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

MOTION FOR JUDGMENT OF DEFENDANTS JOHNSON & JOHNSON AND JANSSEN PHARMACEUTICALS INC. AND BRIEF IN SUPPORT

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Defendants Janssen Pharmaceuticals, Inc.[1] and its parent company Johnson & Johnson ("J&J") (collectively, "Janssen Defendants") hereby move this Court for a judgment in their favor on the State's public-nuisance claim.

I. INTRODUCTION

Striking the appropriate balance between the benefits and risks of opioid pain medications is an enormously complex medical and societal question, one that for years has sparked debate among serious, well-intentioned physicians, researchers, and legislators. Prescribers and regulators in Oklahoma have long understood prescription opioid medicines carry risks: Unmistakable "black box" warnings about addiction have accompanied every long-acting opioid medicine sold in the United States for more than two decades, and state officials have scrutinized the prescribing, diversion, and abuse of prescription opioids since at least the early 2000s. But prescribers and regulators have also long recognized what the FDA stressed as recently as this May: 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."[2] Janssen is committed to participating in this ongoing discussion, and to working with physicians, scientists, regulators, and lawmakers to find consensus on measures that account for both the risks and the benefits of opioid medications. But a courtroom is not the place—and a judge should not be thrust into the role of policymaker.

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

[2] 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).

By seeking to impose liability on a single defendant for a complex social crisis that has taken a tragic toll on this country, the State has put this Court in an untenable position. The State has used this trial—and a slew of illogical, legally defective theories far outside the bounds of Oklahoma precedent—not to "abate" anything but to find a scapegoat. Against the State's attack, Janssen has not hesitated to defend itself. Lawful, strictly regulated, rarely diverted medications like Janssen's Duragesic and Nucynta products could not and did not cause Oklahoma's opioid abuse crisis. This was true two years ago when the State filed its Petition. And after more than 20 days of State evidence and testimony before this Court, it is now plain for everyone to see that this case was never about Janssen's opioid products. The State admitted as much: "Now, this case isn't about their drug[s]."[3] From the start of this trial, the State's target has been Janssen's pocketbook—not its products.

As one State document after another recounts, Oklahoma's opioid abuse crisis was fueled by rampant illegal diversion of hydrocodone and oxycodone pills, which were already flooding Oklahoma's streets by the early 2000s. Duragesic and Nucynta are not hydrocodone or oxycodone pills. Duragesic is a patch that delivers a safe and controlled dose of pharmaceutical fentanyl over 72 hours. Nucynta, which was not marketed until 2009, contains a novel active ingredient, tapentadol, that Janssen correctly anticipated would be less attractive to abusers than conventional opioids. Oklahoma doctors prescribed both products so rarely that the State conspicuously avoided presenting any proof of their market share. And all objective evidence confirms that they were seldom diverted and abused. If this trial has shown anything, it is that there were no ***patch*** mills in Oklahoma. There was surely no ***tapentadol*** epidemic. Although the State has criticized Janssen's marketing of Duragesic, it failed to coherently explain how urging

[3] June 3, 2019 (PM) Trial Tr. (Beckworth Arg.) at 53:22-23.

doctors to use Duragesic ***instead*** of OxyContin—one of the most widely abused opioids in Oklahoma—could have caused Oklahoma's crisis.

The State's effort to hold Janssen alone liable for billions of dollars of government spending to address opioid abuse is a striking about-face. For much of the past two years, Janssen has been an afterthought in a case built around Purdue Pharma, L.P., and its flagship product, OxyContin. The State launched these proceedings with a Petition focused singularly on Purdue, and as the case progressed the State maintained that "Purdue's fraudulent marketing scheme created the opioid epidemic";[4] that Purdue "is the genesis of why we're all here";[5] and that Oklahoma's crisis of opioid abuse "can [be] trace[d] … to a very specific point in time, and that is when OxyContin was brought to market and promoted in an aggressive, concentrated, and targeted way."[6] That focus softened only after the State settled with Purdue in March, concerned that mounting litigation expenses would force the company into bankruptcy. Two months later, citing similar concerns, it settled with Teva, which sold much of the oxycodone and hydrocodone that the State blames for its injuries. Having compromised with the manufacturers of the drugs that fueled its crisis, the State and its contingency counsel pivoted, training their sights on a defendant they believe can satisfy an astronomical judgment.

That shift posed an obvious dilemma: How can the State hold a minor player in the prescription opioid market solely responsible for every dollar the State believes necessary to fund its abatement programs purportedly for both prescription and illegal opioid abuse over the next three decades? Its solution has been brazen. To lay the entire opioid abuse crisis at Janssen's

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[4] Pl. Opp. to Purdue Mot. Quash (May 4, 2018) at 2.

[5] Dec. 5, 2017 Hr'g Tr. at 25:15-21.

[6] Aug. 30, 2018 Hr'g Tr. at 57:17-58:1.

feet, the State has asked this Court to discard one settled legal protection after another and impose liability far beyond what any court, anywhere, has ever allowed. In the process, it has demanded that this Court usurp the legislature and make government policy—on complex social, public health, and educational questions—for decades to come, all at Janssen's expense. These invitations are beyond radical. If this Court accepts them, the damage to everything from lawful business activity to basic associational rights to the separation of powers will persist long after this case concludes.

The State's legal inventions begin with its insistence that Oklahoma's nuisance statute—for 100 years applied almost exclusively to property disputes—can be contorted to punish any commercial activity that a court finds to have harmed a substantial number of Oklahomans. That theory not only breaks with a century of precedent, but also promises to make courts a venue for litigating any number of sprawling societal problems, from obesity allegedly caused by fast food to climate change allegedly caused by fossil fuels. The State may be eager to engineer policy before this Court, but it has balked where other jurisdictions have sought to do the same. Indeed, even as the State pursues sweeping public-nuisance liability against Janssen, it has gone to bat for Oklahoma oil companies in California climate-change litigation, arguing that it would be totally inappropriate for courts to expand public-nuisance doctrines to deal with complex policy issues they were never intended to address. In those cases, Oklahoma's Attorney General has filed amicus briefs insisting that:

- A "judicial determination inserting the common law of public nuisance into the … debates on energy production and environmental policy would be governmentally

untenable";[7]

- The demand for "Defendants to pay to … construct … infrastructure necessary to combat the effects of global climate change for a single major city … could cost several billion dollars and seriously impact Defendants' ability to provide energy to the rest of the country";[8] and
- Courts "face immutable practical limits in terms of gathering information about complex public policy issues and predicting long-term consequences that might flow from judicial decisions."[9]

While the Attorney General obviously recognizes the perils of using public nuisance to tackle exceedingly complex policy problems, he nonetheless asks the Court here to "insert[] the common law of public nuisance" into a raging policy debate, impose "several billion dollars of liability" that could "impact [Janssen's] ability to" develop and market medicines, and use that money to craft solutions to "complex public policy issues" long into the future.[10] As the California cases make clear, that unprecedented demand threatens to expose lawful businesses, in Oklahoma and elsewhere, to massive liability for downstream harms associated with their products. And all under the banner of a statute historically applied to property violations like overgrown hedges and polluted streams. No court should accept that invitation.

The State's assault on settled rules does not stop there. To portray Janssen as the driving force behind ***all*** opioid products, the State proposes that Oklahoma simply arrogate the federal

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[7] *California v. BP P.L.C.*, Case No. C 17-06011-WHA (N.D. Cal), Dkt. No. 224-1 (Apr. 19, 2018) at 18.

[8] *Id.* at 8.

[9] *Id.* at 11.

[10] *Id.* at 8, 11, 18.

government's authority to monitor and regulate controlled substances. In a theory contained nowhere in its Petition—and that its chief expert did not elaborate until two days after the Purdue settlement—the State contends that Janssen should be held liable for Purdue's and Teva's conduct because two former Johnson & Johnson subsidiaries, Noramco and Tasmanian Alkaloids, made raw materials for some of those companies' products. As the State has made clear, this case is not about Janssen's products but "about opioids and all the ones [J&J] supplied."[11] The State's overwhelming reliance on that theory has been inextricable from the rest of its case, serving as a central focus of its star witnesses' testimony and as the linchpin of their causation opinions.

Yet that 11th-hour theory fails as a matter of law. Oklahoma—like most other states—rejects liability for raw-material suppliers, which have no duty to regulate how their customers market and distribute the finished products they make from such materials. And under the Controlled Substances Act, the Drug Enforcement Administration establishes policy on raw-material production, balancing legitimate medical and scientific needs against the potential for diversion. It also sets quotas for how much raw material every U.S. supplier can sell and every U.S. manufacturer can buy, meaning that the nation's top narcotics enforcement agency approved the very raw material sales now forming the basis for the State's case. But that has not stopped the State from asking this Court to breach settled state-law principles, impermissibly second-guess the DEA, and award Oklahoma a massive payday.

The State's other maneuver for pinning the opioid abuse crisis on Janssen flouts basic First Amendment protections. Like many American companies, Janssen hired consultants and contributed to professional organizations. The State has labored to read a nefarious conspiracy

[11] June 3, 2019 (PM) Trial Tr. (Beckworth Arg.) at 53:22-23.

into those common business practices, asserting that Janssen must therefore be responsible for anything that the dozens of doctors and organizations it affiliated with said about opioids over a 20-year period. That defies not only common sense but the Constitution. The First Amendment protects doctors' and advocacy groups' rights to voice their beliefs about medical questions such as pain treatment. That remains so even if they have relationships with Janssen, and even if, decades later, the State of Oklahoma concludes their beliefs were mistaken. Tarring doctors as shills or advocacy organizations as "front groups" cannot strip them of their constitutional rights. The State presented no evidence that Janssen exercised control over any doctor's speech. And it presented no evidence that Janssen created or exercised control over any advocacy group. The State's attempt to spin billions of dollars of liability out of third parties' independent expression tramples not only their right to free speech, but also Janssen's right to associate with parties whose views the State of Oklahoma later criticizes. The Constitution rejects such guilt by association, not least for constitutionally protected speech about matters of indisputable public importance.

The State's attack on the First Amendment continued with hours of testimony about constitutionally protected public advocacy and lobbying of government officials. Much of that evidence involved conduct by Purdue, Teva, and others, in which Janssen played no part. Indeed, the State did not identify a single lobbying activity undertaken by Janssen in Oklahoma that involved false information, let alone activity—true or false—that impacted any doctor's prescribing decision in this State. In any event, participating in the ongoing policy debate over the safety of opioid medications and the consequences of undertreated pain is not a proper ground for imposing liability. Decades of uniform precedent hold that the First Amendment

absolutely protects lawful advocacy and lobbying—yet another longstanding protection that the State would have this Court jettison.

