. 2017) ("expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes" renders causation testimony inadmissible (quoting *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310 (11th Cir. 2014)).

B. The State's Evidence Does Not Support a Finding of Legal Causation

The State also failed to prove that Janssen's marketing proximately caused the State's alleged harms. The "proximate cause of an event must be that which in a natural and continuous sequence, unbroken by an independent cause, produces the event[.]" *Gaines v. Providence Apartments*, 1987 OK 129, ¶ 4, 750 P.2d 125, 126-27. As Janssen's prior briefing explained, the limited acts by Janssen on which the State presented evidence—such as the promotion of Duragesic or a handful of unbranded promotions in the late 2000s—exhibited no "natural and continuous" connection to the opioid abuse crisis. *Id.* Nor did the State's case account for the many independent and intervening potential causes of the crisis just mentioned. The State likewise did not establish a "natural and continuous" connection between Janssen's promotion of its products in the 2000s and injuries the State might suffer over the three-decade course of its proposed abatement plan.

Holding Janssen liable for decades of injuries far removed from its conduct would violate due process under the U.S. and Oklahoma Constitutions. *See* U.S. Const. Amend. XIV; OK Const. Art. 2, § 7. Due process forbids a state from imposing tort liability without the traditional "common law protection[s]"—such as factual and legal causation—essential to guard against the "arbitrary deprivation of property." *Honda Motor Co. v. Oberg*, 512 U.S. 415, 430-32 (1994). Janssen is entitled to judgment because the State's proposal to make Janssen pay billions of

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dollars to address decades of future policy challenges would violate that core due process protection.

V. <u>THE STATE'S CONTRIBUTIONS TO THE OPIOID CRISIS ENTITLE</u> JANSSEN TO JUDGMENT

As Janssen's previous Motion for Judgment explained in depth, a plaintiff that contributes to a nuisance cannot recover at all unless it produces evidence separating the damage caused by its own conduct from the damage allegedly caused by the defendants. *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, ¶ 6, 204 P. 906, 908; *see 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) (emphasis added)). Here, the record shows that, however wellintentioned, State officials and agencies took steps that exacerbated Oklahoma's opioid abuse crisis. They not only eased access to prescription opioids that were heavily abused and diverted, but also failed to take other actions to combat doctor shopping and pill mills. To recover from Janssen, therefore, the State must "separate the amount of damage inflicted by the … defendants from the amount resulting from [its own] acts." *Walters*, 1922 OK 52, ¶4, 204 P. at 908. It offered no basis for such apportionment, and under *Walters* that failure precludes it from recovering against Janssen.

In its opposition to Janssen's prior motion, the State asserted that *Walters* does not apply to intentional torts.⁶⁷ That may be so, but this is not an intentional tort case—the State has presented literally no evidence that Janssen "desired to cause" an opioid-abuse crisis or "kn[ew] that [its] conduct was resulting or substantially certain to result in" an opioid-abuse crisis.

⁶⁷ State's Resp. to Mot. for J. (July 7, 2019), at 50.

Restatement (Second) of Torts § 840A. Quite the contrary, elsewhere in its opposition the State underscores its belief that it does not even need to prove *negligent* conduct by Janssen to recover.⁶⁸ The State has also repeatedly suggested that its policy lapses are excused because Janssen lobbied the Oklahoma government on various matters. Yet it has offered no evidence that lobbying by Janssen influenced a single one of the lapses highlighted in Janssen's motion for judgment.

Second, the State's opposition to Janssen's motion asserted that evidence about its policy lapses is legally insufficient to establish any contribution to the opioid crisis.⁶⁹ But State cannot have it both ways. If the State believes unscientific narrative evidence is good enough to establish causation as to Janssen, it is good enough to establish that the State's own conduct contributed to the crisis. The State's own records establish that contribution, and under *Walters* the State's failure to apportion fault entitles Janssen to judgment.

VI. JANSSEN CANNOT BE HELD LIABLE FOR THE ENTIRE OKLAHOMA OPIOID CRISIS

To hold Janssen liable for other parties' conduct on a joint and several liability theory, the State must show (1) that the tortious acts of multiple parties combining to cause a single, indivisible injury; or (2) concerted tortious conduct. *Kirkpatrick v. Chrysler Corp.*, 1996 OK 136, ¶ 10, 920 P.2d 122, 126. As Janssen's prior Motion for Judgement argued, the State has made neither showing.

A. The State Has Failed to Establish an Indivisible Injury

The State has not established an indivisible injury. Oklahoma courts have found injuries indivisible in only four circumstances, such as physical injury or polluted rivers, none of which

⁶⁸ *Id.* at 37-38.

⁶⁹ *Id.* at 50.

is present here.⁷⁰ Rather than presenting a single indivisible injury, the State's evidence shows a collection of separate harms.

The State's theory is that Janssen caused a large number of different doctors to misunderstand the safety and efficacy of opioid medications, and that individual Oklahomans suffered injury as a result. That claim, which bundles a host individual harms together, is the definition of a divisible injury that can—and must—be apportioned. *See* Restatement (Second) of Torts § 433A ("Damages are to be apportioned among two or more causes where ... there are distinct harms.").

B. The State Has Offered No Evidence of Concerted Conduct

The State also failed to show that Janssen operated in concert with those who caused the opioid crisis. To make a showing of concerted tortious conduct, the State must show "some concerted action on [Janssen's] part causing injury" and "some common purpose or design." *Hammond v. Kansas, O. & G. Ry. Co.*, 1925 OK 211, 234 P. 731, 732. Such a showing would require proof of a "tortious act" 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 presented no such evidence.

The State's opposition to Janssen's prior Motion for Judgment identifies nothing akin to an "agreement" or "conspiracy." The State notes that Janssen held membership in some of the same advocacy groups as other manufacturers and retained some of the same key opinion

⁷⁰ These circumstances are: (1) a personal injury caused by multiple events occurring close in time, *see, e.g., Boyles v. Oklahoma Nat. Gas Co.*, 1980 OK 163, ¶¶ 3-4, 7-11, 619 P.2d 613, 615-17; (2) property damage, *see, e.g., Meyer v. Moore*, 1958 OK 165, ¶ 16, 329 P.2d 676, 681; (3) commingled water pollution *see, e.g., Delaney v. Morris*, 1944 OK 51, ¶¶ 6-8, 145 P.2d 936, 938-39; and (4) cattle that die from drinking commingled water pollution, *see, e.g., Selby Oil & Gas Co. v. Rogers*, 1923 OK 1003, ¶¶ 2-4, 7, 221 P. 1012, 1012-13.

leaders.⁷¹ But a chorus of authority holds that participation in industry groups "provides no indication of conspiracy."⁷² Am. Dental Ass 'n v. Cigna Corp., 605 F.3d 1283, 1295 (11th Cir. 2010); see also In re Musical Instruments & Equip. Antitrust Litig., 798 F.3d 1186, 1196 (9th Cir. 2015) ("mere participation in trade-organization meetings where information is exchanged and strategies are advocated does not suggest an illegal agreement"). Retention of the same experts likewise amounts merely to an allegation of "parallel conduct" that "will not suffice" to show a conspiratorial agreement. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

Finally, the State's observation that Noramco and Tasmanian Alkaloids sold raw materials to other manufacturers⁷³ cannot establish a tortious agreement because "conspiracy 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) (Breyer, J.).

The State has had the chance to review hundreds of thousands of documents from Janssen, Purdue, and Teva, yet has not identified a single one evidencing a tortious agreement between them. Much less has it shown concerted action between Janssen and the countless other people and entities who potentially played a causal role in the opioid abuse crisis. The State's bid to secure joint and several liability on a concerted action theory fails accordingly.

⁷¹ State's Resp. to Mot. for J. (July 7, 2019), at 36.

⁷² Because participation in industry meetings does not establish a conspiracy, a single vague slide that appears to refer Purdue as a "partner" at the "same table" at industry-group meetings does not demonstrate that Janssen and Purdue—or any other manufacturer—hatched a collusive agreement.

⁷³ State's Resp. to Mot. for J. (July 7, 2019), at 36-37.