The State discards still more settled legal rules with its failure to provide causation evidence. Textbook tort law and basic logic hold that a defendant cannot be held liable if it did not cause the plaintiff's injuries. In cases addressing the impacts of pharmaceutical marketing, courts have demanded individualized evidence to prove causation—that a specific statement had a direct effect on a particular doctor's decision—and consistently rejected statistical evidence, holding that statistics alone cannot account for the myriad factors that influence prescribing choices and habits. But here the State did not even offer statistics. Its ostensible causation expert, Andrew Kolodny, made no attempt to measure the impact of Janssen's conduct. He offered nothing that could be described as a method and did not try to account for the untold other factors that fed the opioid abuse crisis, including the medical community's increased emphasis on pain therapy in the 1970s, the conduct of other manufacturers, the State's own policy failures, and social forces that have fueled skyrocketing abuse rates for *all* drugs over the past two decades. He merely took potshots at Janssen for scattered, cherry-picked statements made over a 20-year period and, without considering Janssen's right to promote its products in non-misleading ways, leapt to the conclusion that Janssen caused the opioid crisis. His observational testimony may have served contingency counsel's narrative, but it is not the kind of evidence any court has ever accepted to prove harm from pharmaceutical marketing—much less harms as complex, far-reaching, and varied as the ones the State asserts here. In a case seeking to assign responsibility and impose billions of dollars in damages for a confounding social problem, an expert's unsupported say-so is not and should never be enough.

In each of these demands, the State sends this Court into uncharted legal waters. But its proposed remedy asks this Court to drift into the abyss. The Oklahoma public-nuisance statute gives the State a single remedy: to abate the "act" or "omi[ssion]" constituting the public nuisance. 50 O.S. §§ 1, 11. Until now, that was a simple matter: Courts could prohibit or mandate some action affecting property—say, enjoin operation of noisy machinery or require a city to treat its sewage before dumping it into streams. The plan set forth by the State's witnesses here is something altogether different. Those witnesses do not ask Janssen to stop doing (or do) anything. Rather, they urge ***the Court*** to take the helm. Under the State's proposed remedy, it falls to this Court to authorize a wish list of new spending programs, to triple the budget of the Oklahoma Department of Mental Health and Substance Abuse Services, to mandate the hiring of 1,700 new public employees, to pay for existing services already provided by Medicaid and private insurance, to oversee these new programs' operation for 30 years—and then to hand the $17 billion tab for this colossal legislative endeavor to Janssen.

That request not only goes well beyond any reported public-nuisance case, but also shreds basic separation-of-powers principles. Courts are not the place to solve complex social problems. Judges do not create government programs or dictate their funding. And they do not set salaries for state employees. As the Attorney General put it when defending Oklahoma business interests, courts "face immutable practical limits in terms of gathering information about complex public policy issues and predicting long-term consequences that might flow from judicial decisions."[12]

[12] *California v. BP P.L.C.*, Case No. C 17-06011-WHA (N.D. Cal), Dkt. No. 224-1 (Apr. 19, 2018) at 11.

Those deficits could not be starker here. Any abatement plan would necessarily collide with patients' access to lawful opioid products—medications that the FDA to this day endorses for pain-relief treatment. Meanwhile, the ongoing activities of criminal trafficking gangs observe no rule or regulation. Despite these daunting policy challenges, the only evidence the State offered about its plan's wisdom is the testimony of the very state officials whose budgets the plan will inflate. In conflict with their assurances that the plan will abate the opioid abuse crisis, they insist that it will require about the same level of funding in 30 years as it does tomorrow. Nor are they especially confident in its efficacy, warning that abatement of opioid abuse will take "at least" 30 years. Notably, the State's purported plan of abatement does not include a defined endpoint, nor is there any clear analysis or direction indicating how the "plan" will result in the State's vague goals. If the legislature wished to rely on equivocal promises from three administrators to enact a multibillion-dollar roster of spending programs, that would be its prerogative. But under bedrock separation-of-powers principles, this Court cannot enact spending programs to address difficult social problems.

Recognizing these elementary principles, Oklahoma law forbids the Attorney General from using court judgments to fund his preferred policies. The statute defining the Attorney General's duties directs him to pay "into the State Treasury, immediately upon its receipt, all monies [he] receive[s] ... belonging to the State." 74 O.S. § 18b(A)(11). That includes every dollar of the $17 billion he seeks here. In addition to misreading the nuisance statute and violating the separation of powers, the Attorney General's proposal to earmark an award against Janssen to a litany of public-policy initiatives blatantly violates this statutory mandate, and oversteps his legal authority.

In short, the State's hastily revised theories and flagrantly unreliable evidence have saddled this Court with a case that is both a legal miscarriage and a practical fiasco. None of it withstands scrutiny and none of it can be implemented without inviting unworkable havoc and setting destructive legal precedents. As explained in greater detail below, the State's campaign to reap an unwarranted and historically unprecedented windfall at Janssen's expense should end here and now.

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 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

The State's case-in-chief dissected a smattering of statements handpicked from hundreds of thousands of Janssen documents spanning 25 years—a line plucked from a sales

representative's notes here, an obscure brochure there. But its true qualm, which the State did not hide, was that Janssen marketed opioids at all. The State's designee—the Commissioner of its Department of Mental Health and Substance Abuse Services—put the matter bluntly: "I do not believe that you should be marketing opioids."[13] Its marketing expert, Renzi Stone, similarly opined that while there generally "is nothing wrong with targeting customers that you want to purchase your product," Janssen's opioid medicines were different because "the product you're marketing kills people."[14]

But marketing opioid medicines for the treatment of chronic pain is not unlawful. The FDA continues to approve them for that purpose, and both the First Amendment and FDA regulations protect promotion of prescription medicines for approved indications. To be sure, truthful promotions about lawful medications might cause doctors to prescribe a medicine more often—when that happens, its benefits as well as its risks will reach more patients. But that does not and cannot make such promotion tortious. It therefore does not matter how many times Janssen sales representatives talked to Oklahoma doctors, or how many boxes of their notes the State received in discovery.[15] To hold Janssen liable, the State must identify unlawful, unprotected conduct by Janssen, and prove ***that conduct***—and ***only*** that conduct—caused its injuries. *See* 50 O.S. § 1 ("A nuisance consists in unlawfully doing an act, or omitting to perform a duty...."); *Atchison, T. & S.F. Ry. Co. v. Kelly*, 1928 OK 256, ¶ 6, 266 P. 775, 776, ("[T]his defendant was liable for such injury only as was the direct result of its wrongful act.").

[13] June 26, 2019 (PM) Trial Tr. (White Test.) at 133:18-19.

[14] June 10 (PM) Trial Tr. (Stone Test.) at 127:3-6, 128:7-10.

[15] *See* May 30, 2019 (AM) Trial Tr. (Beckworth Arg.) at 18:6-18, 71:8-12; May 30, 2019 (AM) Trial Tr. (Pate Arg.) at 23:16, 25:6-11.

Rather than do that, the State loaded its case with extraneous evidence about legally protected activities such as Noramco's federally authorized active pharmaceutical ingredient ("API") sales, third-party speech about medicine, and lobbying. And its evidence about Janssen's actual promotion of Duragesic and Nucynta does not resemble anything ever before recognized as a public nuisance in any Oklahoma court. 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

The State's evidence bears no resemblance to any public-nuisance theory previously recognized by any Oklahoma court. As Janssen has emphasized from the beginning of this trial, one hundred years of 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. Binding Oklahoma caselaw states these limitations explicitly: "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."[16] *Fairlawn Cemetery Ass'n v. First Presbyterian Church, U.S.A. of Okla. City*, 1972 OK 66, ¶ 14, 496 P.2d 1185, 1187. Consistent with that limitation, cases applying Oklahoma's public-nuisance statute deal with menaces such as "keeping a large number of cats on ... residential property," *Boudinot v. State ex rel. Cannon*,

[16] *See also, e.g., Morain v. City of Norman*, 1993 OK 149, ¶ 14, 863 P.2d 1246, 1250 ("In *Briscoe v. Harper Oil Co.* ... we noted that a nuisance was 'an unreasonable, unwarranted, or unlawful use by a person or entity of property lawfully possessed, but which works an obstruction or injury to the right of another' .... Thus, in order to find City liable for nuisance, the flooding to the plaintiffs' properties must have been caused by City *using lawfully possessed property* in an unreasonable, unwarranted or unlawful manner (misfeasance) or failing to perform some duty (nonfeasance)." (emphasis added)); *Dobbs v. City of Durant*, 1949 OK 72, ¶ 5, 206 P.2d 180, 182 ("No princip[le] is better settled than that where a business is conducted in such a manner as to interfere with the reasonable and comfortable enjoyment by others of their property or which occasions material injury to the property, a wrong is done to the neighboring owners for which an action will lie ....").

1959 OK 97, ¶ 16, 340 P.2d 268, 269, permitting "hedge[s] … to grow to such proportions as to … prevent[] traffic through [an] alley," *Updegraff v. City of Norman*, 1955 OK 195, 287 P.2d 909, 912, or operating a "cotton oil mill and cotton gin" that causes "loud offensive noises, and … taint[ing] and corrupt[ing] the atmosphere with dust and lint," *Epps v. Ellison*, 1921 OK 279, ¶ 1, 200 P. 160, 160.

Here, the State has attempted to shoehorn a sprawling case about pharmaceutical marketing, drug addiction, and abuse and misuse of prescription-only medications into the narrow and well-defined boundaries of 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." *Briscoe v. Harper Oil Co.*, 1985 OK 43, ¶ 9, 702 P.2d 33, 36. Although the State packed its case with evidence about independent third parties, its evidence against ***Janssen*** distills to a straightforward product-liability claim: The State generally alleges that Janssen misleadingly marketed lawful, highly regulated products, and that Oklahomans suffered injury as a result. As Janssen's prior briefs in this case have explained, courts have rightly "enforced the boundary between the well-developed body of product liability law and public nuisance law" for fear of turning nuisance law into "a monster that would devour in one gulp the entire law of tort." *People v. Sturm, Ruger & Co.*, 309 A.D. 2d 91, 97 (N.Y. App. Div. 2003). "All a creative mind would need to do is construct a scenario describing a known or perceived harm of a sort that can somehow be said to relate back to the way a company or an industry makes, markets and/or sells its nondefective, lawful product or service, and a public nuisance claim would be conceived and a lawsuit born." *Id.* at 96. Recognizing that a body of law policing loud noises and smelly animals is a crude instrument to regulate the nationwide sale

of highly regulated products, one court after another has rejected exactly the sort of sweeping product-based nuisance claim the State has presented here.[17]

Well-aware that its case runs counter to a century of unbroken Oklahoma precedent, the State has made cursory and transparently woeful attempts to anchor its theories in property use—eliciting brief testimony, for example, that Janssen's sales representatives trained in their Oklahoma homes, that an unspecified Oklahoman was pulled over under the influence of opioids, and that individuals with opioid abuse disorder have on occasion trespassed in search of pills.[18] But those disingenuous gestures only underscore how little the case has to do with property. If the mere use of a home office or a conference room were sufficient to support the State's theory, then ***any*** injurious conduct not taking place in outer space or international waters

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[17] *See, e.g.*, *Ashley Cnty. v. Pfizer, Inc.*, 552 F.3d 659, 671-72 (8th Cir. 2009) (rejecting a public-nuisance claim challenging sales of cold medicine because the court was "very reluctant to open Pandora's box to the avalanche of actions that would follow if we found this case to state a [public-nuisance] cause of action under Arkansas law"); *District of Columbia v. Beretta U.S.A. Corp.*, 872 A.2d 633, 646-51 (D.C. 2005) (finding that adopting a "right of action for public nuisance applied to the manufacture and sale of guns generally" could lead to "a proliferation of lawsuits 'not merely against these defendants[] but ... against other types of commercial enterprises'—manufacturers, say, of liquor, antidepressants, SUVs, or violent videogames"); *Rhode Island v. Lead Indus. Ass'n*, 951 A.2d 428, 456 (R.I. 2008) (ruling in a lead paint case that public-nuisance law "never before has been applied to products, however harmful"); *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"); *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W. 2d 513, 521 (Mich. Ct. App. 1992) (noting in an asbestos case that nuisance law "is fraught with conditional rules and exceptions that turn on the facts of individual cases, and the cases almost universally concern the use or condition of property, not products").

[18] *See, e.g.*, May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 45:19-22 ("Sales representatives would have trained in their homes."), *id.* at 46:11-17 (stating that sales representatives trained "[o]n Oklahoma dirt"), *id.* at 61:23-62:22 (stating that continuing medical education events occurred at state universities and on state property), *id.* at 65:22-66:3 (stating that education and sales representative compensation occurred on property in Oklahoma).

could give rise to a nuisance claim. And a 30-year, $17 billion abatement plan is a curious way to address traffic violations or break-ins.

In any event, the State's case lacks even that contrived connection to Oklahoma property. The State has flooded this case with evidence about out-of-state third parties, including academics in Wisconsin, lobbyists in Washington, D.C., and key opinion leaders ("KOLs") in New York, among many others.[19] It has faulted Janssen for a New Jersey charity's donation to an out-of-state association of state medical boards.[20] Indeed, it has built the heart of its case around subsidiaries that grew poppies in Tasmania and made active pharmaceutical ingredients in Delaware before selling their products to manufacturers in other states. The State's lip-service to property occupied about two minutes of its month-long case-in-chief. This is barely a case about conduct in Oklahoma, much less the use of property in the state.

A court willing to extend nuisance rules to encompass harms from product sales risks opening the floodgates to a "staggering" tide of litigation. *In re Firearm Cases*, 126 Cal. App. 4th 959, 991 (2005). "General Motors could be sued by someone who was hit by a Corvette that had been stolen by a juvenile. The plaintiff would allege that General Motors knew that cars that can greatly exceed the speed limit are dangerous, and through advertising … it increased the attractiveness of the car … and thus increased the likelihood that a juvenile would steal a

[19] *See, e.g.*, June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 5:25-6:21-8:2, 30:21 (discussing the Wisconsin Pain and Policy Study Group); June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 110:19-23 (claiming lawyer and former regulator, Robert Angarola, testified before Congress in an effort to change the "80/20" rule); State Ex. 879, Russell Portenoy Declaration at 1, 2, 35 (*admitted May 30, 2019*).

[20] 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).

Corvette and operate it in an injurious manner." *Id.* (quoting *Ileto v. Glock, Inc.*, 370 F.3d 860, 862 (9th Cir. 2004) (Callahan, J., dissenting from denial of rehearing en banc)).

Oklahoma businesses would not be immune. Imaginative plaintiffs' lawyers have already brought multibillion-dollar nuisance claims against oil producers, including prominent Oklahoma corporations like Devon Energy, on the theory they misled the public about the risks of climate change. *See, e.g.*, *County of San Mateo v. Chevron Corp.*, 294 F. Supp. 3d 934, 937 (N.D. Cal. 2018) (remanding public-nuisance action against oil and energy companies "seek[ing] abatement of greenhouse gas emissions"), *appeal docketed*, No. 18-15502 (9th Cir.). The plaintiffs' storylines in those cases hew closely to what the State has sought to prove here—that the oil-and-gas industry knew of its products' effect on global warming but employed false and deceptive marketing tactics to cover up the alleged harms. It is hard to imagine the State embracing such a novel theory if the target were an industry that, as former Governor Mary Fallin observed, "continues to produce countless opportunities for wealth generation for Oklahoma families."[21] Indeed, just a week after arguing against Janssen's summary judgment motion in this case, the Attorney General told a federal court in California that "the common law of public nuisance" does not "authorize[] courts to assign as they see fit responsibility for remedying climate change."[22] And even as the State's marketing expert, Renzi Stone, criticized Janssen's marketing, one of his clients—Fortune 500 petroleum explorer Hess Corporation[23]—was named

[21] Daniel J. Graeber, *Today is Oilfield Prayer Day in Oklahoma*, United Press Int'l (Oct. 13, 2006), https://www.upi.com/Energy-News/2016/10/13/Today-is-Oilfield-Prayer-Day-in-Oklahoma/7521476354523.

[22] Brief for Indiana & 17 Other States as Amici Curiae in Support of Defendants-Appellees at 3, *Oakland v. BP P.L.C.*, No. 18-16663 (9th Cir. May 17, 2019).

[23] *See* Saxum Strategic Communications, *Why Energy?*, http://saxum.com/what-we-do/energy (last visited June 15, 2019).

as a defendant in one of the California lawsuits, based in part on its "promotion" and "marketing ... of fossil fuel products."[24]

Adopting the State's unbounded reading of the nuisance statute would also 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; *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?"). Here, the State demands billions of dollars under sweeping 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. For more than a century, what's given that elusive language meaning is its anchor in the common law of nuisance, with its focus on property disputes and historically recognized "nuisances per se." *See, e.g.*, *Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 36 (defining nuisance as a "class of wrongs arising" arising from "unreasonable, unwarranted, or unlawful use by a person or entity of property lawfully possessed").

The State's proposal to wrench that statutory language from its historical context and apply it to any identifiable social harm destroys that meaning, and leaves Oklahoma with a statute so capacious that it provides no meaningful notice of the conduct it targets. And imposing billions of dollars of liability based on such unbounded statutory language would violate

[24] *See* Ntc. of Removal, 2017 WL 3699867, Exhibit B at 14, *County of San Mateo v. Chevron Corp.*, 294 F. Supp. 3d 934 (S.D.N.Y. 2018).

Janssen's right to fair warning. *See, e.g.*, *Samson Resources Co. v. Cloud*, 1991 OK CIV APP 55, ¶ 8, 812 P.2d 1378, 1381 ("If 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.").

In short, the State's presentation of evidence at trial has confirmed that the State is not pursuing a public-nuisance case at all, but a product-liability case alleging harms from the marketing and sale of goods on a national market. That basic disconnect from a century of public-nuisance precedent requires judgment for Janssen.

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

Unprecedented in its scope, the State's case seeks to impose massive, punitive liability on Janssen for taking what the State believes to be the wrong side of an ongoing scientific and medical debate. For decades, the scientific and medical communities have deliberated about the importance of treating chronic pain and the value of opioid analgesics in that endeavor. That debate began more than a decade before Janssen started marketing Duragesic. And while it continues to this day, countless scientists, doctors, and expert organizations—including the FDA—hold that opioids can safely and effectively treat chronic non-cancer pain, rejecting the extreme minority views that form the foundation of the State's case. The State faults Janssen for its participation and position in that debate, not just for how it marketed its own drugs but also for supporting medical research, sponsoring continuing medical education events, associating with nonprofit advocacy organizations, and lobbying the government. But the First Amendment forbids the government from using tort law to pick winners and losers in debates about matters of public concern. It likewise bars the government from harshly punishing those it disagrees with—indeed, that is its primary aim—even if the government believes that the offending speech

caused harm. The First Amendment therefore blocks the State from recovering billions of dollars based on speech by Janssen and others.

The State's case similarly tramples the First Amendment's protections on association and lobbying. It seeks to hold Janssen liable for speech by third parties, including doctors and advocacy organizations, because Janssen had financial and other relationships with them. It likewise seeks to punish Janssen for lobbying and other advocacy intended to influence public policy. The First Amendment freedoms of association and petition squarely preclude such liability.

Allowing the State to pursue a liability theory based on First Amendment-protected activity risks dramatic and wide-ranging repercussions for all manner of public debate. Medical progress in America frequently results from the advocacy of corporations, experts, and nonprofit groups, often supported by lobbying efforts. Countless other businesses likewise contribute to public debate on controversial public-health issues from abortion to gun violence to the environment. Like Janssen, they do so by marketing their products, by sponsoring research, by affiliating with experts and advocacy groups, and by lobbying their government. Allowing state governments to impose billions of dollars of liability on companies exercising these rights because the governments—with the benefit of hindsight—believe the companies got things wrong would cast a long shadow over such advocacy efforts, as "[u]ncertainty about how a court will view these, or other, statements, [could] easily chill a speaker's efforts to engage in public debate." *Nike, Inc. v. Kasky*, 539 U.S. 654, 680 (2003) (Breyer, J., dissenting).

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

The State's case targets speech that addresses vigorously debated medical, scientific, and public-health questions—speech the First Amendment fully protects. The First Amendment shields 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, 1075. It likewise protects 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). 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," and state laws infringing such speech "must be subjected to heightened judicial scrutiny." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). Attempts to impose "content-based burden[s]" on pharmaceutical marketing thus must pass "heightened judicial scrutiny." *Id.* at 565. Indeed, "[c]ontent-based regulations" on speech "are presumptively invalid." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992).