C. Janssen's Market Share Provides A Reasonable Basis For Apportionment

Moreover, the alleged injuries could easily be apportioned—and therefore would have to be apportioned—based on Janssen's market share. Under the common law, all that is needed is a "reasonable basis" for apportionment, not a perfect one. Restatement (Second) of Torts § 433A(1)(b) (1965). Even where apportionment is "difficult," a basis that provides a "rough estimate" of individual responsibility is preferable to saddling a defendant with liability for harm caused by someone else. *Id.* § 433A cmt. b.

Courts often use market share to apportion liability where manufacturers of related or interchangeable products caused alleged harms. In a series of recent cases, some under public-nuisance theories, states and municipalities sued gasoline manufacturers whose products contained an additive that contaminated groundwater. The "fungible nature" and "commingling of many suppliers' products during transportation and distribution," *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 379 F. Supp. 2d 348, 362 (S.D.N.Y. 2005), made it difficult to measure the damage caused by a particular manufacturer's product. Those courts therefore embraced market share as a reasonable way to "approximate the harm caused" by each manufacturer. *Id.* at 376; *see State v. Exxon Mobil Corp.*, 126 A.3d 266, 296 (N.H. 2015).

Market share is an especially "reasonable" basis for apportionment because "reasonableness" is determined under the circumstances. *See Waller ex rel. Estate of Hunt v. Danville, VA*, 556 F.3d 171, 175 (4th Cir. 2009) ("Reasonableness in law is generally assessed in light of the totality of the circumstances."). Here, those circumstances include: (1) the State's opposition to Janssen's efforts to secure "participant level claims data"⁷⁴ that would have allowed Janssen to establish the lack of harm attributable to its marketing by gathering doctor-

⁷⁴ Def's Mot. to Compel Discovery Regarding Claims Data (Sept. 7, 2018) at 1-4.

and patient-specific evidence and performing sampling or case studies; and (2) broken promises from the State to provide a statistical model to prove causation—"how many doctors bought into" marketing messages.⁷⁵ The State's refusal to produce individualized evidence from which Janssen could demonstrate lack of harm—and then its refusal to provide the aggregate measurements it promised as an alternative—only strengthens the conclusion that market share would be a reasonable basis for apportioning damages.

There is no question that Janssen's share of the Oklahoma market was negligible during the period relevant to this litigation. Janssen's statistical expert, Dr. Laurentius Marais, testified that from 1996 to 2017, Janssen's share of Duragesic, Nucynta, and Nucynta ER prescriptions reimbursed by SoonerCare was .82 percent.⁷⁶ From 2004 to 2018, those same Janssen products accounted for .36 percent of the total number opioid prescriptions reimbursed by HealthChoice, a health plan for employees of the State.⁷⁷ And from 2008 to 2017, Duragesic, Nucynta, and Nucynta ER accounted for .20 percent of all opioid prescriptions reimbursed by BlueCross BlueShield, one of the largest private payors in the nation.⁷⁸ Although the State has never linked them to its injuries, Dr. Marais also provided market share calculations including Sandoz generic fentanyl patches and Janssen's branded tramadol products—Ultram, Ultram ER, and Ultracet.⁷⁹ He further found that Duragesic was associated with between 0.05 and 0.13 percent of SoonerCare opioid use disorder, that Nucynta was associated with between 0.02 and 0.04 percent of such diagnoses, and that Janssen tramadol products were associated with between .02 and

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⁷⁵ Hr'g Tr. (Dec. 5, 2017) at 136-37.

⁷⁶ July 11, 2019 (Marais) Trial Tr. at 34:6-36:3, 36:21-24, 37:4-15; Court Ex. 201 at 1-2.

⁷⁷ July 11, 2019 (Marais) Trial Tr. at 36:12-18; Court Ex. 201 at 1.

⁷⁸ July 11, 2019 (Marais) Trial Tr. at 36:19-20; Court Ex. 201 at 1.

⁷⁹ Court Ex. 201 at 1, 3-4; July 11, 2019 (Marais) Trial Tr. at 37:16-38:4, 38:5-25.