The government's thesis here—rejected by a chorus of doctors, scientists, and regulators, including the FDA—is that Janssen and various third parties got the science of chronic pain wrong.[25] The State and its experts, expressing the views of a vocal minority, contend that the

[25] *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

problem of chronic pain is overstated, that opioids cannot safely and effectively treat chronic pain, that opioids cannot improve the lives of chronic-pain patients, and that doctors cannot manage the risk of opioid addiction with appropriate patient selection. The State wants to punish Janssen for advocating a different view of these important medical and scientific questions, and for associating with others who did so. That is a straightforward content-based penalty for speech on a matter of public concern, one that focuses exclusively on "the idea or message expressed," *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015), and "must be subjected to heightened judicial scrutiny," *Sorrell*, 564 U.S. at 557.

The State cannot avoid that conclusion by asserting that Janssen and countless others were wrong about these scientific questions. The First Amendment recognizes "[t]hat erroneous statement is inevitable in free debate, and that it must be protected if the freedoms of expression are to have the 'breathing space' that they 'need to survive.'" *New York Times Co. v. Sullivan*, 376 U.S. 254, 271-72 (1964). Courts therefore reject a "general exception to the First Amendment for false statements." *United States v. Alvarez*, 567 U.S. 709, 718 (2012); *see also Sullivan*, 376 U.S. at 271 ("Authoritative interpretations of the First Amendment guarantees have consistently refused to recognize an exception for any test of truth—whether administered by judges, juries or administrative officials…."). This "breathing space" is essential in scientific debates no less than in political ones, *Sullivan*, 376 U.S. at 271, as allowing governments to play favorites in scientific controversies would invite intervention in all manner of public controversies. Imposing liability for disfavored scientific speech will inevitably chill scientific inquiry and debate.

(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").

Finally, the government cannot avoid heightened scrutiny by casting Janssen's activities as commercial speech. The State largely targets speech that is not commercial at all: medical education and advocacy by doctors, nonprofits, and other third parties. *See infra* Section III.B. Regardless, the rationales behind the commercial speech doctrine—a doctrine disfavored by several U.S. Supreme Court justices[26]—do not apply here. The doctrine rests on the presumption that speech about commercial transactions is "more easily verifiable ... than ... news reporting or political commentary," *Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976), a premise clearly inapplicable in a case involving complex scientific and policy questions that remain the subject of active debate. The doctrine likewise assumes that companies would never "forego[] entirely" commercial speech because they have such strong motivation to advertise. *Id.* But the doctrine doesn't account for the kind of radical liability the State proposes or the unprecedented damages it seeks—both of which would be certain to cast a shadow over commercial speech in a range of industries. What's more, Janssen's speech addressed scientific questions that were and remain matters of exceptional public importance. And 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 First Amendment fully protects Janssen's expression about matters of ongoing scientific controversy and categorically bars the State's use of tort liability to punish Janssen for that speech. *See Snyder v. Phelps*, 562 U.S. 443, 460-61 (2011).

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[26] *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367-68 (2002) ("[S]everal Members of the Court have expressed doubts about the [commercial speech doctrine] and whether it should apply in particular cases.").

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

Even assuming Janssen's conduct indeed amounts to commercial speech, the State's claims would fare no better. Under the commercial speech doctrine, "*[t]ruthful* advertising related to lawful activities is entitled to the protections of the First Amendment." *In re R. M. J.*, 455 U.S. 191, 203 (1982) (emphasis added). As discussed above, the State's position here is that Janssen and others took the wrong side of a scientific question; the State insists that the minority position on scientific questions related to chronic pain is *the truth*, and any deviating message is the sort of misleading communication that warrants sanctions on constitutionally protected speech. But 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). A State cannot restrict commercial speech on the ground that the speech in question reflects a position at odds with the State's view on an ongoing scientific question. *See id.* at 579 ("The State may not burden the speech of others in order to tilt public debate in a preferred direction.").[27]

The First Amendment, moreover allows states to prohibit only "inherently misleading" commercial speech. *Pearson v. Shalala*, 164 F.3d 650, 656-58 (D.C. Cir. 1999) (*Pearson I*). That category is exceedingly narrow: it encompasses just those statements that are "incapable of being presented in a way that is not deceptive." *Revo v. Disciplinary Bd. of the Supreme Ct. for the*

[27] In the context of the federal False Claims Act, which prohibits the submission of false claims to the government, courts have held that a claim is not "false" merely because one side of a scientific debate disagrees with that claim. *See, e.g., U.S. ex rel Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992), *overruled on other grounds*, *U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121 (9th Cir. 2015). "What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The [FCA] would not put either Ptolemy or Copernicus on trial." *Wang*, 975 F.2d at 1421.

State of N.M., 106 F.3d 929, 933 (10th Cir. 1997). By contrast, the State cannot punish "potentially misleading speech" that is supported by "some credible evidence." *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 15 (D.D.C. 2011). Any burden the State places on such "potentially misleading" speech must "directly" advance a "substantial" government interest and be "reasonabl[y]" tailored to serve that interest. *Pearson I*, 164 F.3d at 655-56.

None of the speech the State challenges here was "incapable of being presented in a way that is not deceptive." *Revo*, 106 F.3d at 933. The State presented extensive evidence, for example, on the FDA's 2004 warning that Janssen's comparisons of Duragesic and OxyContin were "false and misleading."[28] But that finding simply reflected the FDA's conclusion that ***the particular data Janssen cited*** was not "substantial evidence" for those comparisons.[29] In fact, extensive ***additional*** evidence confirms that Duragesic ***was*** less prone to abuse than OxyContin: the non-profit RADARS system continues to show that Duragesic is less frequently abused than other opioids;[30] when the State's Drug Utilization Review Board saw rampant abuse and diversion of oxycodone and hydrocodone, it conducted an audit that showed Duragesic use fell within "acceptable parameters";[31] and the State's own witnesses confirmed that they abused other opioids but not Duragesic, because they knew it could not be safely abused[32] or did not like

[28] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 7:23-11:2, 12:12-25, 16:2-19; *see also* May 28, 2019 (AM) Trial Tr. (Beckworth Arg.) at 43:23-44:7 (Janssen's use of DAWN data in detailing was "false and misleading").

[29] State Ex. 38, 2004 FDA Warning Letter (criticizing Janssen's comparative efficacy claims) (*admitted May 30, 2019*); May 31, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 82:19-86:6.

[30] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 17:19-19:17.

[31] June 25, 2019 (PM) Trial Tr. (White Test.) at 62:18-64:1.

[32] June 7, 2019 (AM) Trial Tr. (McGregor Test.) at 37:20-38:10.

how it made them feel.[33] In other words, even if the data Janssen happened to cite in 2004 was not up to the FDA's standards, there is indisputably "some credible evidence" that Janssen's safety comparisons to OxyContin were true. They therefore fall within the First Amendment's protections. *See, e.g.*, *Pearson v. Shalala*, 130 F. Supp. 2d 105, 118 (D.D.C. 2001) (*Pearson II*).

The same is true of Janssen's reliance on the Porter & Jick study. Although the State's witnesses opined that the study's hospital setting is not representative, the Janssen statements the State introduced ***prominently disclose*** that the study was limited to hospital patients and make clear that its results therefore represent an extreme low-end estimate of addiction potential.[34] Those statements framed the study's results as merely one data point among many about opioids' addictive potential—citing it alongside studies showing a higher addiction potential in other populations and settings.[35] Under the First Amendment, that kind of a disclosure is all that is necessary. *See, e.g.*, *Alliance for Natural Health U.S.*, 786 F. Supp. 2d at 15.

Similarly, state expert Andrew Kolodny testified that a Janssen-sponsored website's statements about "pseudoaddiction" were "dangerous educational messages" and "not responsible."[36] But that does not make them false. In fact, the FDA-approved labels for Janssen's medications continue to teach the concept of pseudoaddiction.[37] Kolodny's belief that this FDA-

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[33] June 14, 2019 (AM) Trial Tr. (Hoos Test.) at 88:10-23.

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

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

[36] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 140:25-141:21.

[37] *E.g.*, Janssen Ex. 2787, 2016 Nucynta ER Label ("'Drug-seeking' behavior is very common in persons with substance use disorders… . Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.").

endorsed concept is harmful does not make it misleading at all, much less "inherently misleading" for purposes of the First Amendment.

The commercial speech doctrine does not permit the State to punish such statements with astronomical tort liability. It requires a "fit between the government's ends and ... means" that is "reasonable." *Pearson I*, 164 F.3d at 655-56. Here, the State's demand that Janssen subsidize a bonanza of government programs over a 30-year period bears no "reasonable" "fit" to any interest it might have in regulating the contents of commercial statements that address matters of public concern, had scientific support, and included important disclosures. The First Amendment therefore forecloses the State's request for billions in damages based on those statements. *Cf. United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012) ("complete" ban on certain statements by pharmaceutical manufacturers was "more extensive than necessary" to achieve government's aims).

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

The State cannot escape that conclusion by pointing to the speech and lobbying efforts of third parties with which Janssen associated. The State's case hangs on evidence that Janssen associated with doctors, academics, and nonprofit groups whose research and advocacy allegedly influenced the medical community's perceptions of opioids. But public statements about medicine by doctors, professors, and nonprofit groups do not qualify as commercial speech under any definition of the term. The First Amendment fully protects these statements, and Janssen cannot be held liable for them. The State's attempt to punish Janssen for its lobbying—and for lobbying by third-party organizations—likewise violates Janssen's First Amendment rights. Unbroken authority holds that the First Amendment's Petition Clause safeguards the right to lobby governments about the passage and enforcement of laws. And by trying to hold Janssen

responsible for the conduct of countless third-party groups and doctors simply because it had financial relationships with them, the State violates Janssen's First Amendment freedom of association. The Court should enter judgment for Janssen and repudiate the State's theory, which seeks to hold Janssen liable for speech, lobbying, and associations involving public scientific debate in violation of the First Amendment.

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

The State's case relies on guilt by association. Through the testimony of its experts, the State has trafficked in innuendo to suggest that Janssen's associations with third parties somehow make it culpable for those parties' every statement about chronic pain or opioid therapy. But statements by doctors, academics, and nonprofit groups do not qualify as commercial speech—regardless whether Janssen associated with them. Their statements about public-health and medical issues are classic First Amendment-protected speech, and the State cannot impose liability for them.