0.13.⁸⁰ By contrast, OxyContin was associated with between 0.75 and 2.46 percent of diagnoses,⁸¹ while hydrocodone products—which SoonerCare to this day prefers—were associated with 25.93 to 41.51 percent of OUD diagnoses.⁸²

Janssen's low market share and its drugs' infinitesimal contributions to opioid use disorder provide a reasonable basis for apportioning the harms caused by promotions devised to promote those products.

D. Imposing Joint and Several Liability For A Complex Social Problem Would Violate the Due Process Clause

Finally, the State seeks an expansion of joint and several liability that would both defy Oklahoma law and the Due Process Clause of the Fourteenth Amendment, which "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). Joint and several liability has historically applied to circumstances where defendants acted in concert or where a small number of tortfeasors contributed to a single, unitary injury. Those are not the circumstances here—Janssen did not act in concert with any other manufacturer (much less every party that contributed to the opioid abuse crisis) and the State alleges a range of diverse and separate injuries. If Janssen is required to pay every penny purportedly needed to address the opioid abuse crisis over the next three decades, its liability will be massively disproportionate to its alleged fault. Such an outcome would run afoul of the bedrock principle that liability should reflect only "the consequences of [a defendant's] own acts," *Holmes*, 503 U.S. at 268, and result in liability that is "wholly disproportioned to the offense," *BMW*, 517 U.S. at 575. The due process clauses of the

⁸⁰ Court Ex. 207; July 11, 2019 (Marais) Trial Tr. at 77:6-22, 78:7-79:1, 79:2-81:22, 81:23-82:25.

⁸¹ Court Ex. 207 at 1-2; July 11, 2019 (Marais) Trial Tr. at 77:23-78:6, 78:7-79:1.

⁸² Court Ex. 207 at 3-4; July 11, 2019 (Marais) Trial Tr. at 79:2-81:22.

United States and Oklahoma constitutions forbid this result. As Janssen's prior motion explained, the Eighth Amendment's Excessive Fines Clause likewise prohibits such massively outsized liability. *See Timbs v. Indiana*, 139 S.Ct. 682, 686 (2019); *United States v. Halper*, 490 U.S. 435, 447 (1989).

VII. <u>THE STATE HAS FAILED TO PROVE ITS ENTITLEMENT TO ITS SOLE</u> <u>REQUESTED REMEDY</u>

A. The Oklahoma Nuisance Statute Does Not Authorize the State to Recover the Costs of Remedying the Consequences of a Nuisance

As explained in depth in Janssen's summary judgment motion, trial brief, and prior Motion for Judgment, the Court must also enter judgment for Janssen because Oklahoma law does not authorize the only remedy the State seeks: "abat[ing]" the "public nuisance." 50 O.S. § 11. The State can "abate" only the defendant's *conduct*—not the allegedly resulting harms: "A nuisance consists in unlawfully *doing an act, or omitting to perform a duty.*" *Id.* § 1 (emphasis added). But here, the State is abatement plan does not seek to abate any "act" or "omi[ssion]" by Janssen. Instead, the State aims to "abate the opioid epidemic"⁸³—that is, to address the harms the State alleges resulted from Janssen's actions. But the opioid epidemic is not conduct—by Janssen or anyone else—and cannot constitute a nuisance; rather, it is the "injury" or "damage" allegedly resulting from such conduct. *Briscoe*, 1985 OK 43, ¶¶ 9-11, 702 P.2d at 36. The fact that

⁸³ See, e.g., May 28, 2019 (AM) Trial Tr. (State Opening) at 10:9-11 (arguing that the State's abatement plan aims to "bring an end to the opioid epidemic in Oklahoma"); *id.* at 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 38:1 (acknowledging that the plan aims to "abate the crisis"); June 21, 2019 (AM) Trial Tr. (Hawkins Test.) at 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").

Oklahoma law does not authorize the State to collect for such injuries is yet another reason why this Court must grant judgment in Janssen's favor.

B. The Oklahoma Constitution Bars Courts from Awarding Payment to Address the Consequences of a Nuisance in a Bench Trial

In addition, the State's requested remedy is unavailable in a bench trial, compelling judgment for Janssen. Oklahoma law demands 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. 2 § 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...."). Although no jury is required where a cash recovery is "incidental to and dependent upon [an] equitable issue," *Russel v. Freeman*, 1949 OK 256 ¶ 6, 214 P.2d 443, 444, no dominant equitable issue exists here. As Janssen has previously explained, a cash recovery is not incidental; it is the State's only aim. Both federal and Oklahoma constitutional requirements foreclose the State from proceeding without a jury. *See* Okla. Const. art. 2 § 19; U.S. Const. amend. VII; *see also* 12 O.S. § 556.