Here, the State suggests Janssen somehow bears liability for statements made by doctors, academics, and advocacy groups because it supported those third parties financially, or otherwise shared some affiliation with them. But those third parties' speech in medical conferences, treatment guidelines, and other public advocacy was not advertising and did not reference specific products or services. And the State has offered nothing but oblique aspersions to suggest the speakers had economic motivation. Their speech thus bore none of the hallmarks of commercial speech, and the First Amendment fully protects it. *See Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 879 F.3d 101, 108 (4th Cir. 2018) ("Courts rely on three factors to identify such commercial speech: (1) is the speech an

advertisement; (2) does the speech refer to a specific product or service; and (3) does the speaker have an economic motivation for the speech.").

Third-Party Groups. The State seeks to impose liability on Janssen for the statements, publications, and activities of third-party advocacy and trade organizations. Like most pharmaceutical manufacturers, Janssen supports third-party advocacy organizations "across all therapeutic areas, not just in pain," including groups such as the American Cancer Society, the Alzheimer's Association, and the American Medical Association.[38] In the pain field, Janssen provided funding to groups, including the American Pain Society ("APS"), that engaged in educational activities and various forms of advocacy on behalf of their constituents.[39] Such "professional association[s]" provide a "forum for exchanges of information" on medical and scientific topics—"matters of substantial public interest." *Marrese v. Am. Academy of Orthopaedic Surgeons*, 726 F.2d 1150, 1159 (7th Cir. 1984).

The State's case centers on statements and activities of advocacy groups Janssen associated with—often only loosely. For example, the State's chief causation expert, Andrew Kolodny, testified that a consensus statement by APS and the American Academy of Pain Medicine ("AAPM") on "The Use of Opioids for the Treatment of Chronic Pain" "changed the culture of prescribing in the United States" "more than any other single document."[40] He further testified that Janssen was responsible for the consensus statement's content merely because some of the individuals the document listed as "committee members" had done work for Janssen in

[38] June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 105:14-19.

[39] *Id.* at 105:9-19, 106:12-18.

[40] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 45:9-17.

unrelated capacities.[41] Similarly, the State has pointed to countless other third-party statements or actions with at best tenuous connection to Janssen.[42] These include APS's promotion of the concept of "pain as a fifth vital sign,"[43] and the Federation of State Medical Boards' Model Guidelines on Prescribing Opioids for Chronic Pain.[44] *See also infra* Section III.B.2.

Key Opinion Leaders. The State has likewise suggested that Janssen should be held liable for speech by "key opinion leaders"—prominent "thought leaders" who Janssen retained as consultants "to provide[] advice over certain issues or things that are happening in the market" and to help with tasks such as the identification of research opportunities or clinical-trial

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[41] *Id.* at 42:6-44:24.

[42] *See, e.g.*, June 12 (PM) Trial Tr. (Kolodny Test.) at 43:13-44:4 (asserting that APF was "artificially created and it was not grassroots" but it was "[m]eant to look like a grassroots group"); *id.* at 75:14-77:22, 78:19-80:16 (interpreting an APF "Pain Resource Guide" to inappropriately suggest that patients should seek out doctors who prescribe opioids, and that the risk of addiction to opioids is relatively low); Portenoy Depo. Tr. at 206:21-207:2, 207:10-208:8, 208:16- 209:5 (played May 29, 2019) (asserting that Janssen supported advocacy organizations that hosted certain conferences that included messages that inadequately represented the risks of long-term opioid therapy); Gilson Depo. Tr. at 70:12-72:11, 74:11-15, 74:19-25 (played June 7, 2019) (discussing the book *Responsible Opioid Prescribing: A Physician's Guide* by Dr. Scott Fishman, which Janssen did not fund, particularly the book's position on the concept of "pseudoaddiction"); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 16:22-18:11 (claiming that the Joint Commission on Accreditation of Health Care Organizations, which Kolodny asserts without evidence was influenced by J&J, and which adopted the "pain as the fifth vital sign" concept, "has tremendous influence on the way that healthcare is delivered in the United States"); May 30, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 104:9-105:25 (discussing an APF press release the State asserts understates the risk of opioid addiction).

[43] *See, e.g.*, June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 71:12-72:17 (discussing a 2003 business plan in which pain as a "fifth vital sign" was referred to as a "Growth Driver").

[44] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 15:6-16:11 ("And so the Model Guideline and the Model Policy did help change the way states were regulated [*sic*] opioid prescribing. And that model policy, I should point out, along with the APS, AAPM consensus statement were packaged into materials that were given to doctors by sales reps and disseminated hundreds of thousands of copies were disseminated [*sic*] across the country.").

design.[45] But the bulk of the State's evidence about key opinion leaders focuses on those leaders' ***own*** work—not any work they did for Janssen.

Again, Kolodny faults Janssen for the APS and AAPM consensus statement because the document listed as "committee members" various key opinion leaders who also consulted for Janssen.[46] Another State expert, Danesh Mazloomdoost, testified that the scientific work of key opinion leaders caused Janssen and J&J's "influences" to "kind of infiltrate[] and spread like a virus of ideas in everybody's mind and bec[o]me … the fabric of how we developed the science."[47] As an example, Mazloomdoost asserted that "key opinion leaders influenced by pharmaceutical marketing" authored medical textbooks with "influences from companies like Johnson & Johnson."[48] The State has likewise presented evidence that Janssen sponsored professional society conferences that used some of Janssen's sponsorship funds to pay honoraria to key opinion leaders who gave presentations.[49] At every turn, the State has cited the activities of key opinion leaders as evidence of Janssen's purportedly insidious influence.[50] Yet it has not

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[45] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 96:18-24.

[46] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 41:3-44:24.

[47] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 44:9-45:4.

[48] *Id.*

[49] Portenoy Depo. Tr. at 47:18-48:1 (played May 29, 2019).

[50] *See, e.g.*, June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 67:7-21 (asserting that "for some [KOLs], opioid manufacturers were paying them because they said things that helped opioid manufacturers sell more opioids"); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 10:1-11:1, 31:13-32:3 (testifying that KOLs had relationships with industry groups, and that Janssen worked with many KOLs); June 4, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 90:14-18 (explaining that Janssen works not only with KOLs with whom it agrees, but also KOLs with whom it does not); May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 95:14-96:13 (testifying that "oftentimes, Janssen would bring forth [KOLs]" who "are thought leaders in their therapeutic area," and that "Janssen doesn't determine who the KOLs or the thought leaders are[,] [t]he community in which they practice medicine does"); May 29, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 19:6-20:14 (discussing document listing KOLs); Portenoy Depo. Tr. at 63:2-5, 66:3-6, 66:8, 66:10-14, 66:16, 67:11-16, 67:18-68:1, 239:12-15, 239:17 (played May

offered a shred of evidence to suggest that these key opinion leaders' independent writing, speaking engagements, or other activities represented anything other than their own speech as prominent doctors and academics.

Continuing Medical Education Programs. Clinicians attend Continuing Medical Education ("CME") seminars to satisfy state medical boards' requirements. Unlike the speakers bureau Janssen funded—which promoted Janssen products—CMEs operate independent of Janssen and other pharmaceutical companies and do not promote any particular product.[51] As the State's own witness acknowledged, medical professionals independently develop all content for CMEs.[52] Despite Janssen's lack of involvement in the CME content, the State seeks to hold Janssen liable for content with which the State disagrees based solely on Janssen's sponsorship.

Kolodny testified that CMEs funded by opioid manufacturers presented the idea "that patients have been suffering needlessly because of an overblown fear of addiction," and that opioids can "improve the quality of life in … patients who might suffer with chronic pain," causing prescribing to "t[ake] off" and leading "to an epidemic of addiction in overdose deaths."[53] In support of this theory, the State presented evidence that, for example, Janssen sponsored the National Pain Education Council, which developed CMEs, including "Appropriate

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29, 2019) (criticizing use of KOLs); Gilson Depo. Tr. at 312:2-8, 312:10-16, 312:21-313:3 (played June 7, 2019) (analyzing document suggesting KOL June Dahl intended to lobby Medicare); State Ex. 967, Email from B. Moskovitz to M. Riajenova (July 8, 2003) (*admitted May 29, 2019*) (listing KOLs who were "well known, respectable researche[r]s, teachers and clinicians in the Pain Management area," and providing extensive qualifications for each).

[51] May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 60:10-25.

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

[53] June 11, 2019 (AM) Trial Tr. (Kolodny Test.) at 76:24-77:13.

Opioid Pharmacotherapy for Chronic Pain Management."[54] Janssen funded that program "through an unrestricted educational grant" and "had nothing to do with the content development of the program."[55] Mazloomdoost nevertheless criticized the CME's content at length[56]—asserting, for instance, that it overstated the importance of opioid therapy as a pain-management tool for clinicians,[57] and that it paid too little attention to the potential for opioid dependence.[58]

But those criticisms have nothing to do with Janssen. The undisputed evidence—acknowledged by the State's own experts—shows that companies like Janssen are "not … able to influence the CMEs that they … sponsor."[59] State witness Russell Portenoy confirmed that the ***speakers***—not pharmaceutical companies—control the content of CME programs.[60] He also testified that he never presented or observed any CME that failed to capture the appropriate risk/benefit picture of opioid therapy for chronic, non-cancer pain.[61] Doctors' educational presentations to other doctors about medical issues represent pure First Amendment speech. The State's attempt to impose liability on Janssen for such speech represents another example of its impermissible attempt to punish Janssen for third parties' protected expression.

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[54] State Ex. 975, Nat'l Pain Educ. Council, "Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program" (*admitted June 4, 2019*).

[55] May 29, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 25:20-24.

[56] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 48:12-62:24.

[57] *Id.* at 51:13-18.

[58] *Id.* at 61:6-14.

[59] *Id.* at 49:18-20; *see also* May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 60:13-25 (Janssen "would not have any role in the content development of those CME programs …. [W]e're not influencing that content.").

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

[61] *Id.* at 335:11-336:21.

None of the above-referenced speech—from KOLs, CMEs, or third-party groups—qualifies as commercial speech, and none can serve as a permissible basis for liability under the First Amendment. The speech did not occur in advertisements and was not connected to any particular product. *Greater Baltimore Ctr.*, 879 F.3d at 108; *Proctor & Gamble*, 222 F.3d at 1274. Rather, it consisted of medical textbooks, presentations by doctors in professional contexts, public advocacy by academics, and advocacy and educational materials produced by nonprofit organizations. Such speech about a live topic in the medical and scientific communities—the treatment of pain—"occupies the highest rung of the hierarchy of First Amendment values and is entitled to special protection" because it unquestionably relates to matters of public concern. *See, e.g.*, *Connick*, 461 U.S. at 145; *Miller*, 413 U.S. at 34; *Magnusson*, 2004 OK 53, ¶ 12, 98 P.3d at 1075. The State cannot impose liability merely because it disagrees with this speech, even if it asserts the speech was erroneous. *Sullivan*, 376 U.S. at 271. To do so would be a presumptively invalid restriction based on content alone. *R.A.V.*, 505 U.S. at 382.

Nor can the State circumvent these protections by casting KOLs as shills or advocacy organizations as "front groups." The State offered no evidence that Janssen influenced a single KOL, many of whom advocated opioid therapy long before Duragesic's 1990 introduction. And it has offered no evidence that Janssen started or controlled any of the organizations it disparages as front groups. The State's sprawling case, relying on innuendo to hold Janssen liable for a wealth of third-party speech on matters of public concern, violates core First Amendment protections. Accordingly, the Court must enter judgment in Janssen's favor.

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.

Unable to meaningfully argue that Janssen's own conduct caused the State injury, the State instead has staked its case on a wealth of evidence about third parties with which Janssen had relationships. For instance, the State's chief expert cites the APS and AAPM 1996 consensus statement as "one of the single most damaging documents when we look back at the history of our opioid crisis."[62] But the only evidence the State has mustered to tie Janssen to that document is to observe that Janssen held membership in and contributed to the organizations,[63] jointly funded a 1999 survey with them,[64] and retained some members of the organizations as key opinion leaders.[65] Similarly, the State has introduced a wealth of evidence about Pain Care Forum meetings Janssen did not attend,[66] as well as emails on which it was not copied[67]—asserting those materials are nevertheless relevant because Janssen was a "day-one Pain Care Forum member" or because other organizations and individuals with which Janssen associated were present.[68] The State's efforts culminated with Kolodny describing a litany of third-party

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[62] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 27:11-16.

[63] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 8:20-25, 14:19-23.

[64] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 112:18-113:23.

[65] June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 10:1-13, 12:12-19.

[66] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 96:17-104:20; State Ex. 1497, 1497, Pain Care Forum Media Committee Report (Jul. 17, 2009) (*admitted June 12, 2019*).

[67] *Id.* at 94:18-95:25; State Ex. 1413, Email from K. Foley to R. Sackler (Apr. 4, 2001) (*admitted June 12, 2019*).

[68] *Id.* at 95:19-25; *id.* (Beckworth Arg.) at 103:5-8.

groups—including professional societies,[69] accreditation organizations,[70] and academic departments[71]—and suggesting Janssen was vicariously liable for their conduct because it was a member of those organizations, contributed to them, or retained individuals who were members in unrelated capacities.[72]

Under the First Amendment, however, "[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). 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). 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"

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[69] *See, e.g.*, June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 8:20-9:25, 11:15-17 (discussing APS, AAPM, and ASPMN); *id.* at 30:18-25 (discussing APF, AAPM, APS, The Center for Practical Bioethics, Joint Commission, and Federation of State Medical Boards); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 59:3-23 (discussing APS, APF, and AAPM); *id.* at 113:6-23 (discussing PCF, APS, and AAPM).

[70] *See, e.g.*, June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 16:22-18:17, 30:21-22 (discussing the Joint Commission on Accreditation of Health Care Organizations).

[71] *See, e.g.*, *id.* at 5:25-6:21-8:2, 30:21 (discussing the Wisconsin Pain and Policy Study Group).

[72] *See, e.g.*, Portenoy Depo. Tr. at 15:17-25, 16:1-6, 19:3-11, 57:14-17 (played May 29, 2019) (Portenoy, who Janssen occasionally paid as a speaker, formerly held Board positions on APS and APF, both organizations to which Janssen contributed); June 13, 2019 (AM) Trial Tr. (Kolodny Test.) at 5:16-6:6 (asserting that June Dahl worked with PPSG and had a financial relationship with J&J); *id.* at 8:24-9:25 (claiming that J&J provided funding to and was on the corporate council of the APS, which "was able to convince the Joint Commission to really operationalize the [pain as the fifth vital sign] slogan by introducing pain standards"); *id.* at 11:2-12:11 (testifying that Janssen contributed to AAPM, which "advocate[d] against any kind of intervention that would have resulted in less prescribing").

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's bid to hold Janssen liable for advocacy groups' conduct fails both prongs of that test. The First Amendment fully protects those groups' speech, *see supra* Section III.B.2, so the State cannot suggest Janssen associated with an "an organization possessing unlawful aims and goals," *NAACP*, 458 U.S. at 919-20; *see also Gaylord Entm't Co. v. Thompson*, 1998 OK 30, ¶ 42, 958 P.2d 128, 148-49 ("A conspiracy to carry on an activity that is lawful and shielded by fundamental law cannot be deemed tortious."). And although the State and its experts have presented extensive speculation and conjecture, they have offered no concrete evidence (other than a handful of brochures Janssen openly supported[73]) that Janssen associated with ***any*** advocacy groups specifically to further the messages the State challenges. Its attempt to hold Janssen liable for engaging with those groups impermissibly violates Janssen's First Amendment freedom of association.

Imposing liability on Janssen for its associations with these groups "could generally chill the exercise of the freedom of association by those who wish to contribute to, attend the meetings of, and otherwise associate with trade groups and other organizations that engage in public advocacy and debate." *In re Asbestos Sch. Litig.*, 46 F.3d at 1296. American businesses routinely affiliate with advocacy organizations and other nonprofits who do work relevant to their missions. Such relationships progress in a host of fields—including medicine. Allowing the State to punish businesses who engage in such association when it believes the third parties'

[73] 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 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.

work caused harm would deter association and damage relationships that drive scientific and economic progress in countless fields.

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

Not content to punish Janssen for protected speech and association, the State also seeks to impose liability for Janssen's protected lobbying activity. The First Amendment protects the "right of the people ... to petition the Government." U.S. Const. amend. I. And the U.S. Supreme Court, recognizing this important right, 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," those who petition all departments of government for redress are generally immune from liability. *Empress LLC v. City & Cty. of San Francisco*, 419 F.3d 1052, 1056 (9th Cir. 2005). That robust First Amendment protection bars civil liability for lobbying, a textbook petitioning activity. *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"); *Manistee Town Ctr. v. City of Glendale*, 227 F.3d 1090, 1092-93 (9th Cir. 2000) (*Noerr-Pennington* protects "petitions directed at any branch of government, including the executive, legislative, judicial and administrative agencies"); *C.H. (Skeet) Smith Trucking Co. v. Bill Hodges Trucking Co.*, 671 F. Supp. 1329, 1333 (W.D. Okla. 1987) (*Noerr-Pennington* doctrine immunizes "activities comprising mere solicitation of governmental action with respect to the passage and enforcement of laws").

The State ignores these settled constitutional principles, presenting extensive evidence to suggest Janssen should be held liable for its own and others' efforts to shape federal and state

policy. The State's chief expert broadly challenges lobbying—by Janssen and others—aimed at ensuring policymakers and regulators considered the medical needs of chronic-pain patients when crafting drug policy.[74] The State also attacks Janssen's efforts to dissuade regulators from scheduling tramadol, a drug used in several Janssen medications.[75] It targets Janssen's efforts to change federal laws that favored opium imports from Turkey and India.[76] And much more.[77] But try as the State might to paint these activities in a bad light, it presents no evidence suggesting Janssen broke any laws, failed to follow state or federal rules, or engaged in anything but ordinary advocacy aimed at protecting its interests and the interests of the patients who relied on its medications for pain treatment.

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[74] *See* June 14, 2019 (AM) Trial Tr. (Kolodny Test.) at 49:19-50:7, 100:13-101:9; June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 52:3-68:23, 141:21-144:9, 146:15-25, 148:12-150:9, 151:20-152:11, 159:17-24; June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 14:19-16:12.

[75] *See* June 3, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 49:15-50:11; State Ex. 463, Email chain between B. Moskovitz, G. Vorsanger, et al. (Feb. 20-21, 2008) (*admitted June 3, 2019*).

[76] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 14:19-15:10 (according to Kolodny, Janssen lobbied Congress to change the "80/20 rule," which, Kolodny says, requires 80% of opium imported into the United States to come from India and Turkey).

[77] *See* Rosen Depo. Tr. at 55:24-56:7 (played June 6, 2019) ("Q. [M]embers [of the Pain Care Forum] spent over $740 million lobbying in this country, correct? A. I'm not aware of that, no. Q. [T]hose entities spent over $140 million lobbying just to the United States Congress? A. I'm not familiar with that."); *id.* at 162:7-163:4 ("Q. PhRMA spends tons of money ... lobbying across this country, right? A. I don't know the number at this time. Q. You [k]now what else is interesting? ... I deposed a guy by the name of Ponder, who was J&J's registered lobbyist that worked for J&J in Oklahoma. Did you know that? A. I don't know that person. Q. [W]hen we filed this lawsuit, he stopped coming to the state. Do you know who he got to do his work instead? A. No, I don't. Q. PhRMA."); *id.* at 279:20--281:6 (noting that some PCF participants supported the National Pain Policy Act, an amendment to the Affordable Care Act convening a committee to study pain-related issues); Gilson Depo. Tr. at 312:2-8, 312:10-16, 312:21-313:3 (played June 7, 2019) (suggesting Professor June Dahl, a retired pharmacology professor, intended to lobby Medicare to adopt the concept of pain as a fifth vital sign); State Ex. 1429, Email chain between Purdue executives H. Udell, B. Rosen, et al. (Mar. 13-14, 2008) (*admitted June 11, 2019*) (discussing PCF's lobbying activities); June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 159:5-160:2 (criticizing APF and PCF lobbying of state governments).

Putting aside that much of the State's lobbying evidence bears no meaningful connection to Janssen,[78] the *Noerr-Pennington* doctrine forecloses the State's effort to impose liability for lobbying activity. In that way, too, the State's sprawling attempt to place Janssen at the heart of a vast and poorly defined "campaign" to promote opioids clashes with fundamental constitutional protections.