As explained, the State's "abatement plan" does not seek to enjoin a public nuisance being committed by Janssen—there is no conduct for the State to enjoin. The only "abatement" remedy the State seeks is a massive payment to create an array of government programs, all targeted toward curing the alleged *injury* the State alleges Janssen caused. But Oklahoma precedents make clear that injuries are not a nuisance—and money paid to address them is damages. As the Oklahoma Supreme Court put it in *Oklahoma City v. Page*, "[n]uisance is a wrong, and damage is the result." 1931 OK 764, ¶ 10, 6 P.2d at 1036.

The conclusion that the State's claim seeks damages is confirmed by its request for Janssen to pay billions of dollars toward services already funded by Medicaid and private

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insurance—including non-opioid pain therapies;⁸⁴ Screening, Brief Intervention, and Referral to Treatment services;⁸⁵ prenatal screening services,⁸⁶ neonatal treatment services,⁸⁷ transportation services,⁸⁸ and addiction treatment services⁸⁹—as well as services currently funded by other State and federal programs.⁹⁰ The State's plan seeks nothing more than a massive cash transfer

⁸⁵ State Ex. 4734, Abatement Plan at 26-27 (*admitted June 24, 2019*); June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 78:12-80:2; June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 5:13-9:14 (federal Medicaid would pay \$810 million under the existing Medicaid assistance percentage rate).

⁸⁶ State Ex. 4734, Abatement Plan at 54-55 (*admitted June 24, 2019*); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 12:4-13 (testifying that SoonerCare pays for these costs but that the plan will "shift" the costs to the Janssen Defendants); *id.* at 12:1-11 (federal Medicaid would pay about \$110 million under the existing Medicaid assistance percentage rate).

⁸⁷ State Ex. 4734, Abatement Plan at 56 (*admitted June 24, 2019*); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 16:10-17:20 ("Q. And the cost associated with treating these NAS births, those are things that are currently covered by SoonerCare, right? A. Yes. Q. And so this is another area where we are taking money that is currently covered by Medicaid and saying, Janssen and Johnson & Johnson, you are going to pay for that portion of the State's Medicaid program, right? A. What it says is that neonatal treatment is necessary to abate the opioid crisis, and that the defendants are responsible for abating the opioid crisis.").

⁸⁸ State Ex. 4734, Abatement Plan at 25 (*admitted June 24, 2019*); June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 63:10-65:4 (testifying that these costs are based on costs currently borne by Oklahoma's Medicaid program).

⁸⁹ State Ex. 4734, Abatement Plan at 19, 20 (*admitted June 24, 2019*); June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 77:20-79:20, 82:13-83:5 (testifying that these components of the plan would cover treatment for people currently on private insurance and State Medicaid regardless whether their insurance covers these treatments).

⁹⁰ See, e.g., June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 45:23-46:23 (testifying that the Opioid Overdose Review Board, which would cost \$3.8 million over the 30-year plan, currently exists and that the State could use CDC grants to fund the Board's operations); *id.* at 50:1-52:24

⁸⁴ State Ex. 4734, Abatement Plan at 29-30 (*admitted June 24, 2019*); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 41:16-42:3 (testifying that Janssen would cover the cost of caring for patients on Medicaid based on an estimate of 32,178 people); *id.* at 42:25-43:11 (testifying that the costs used to calculate these services were based in part on Medicaid reimbursement rates because these services are covered by Medicaid); *id.* at 44:1-5 ("Q. Right. And so again, here, we have a situation where what is being proposed by the State is that Janssen and Johnson & Johnson pay for services that are currently provided by SoonerCare, correct? A. Correct."); *id.* at 44:21-45:11 (federal Medicaid would pay approximately \$1.5 billion under the existing Medicaid assistance percentage rate).

from one party to another. *See also, e.g.*, 74 O.S. § 18b(A)(11) (requiring Attorney General to immediately forward all funds received in litigation to State treasury). That is damages; not equitable relief. The Court cannot award it in a bench trial.