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

1. Federal Law Preempts Liability for Noramco's and Tasmanian Alkaloids' Federally Regulated Sales

Knowing that Janssen's drugs played only a bit role in Oklahoma's opioids market and were rarely abused or diverted, the State now insists that "this case isn't about [Janssen's] drug[s]... it's about opioids and all the ones they supplied."[79] But to connect Janssen to opioids it neither manufactured nor promoted, the State relies on a theory preempted by federal law: that Janssen should be held liable for the sales of a former J&J subsidiary, Tasmanian Alkaloids, and a former Janssen subsidiary, Noramco, which produced raw materials other manufacturers used to make their drugs. The theory fails because Tasmanian Alkaloids and Noramco sold their products under strict international and federal regulatory systems that state tort law cannot second-guess.

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[78] *See, e.g.*, June 14, 2019 (AM) Trial Tr. (Kolodny Cross) at 101:3-9 (testifying about Purdue's lobbying efforts); June 11, 2019 (PM) Trial Tr. (Kolodny Direct) at 50:18-51:12 (discussing Purdue external affairs document, and describing it as "consistent" with J&J statements but otherwise not connecting it to J&J in any way); Rosen Depo. Tr. at 61:24-63:16, 63:19-63:21, 63:25, 64:2-3, 67:1-5, 67:7-17, 133:16-136:5 (played June 6, 2019) (discussing Purdue correspondence unconnected to Janssen); State Ex. 1429, Email chain between Purdue executives (Mar. 13-14, 2008) (*identified June 7, 2019*) (discussing PCF's lobbying activities).

[79] June 3, 2019 (PM) Trial Tr. (Beckworth Arg.) at 53:22-23.

Under the U.S. Constitution's Supremacy Clause, "the Laws of the United States" are the "supreme Law of the Land." U.S. Const. art. VI, cl. 2. Congress therefore has "the power to preempt state law" through federal legislation. *Arizona v. United States*, 567 U.S. 387, 399 (2012). Congress can preempt state law expressly or implicitly. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76-77 (2008). Among other circumstances, 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*, 567 U.S. at 399. Such "[o]bstacle preemption can apply not only to positive enactments of state law but also to state tort claims alleging violation of a common law duty." *Columbia Venture, LLC v. Dewberry & Davis, LLC*, 604 F.3d 824, 830 (4th Cir. 2010).

Here, the DEA—the nation's top regulatory authority—affirmatively authorized Tasmanian Alkaloids' and Noramco's sales, part of a comprehensive statutory and regulatory scheme designed to ensure reliable supplies of medically necessary drugs. The State's attempt to use tort law to hold Janssen liable for those federally authorized activities would throw that scheme into turmoil and undermine its objectives.

The Controlled Substances Act ("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." 21 U.S.C. § 952(a)(1). Under the DEA's implementing regulations, any American company wishing to purchase narcotic raw materials must receive authorization from the DEA before doing so. *See* 21 C.F.R. § 1312.11. To secure that authorization, a company must apply to the DEA for an import permit. *See id.* § 1312.12. And, under federal regulations, the DEA can issue an import permit only if it finds that importation "necessary to provide for medical, scientific, or other

legitimate purposes," *id.* § 1312.13(a)(1), or necessary for "medical and scientific … or other legitimate needs … during an emergency where domestic supplies … are found to be inadequate," *id.* § 1312.13(a)(2). In other words, no entity can import ***any*** raw material from Tasmanian Alkaloids without explicit DEA authorization, and the DEA can grant authorization only if it concludes that the material is necessary to fulfill the CSA's objective of securing sufficient raw material to meet the nation's medical and scientific requirements.

A similar regime governs Noramco's production and sales of API. The CSA's opening sentence recognizes that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). To that end, the CSA and its accompanying regulations require the DEA to base quotas for controlled substances on "the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a)(1); 21 C.F.R. § 1303.11(a), (b); *see also* 21 C.F.R. § 1303.12 (procurement quotas "determine the estimated needs for, and … insure an adequate and uninterrupted supply of, basic classes of controlled substances").

The DEA follows that mandate by annually setting three levels of API quotas:

- **Aggregate quotas** dictating how much API should be produced nationwide each year. *See* 21 U.S.C. § 826(a); 21 C.F.R. §§ 1303.11, 1303.13.
- **Manufacturing quotas** dictating how much API individual producers like Noramco can manufacture each year. *See* 21 U.S.C. § 826(c); 21 C.F.R. §§ 1303.21-1303.27.
- **Procurement quotas** dictating how much API a given drug manufacturer can purchase from producers such as Noramco each year. *See* 21 C.F.R. 1303.12.

A DEA-issued quota gives its holder a federal-law right to manufacture or procure the specified amount of API. *See id.* § 1303.23 (describing API producers' "right to manufacture all or any part of such [manufacturing] quota"); *see* 21 C.F.R. § 1303.12(a) (procurement quotas

"authoriz[e]" drug manufacturers to "procure and use a quantity of a basic class of controlled substances.").

Under this carefully structured and supervised system, the DEA authorized Tasmanian Alkaloids' sales on a case-by-case basis only after finding that each was "necessary to provide for medical, scientific, or other legitimate purpose[]." *Id.* § 1312.13(a)(1). Noramco produced API only in amounts that the DEA deemed "necessary … to provide for the estimated medical, scientific, research and industrial needs of the United States." *Id.* § 1312.11(a). And a manufacturer could purchase Noramco's API only if it held a DEA quota authorizing it to purchase the amount of API necessary to "insure an adequate and uninterrupted supply of … basic classes of controlled substances." 21 U.S.C. § 1303.12(a).

Federal law preempts the State's frontal assault on that system. By insisting Noramco should have stopped supplying API to opioid manufacturers,[80] the State "effectively challenges" the DEA's judgment that Noramco's and Tasmanian Alkaloids' buyers should be able to purchase narcotic 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). Even today, API producers with DEA-issued production quotas sell opioid API to manufacturers with DEA-issued procurement quotas—including Purdue. The prospect of massive state-law tort liability for such sales stands to discourage other companies from engaging in them, undermining a supply chain that the DEA calibrates to meet national medical needs,[81] and thus "stand[ing] as an obstacle to the accomplishment of one of the Federal Statute's

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

[81] *See, e.g.*, U.S. Government Accountability Office, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should*

purposes." *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) (brackets and internal quotation marks omitted); *see also Whistler Investments, Inc. v. Depository Trust and Clearing Corp.*, 539 F.3d 1159, 1166 (9th Cir. 2008) ("Because the [SEC], in accordance with the congressional directive set forth in [the Securities and Exchange Act], has approved [defendant's] creation of the ... Program, ... we hold that state-law challenges to the existence or the operation of the ... Program are federally preempted ...").

Federal law therefore preempts the State's Tasmanian Alkaloids and Noramco theory, just as it preempts any attempt by any state to countermand federal authority, and the State cannot point to those companies' API or raw material sales to establish liability. *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (state laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" are preempted); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588 (6th Cir. 2013) (preempted theories cannot serve as basis for liability).

2. Oklahoma Law Precludes Tort Liability for Suppliers of Raw Materials

Under Oklahoma law, too, the State cannot impose liability on Janssen for Noramco's and Tasmanian Alkaloids' sales of raw materials to pharmaceutical manufacturers. Like other states,[82] 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.*

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be Improved, GAO-15-202 (2015) (finding that DEA failure to meet quota-setting deadlines resulted in repeated shortages for prescription analgesics).

[82] *See also, e.g., Toshiba Int'l Corp. v. Henry*, 152 S.W. 3d 774, 779-83 (Tex. Ct. App. 2004) (Texas law); *House v. Armour of Am., Inc.*, 886 P.2d 542, 553-54 (Utah Ct. App. 1994) (Utah law); *Sanders v. Ingram Equipment, Inc.*, 531 So. 2d 879, 880 (Ala. Sept. 2, 1988) (Alabama law); *Newman v. Gen. Motors Corp.*, 524 So. 2d 207, 209 (La. Ct. App. Apr. 12, 1988) (Louisiana law).

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). Indeed, this limitation on supplier liability is blackletter law. *See* Restatement (Third) of Torts § 5; *Swift*, 2013 OK CIV APP 88, ¶ 19, 310 P.3d at 1132 (citing § 5). In Oklahoma, as elsewhere, 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. Here, neither Noramco nor Tasmanian Alkaloids participated at all, let alone substantially, in designing other manufacturers' patented products. Instead, those other manufacturers (including Purdue) bought API from Noramco, then "made a substantial change in the way the [API] was packaged and distributed, and in instructing how [it] should be used." *Id.* Under *Swift*'s rule, Noramco can bear no liability here.

What's more, the State's public-nuisance theory here attempts to impose liability for conduct further removed from the supplier than the conduct behind the negligence and strict product-liability claims rejected in *Swift*. There, the court held that a component supplier could not be held liable for *its own* failure to warn. Here, the State seeks to hold Noramco liable for *others'* misconduct: principally, marketing by Purdue allegedly designed to boost sales of products made with Noramco's API. No principle of Oklahoma law allows a component supplier to be held *vicariously liable* for an end manufacturer's subsequent misdeeds. On the contrary, *Swift* instructs that "[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 1132-33 (quoting Restatement (Third) of Torts, § 5 cmt. c (alteration omitted)). For that reason, too, the State cannot impose liability on Noramco and Tasmanian Alkaloids for their sales of raw materials.

3. *The State Has Offered No Evidence to Hold Janssen and J&J Liable for Their Independent Subsidiaries' Activities*

The foundational principle of separate corporate personhood precludes holding Janssen liable for any conduct by Noramco or Tasmanian Alkaloids.

The U.S. Supreme Court has recognized that a parent corporation "is not liable for the acts of its subsidiaries," calling this 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). Indeed, courts nationwide uniformly recognize that—absent extraordinary circumstances, none of which exist here—a corporation cannot be held liable for the actions of an independent subsidiary. *See, e.g.*, *Gilbert v. Sec. Fin. Corp. of Okla., Inc.*, 2006 OK 58, ¶ 23, 152 P.3d 165, 175; *Gulf Oil Corp. v. State*, 1961 OK 71, ¶¶ 10-11, 360 P.2d 933, 936; *Richard A. Pulaski Constr. Co. v. Air Frame Hangars, Inc.*, 950 A.2d 868, 877 (N.J. 2008); *State, Dep't of Envt'l Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983).