Casting the relief here as equitable not only violates Janssen's jury-trial rights, but also the Excessive Fines Clause of the United States Constitution.

C. The Separation of Powers Bars Courts from Ordering and Funding Decades of Multifaceted State Government Programs

The State's requested remedy would also violate basic separation-of-powers principles, as it would require the Court to exercise the legislature's exclusive policy-making powers, including the power to set fiscal and public-health policies. *See* Okla. Const. art. V, § 36 (legislative power extends to "all rightful subjects of legislation"); *Okla. Educ. Ass 'n v. State ex rel. Okla. Legislature*, 2007 OK 30, ¶20, 158 P.3d 1058, 1065-66 ("[The] state's policy-making power is vested exclusively in the Legislature" and includes the authority to set "fiscal policy");*Cryan v. State*, 1978 OK 91, ¶ 15, 583 P.2d 1122, 1125 (legislative power includes power to set policies "to protect and serve the public health").

The abatement plan here encompasses dozens of new spending initiatives⁹¹ for decades into the future. It would have this Court authorize over \$700 million in government expenditures

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⁽testifying that Oklahoma's prescription monitoring program, which would cost \$38 million under the 30-year plan, currently is kept and funded by the Oklahoma Bureau of Narcotics and receives additional funding from CDC and other federal grants); *id.* at 55:3-19 (testifying that the Janssen Defendants would have to pay for the State to establish a centralized state-run health information exchange at a cost of \$735 million over the 30-year plan, even though a current health information exchange exists that is run by a private vendor); *id.* at 94:2-95:9 (testifying that the Janssen Defendants would pay \$1.6 billion over the 30-year plan to fund school counselors, even if the Legislature appropriates requested funds for those positions).

⁹¹ State Ex. 4734, Abatement Plan, Ex. 1, at 8 (admitted June 24, 2019).

every year from now until 2048, at a total cost of \$17.8 billion, all to be paid for by Janssen.⁹² Under basic separation of powers principles, courts do not establish new government spending programs and do not determine how such programs will be funded. *See Okla. Educ. Ass 'n*, 2007 OK 30, ¶ 25, 27, 158 P.3d at 1066; *see also Missouri v. Jenkins*, 515 U.S. 70, 133 (1995) (Thomas, J., concurring) ("These functions involve a legislative or executive, rather than a judicial power.... Federal judges cannot make the fundamentally political decisions as to which priorities are to receive funds and staff...."). This Court should reject the State's request for a remedy that the Court lacks authority to grant.

D. The State Has Failed to Show Its "Abatement Plan" Will "Abate" The Opioid Crisis

Finally, as Janssen's prior Motion for Judgment explained, the State's abatement plan is untenable because the State has failed to prove that its plan is necessary or sufficient to eliminate (or even reduce) the opioid crisis. Abatement means "[1]he act of eliminating or nullifying." Black's Law Dictionary (11th ed. 2019). *Oklahoma City v. Hoke*, 1919 OK 244, 75 Okla. 211, 182 P. 692. Consistent with that definition, abatement 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), and public entities in Oklahoma consistently request injunctive relief that "eliminat[es] or nullif[ies]" the entirety of the offending conduct, *see, e.g., Oklahoma ex rel. Field v. Hess*, 1975 OK 123, ¶¶ 1-3, 540 P.2d 1165, 1167, 1171; *Curlee v. Oklahoma ex rel. Edmondson*, 1957 OK 72, ¶¶ 1-4, 309 P.2d 1064, 1064-65. Moreover, 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.

⁹² *Id.*, Ex. S-1, at 11.

The State has not met its burden to prove by a preponderance of the evidence that its plan is either sufficient or necessary to end the opioid abuse crisis. To prove effectiveness, the State offered conclusory testimony by the very government administrators whose budget the Plan would massively inflate. But those same administrators also testified that the opioid abuse crisis would take "at least 30 years" to abate, ⁹³ while the State's star witness testified that "everyone in this room will be experiencing the effects of this epidemic for the rest of our lives."⁹⁴ Indeed, the abatement plan's annual funding structure assumes it will not cure the crisis: The State would have Janssen pay for the same services at approximately the same level—between \$727,219,744 and \$789,186,743 annually—every year from 2020 to 2048.⁹⁵ If the problem of opioid abuse actually abated under the plan, it would not require the same level of resources in 2048 as it does today. ODMHSAS administrator Jessica Hawkins admitted that the State does not even have an "evaluation plan yet to accompany this abatement plan."⁹⁶ At other points, State witnesses testified the benchmark of success would be return to "pre-1996 levels" of statistics like high-

⁹³ June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 47:21-49:10 (emphasis added) (testifying that the crisis "has taken at least 20 years to develop to this point. It will take at least that amount of time to begin to abate the problem. In my opinion, it will take much longer and in this case, at least 30 years.").

⁹⁴ June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 47:21-49:10 (emphasis added) (testifying that the crisis "has taken at least 20 years to develop to this point. It will take at least that amount of time to begin to abate the problem. In my opinion, it will take much longer and in this case, at least 30 years.").

⁹⁵ See State Ex. 4734, Abatement Plan at 16 (Table 3) (*admitted June 24, 2019*); June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 58:25-59:3 (testifying that the State proposes to spend between \$727 million and \$789 million in 2019 dollars every year between years 2 and 30 of the plan).

⁹⁶ June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 64:20-23.

school painkiller misuse,⁹⁷ but acknowledged they did not know what those levels were⁹⁸ or even whether they were measured in 1996.⁹⁹

The same witnesses also admit that the plan calls for *more* than is necessary to abate—for example, the plan does not contemplate any reduction in expenditures if measures of abuse return to pre-1996 levels.¹⁰⁰

Equivocal, contradictory assertions about fuzzy metrics for which the State lacks baseline data are not legally sufficient to establish that the requested catalog of spending programs will solve anything—let alone a problem as complex as the opioid crisis. In the absence of such proof, the State's plan cannot qualify as abatement, and this Court cannot order its launch.

E. The State's Proposed Remedy Violates the Excessive Fines Clause

Finally, a court order purporting to award billions of dollars to the State as an equitable matter under a quasi-criminal statute would constitute a punitive remedy—especially in a politically charged case overflowing with punitive rhetoric from the Attorney General, his counsel, and the State's witnesses.¹⁰¹ "It is commonly understood that civil proceedings may advance punitive as well as remedial goals." *United States v. Halper*, 490 U.S. 435, 447 (1989).

⁹⁷ Id. at 86:22-87:11.

⁹⁸ See id.; see June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 44:17-45:16, 48:17-49:14.
⁹⁹ June 24 (PM) Trial Tr. (Hawkins Test.) at 90:24-91:21 (testifying that measurements of opioid use disorder prevalence began "around" 2003).

¹⁰⁰ June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 96:8-19.

¹⁰¹ See e.g., June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 44:6-15 (testifying Janssen should pay for programs already funded by federal programs because "[t]hese are the costs of services and Janssen and Johnson & Johnson should be responsible to abate the opioid crisis"); July 8, 2019 (AM) Trial Tr. (Beckworth Arg.) at 62:11-17 ("Unless somebody builds a wall around Princeton, New Jersey, that shuts this company down, it 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 mismarketed them and we deceived the public and doctors. You need to reassess what you were told because we lied. Until that happens, this problem is going to get worse and worse and worse.").

The State's punitive intent in this trial has been unmistakable, and its attempt to extract billions of dollars in "abatement" remedies represents a grossly disproportionate punishment that violates the Excessive Fines Clause. *See Austin v. United States.* 509 U.S. 602, 609-10 (1993) ("The Excessive Fines Clause limits the government's power to extract payments, whether in cash or in kind, as punishment for some offense.").

VIII. CONCLUSION

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

Dated: July 12, 2019

Respectfully submitted.

By: Stephen D./Brod David K. Roberts

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CERTIFICATE OF MAILING

Pursuant to OKLA. STAT. tit. 12, § 2005(D), this is to certify on July 12, 2019, a true and

correct copy of the above and foregoing has been served via email to the following:

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