To pierce Janssen's corporate veil and hold it liable for Noramco's or Tasmanian Alkaloids' conduct under Oklahoma law,[83] the State must prove that either subsidiary's "separate corporate existence is a design or scheme to perpetrate fraud" or that either subsidiary "is so organized and controlled and its affairs so conducted that it is merely an instrumentality or adjunct of" Janssen. *Gulf Oil Corp.*, 1961 OK 71, at ¶ 10, 360 P.2d at 936; *NLRB v. Greater Kansas City Roofing*, 2 F.3d 1047, 1053 n.8 (10th Cir. 1993); *Richard A. Pulaski Constr. Co.*, 950 A.2d at 877-78; *see also Frazier v. Bryan Mem. Hosp. Auth.*, 1989 OK 73, 775 P.2d 281,

[83] It is unclear whether Oklahoma's substantive law controls veil-piercing here. *See Canal Ins. Co. v. Montello, Inc.*, 822 F. Supp. 2d 1177, 1181 (N.D. Okla. 2011) (applying Oklahoma choice of law rules, and holding law of state of incorporation governed veil-piercing analysis). Ultimately, however, the choice of law is irrelevant, because even under Oklahoma's less stringent standard for veil piercing, the State's attempt to hold Janssen responsible for Noramco and Tasmanian Alkaloids' conduct fails as a matter of law.

288 (listing factors for deciding whether to disregard principle of separate corporate personhood, which "hinge[] primarily on control" (emphasis omitted)). In short, the State must establish that Noramco and Tasmanian Alkaloids exist "merely [as] a dummy or sham." *Gulf Oil Corp.*, 1961 OK 71, at ¶ 10, 360 P.2d at 936; *accord Okla. Oncology & Hematology P.C. v. US Oncology, Inc.*, 2007 OK 12, ¶ 24 n.17, 160 P.3d 936, 945; *King v. Modern Music Co.*, 2001 OK CIV APP 126, ¶ 16, 33 P.3d 947, 952. But the State has failed to present any evidence to meet that burden.

Instead, the State hopes to pierce the corporate veil merely by noting that Janssen and J&J owned and profited from their subsidiaries. But Defendants' prior ownership of Noramco and Tasmanian Alkaloids alone cannot establish parent liability as a matter of law. *See, e.g.*, *Wallace v. Tulsa Yellow Cab Taxi & Baggage Co.*, 1936 OK 665, 61 P.2d 645, 648; *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1364 (10th Cir. 1993); *Kirno Hill Corp. v. Holt*, 618 F.2d 982, 985 (2d Cir. 1980); *Harris v. Am. Int'l Grp., Inc.*, 923 F. Supp. 2d 1299, 1308 (W.D. Okla. 2013); *Ventron*, 468 A.2d at 164; *Canter v. Lakewood of Voorhees*, 22 A.3d 68, 75 (N.J. App. Div. 2011). If that were enough, the longstanding principle of corporate separateness would never apply.

In its opening, the State suggested that Noramco and Tasmanian Alkaloids furnished Janssen and J&J with "motive" and "opportunity."[84] But after two years of litigation, dozens of depositions, and hundreds of thousands of documents produced, the State has come up empty-handed. It has presented nothing to suggest anyone in Janssen's marketing department sought to do anything other than promote Janssen's own medications.[85] To the contrary, the State's

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[84] May 28, 2019 (AM) Trial Tr. (Beckworth Arg.) at 54:25-56:19.

[85] Indeed, Janssen's corporate designee, Kimberly Deem-Eshleman, testified that she had virtually no knowledge of Noramco and Tasmanian Alkaloids, and did not even know Tasmanian Alkaloids was a former J&J subsidiary. *See, e.g.*, May 30, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 39:22-23 ("I have no knowledge, personal knowledge, of Noramco

causation expert, Kolodny, conceded that Noramco and Tasmanian Alkaloids caused Oklahoma's opioid crisis by supplying raw material for opioid drugs—*not* by influencing Janssen's marketing.[86] Basic corporate-veil principles preclude that theory.

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

The State has failed to prove its case 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. The State argues that Janssen precipitated the opioids epidemic by promoting Duragesic for chronic non-cancer pain. To that end, multiple witnesses for the State have testified that such promotion was misleading, and a cause of Oklahoma's opioid crisis.[87] But federal law bars the State from punishing Janssen for promoting its medications for lawful, FDA-approved uses.

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and of these dealings."); May 29, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 43:13-18 ("Q. Tasmanian Alkaloids was a company Johnson & Johnson owned at this time as well. Correct? A. [T]his is so outside of my understanding ... I have no idea.").

[86] *See, e.g.*, June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 47:2-8 (J&J is the opioid "king pin" because Noramco supplied API to other manufacturers); *id.* at 31:13-17 (opining that Janssen should have ceased supplying Purdue and affiliates with API).

[87] *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."); *id.* at 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"); June 10, 2019 (PM) Trial Tr. (Stone Test.) at 50:13-18 (criticizing statement that "Duragesic is effective and safe to use in moderate to severe chronic pain").

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

Federal and Oklahoma law allow for the use of long-acting opioids to treat chronic pain. Holding Janssen liable for promoting opioids for that purpose would therefore infringe Janssen's right to free speech.

The U.S. Supreme Court has repeatedly recognized that the First Amendment prohibits a state from doing indirectly by regulation of speech what it could do directly by regulating conduct. *See, e.g.*, *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 193 (1999); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 509-13 (1996) (Stevens, J.) (invalidating "commercial speech ban target[ing] information about entirely lawful behavior"). Accordingly, the Court has held that states cannot ban marketing for lawful activities or products. *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). In other words, "[i]f it is lawful to sell a product … it must be lawful to inform consumers that the product is available to buy." *United States v. Caputo*, 517 F.3d 935, 938 (7th Cir. 2008) (Easterbrook, J.); *see also GJJM Enters., LLC v. City of Atl. City*, 352 F. Supp. 3d 402, 405-08 (D.N.J. 2018) (statute allowing patrons to bring beer and wine to certain establishments but barring those establishments from advertising BYOB violated First Amendment).

The State violates this principle by impermissibly targeting conduct by way of speech. The State faults Janssen for promoting opioid medications to treat chronic non-cancer pain. But the FDA explicitly authorized Janssen to *sell* those medications for exactly that purpose, 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."[88] Nor did anything in Oklahoma forbid opioid prescriptions for that purpose. Under the First Amendment, the State cannot use tort law to ban Janssen from informing Oklahoma doctors about lawful uses for its lawful products. *Cf. Caronia*, 703 F.3d at 167 ("The government's construction of the [Food, Drug, and Cosmetics Act] legalizes the outcome … but prohibits the free flow of information that would inform that outcome.").

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

The U.S. Supreme Court has repeatedly held that 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). 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). The Supreme Court recently reaffirmed that federal law preempts state tort law challenging a prescription drug's labeling where "clear evidence" shows that the FDA was fully informed "of the justifications for the [label change] required by state law and that the FDA, in turn, informed the drug

[88] *See, e.g.*, Janssen Ex. 2787, Nucynta ER Label (2016) at 7 (*admitted June 4, 2019*); *see also* Janssen Ex. J2776, Duragesic Label (Jan. 2018) at 1 (*admitted June 4, 2019*).

manufacturer that the FDA would not approve [the] change to the drug's label." *Albrecht*, 139 S. Ct. at 1672.

Here, the State seeks exactly what federal law forbids: to find Janssen liable for promotional statements that match its medications' FDA-approved labels. Most notably, the State's medical experts opined that Janssen's marketing was misleading because it promoted long-acting opioid medications for the treatment of chronic non-cancer pain.[89] But the FDA approved, and still approves, those medications for precisely that use: "the management of[] pain severe enough to require daily, around-the-clock, long-term opioid treatment."[90] *See supra* Section III.B.1. And the FDA's approval means the FDA has found "substantial evidence that the drug will have the effect it purports or is represented to have" and that opioid medications are safe and effective for the treatment of chronic pain, including chronic non-cancer pain. 21 U.S.C. § 355(d). The State's theory that Janssen should not have promoted long-acting opioid medications for chronic non-cancer pain thus reduces to the premise that it should have departed from—and narrowed—its labeling's discussion of those medicines' FDA-approved indications. *See* 21 C.F.R. § 202.1(*l*)(2) (defining array of marketing materials as "labeling").

But federal law strictly limits manufacturers' ability to change drug labeling, allowing alterations only when there is "newly acquired information" that requires a manufacturer to,

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[89] *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").

[90] Janssen Ex. 2787, Nucynta ER Label (2016) at 7 (*admitted June 4, 2019*); *see also* Janssen Ex. J2776, Duragesic Label (Jan. 2018) at 1 (*admitted June 4, 2019*).

among other things, "delete false, misleading, or unsupported indications for use or claims for effectiveness." 21 C.F.R. § 314.70(c)(6)(iii). The State has not pointed to any new information that calls into question the FDA's approval of opioids for chronic non-cancer pain, and that alone dooms its claim. *See, e.g.*, *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) (finding no "newly acquired information" where studies cited by plaintiffs did not "reveal[] risks of a different type or greater severity or frequency than previously included in submissions to the FDA").

And even if the State had cited such new information, there is no question the FDA would have rejected the State's demanded label change. In 2012, Physicians for Responsible Opioid Prescribing ("PROP")—a group spearheaded by Kolodny—filed a citizen petition with the FDA, demanding that 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."[91] 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 the absence of cancer."[92]

The FDA's rejection of Kolodny's petition is fatal to the State's public-nuisance claim, offering crystal-clear evidence that the FDA would have rejected a similar manufacturer-initiated

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[91] Janssen Ex. 1460, Ltr. from PROP to FDA (July 25, 2012) ("PROP Letter") at 2 (*admitted June 13, 2019*).

[92] Janssen Ex. 1576, Ltr. from FDA to A. Kolodny o.b.o. PROP (Sept. 10, 2013) at 9 (*admitted June 13, 2019*).

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).

Indeed, just last month, a North Dakota trial court cited the FDA's rejection of Kolodny's petition as confirmation that the FDA would not allow opioid medication manufacturers to unilaterally change their marketing to omit reference to chronic non-cancer pain. *See 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). Janssen's promotion of opioid medications for that FDA-approved indication thus cannot serve as a basis for liability.

The same preemption principles also wipe out the State's claim that Janssen falsely implied scientific support for the concept of "pseudoaddiction"—drug-seeking behavior that mimics addiction but that occurs in patients with undertreated pain.[93] But 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 Kolodny's petition.[94] Specifically, the FDA-approved labeling for extended-release opioids discusses "[d]rug-seeking behavior" among "addicts and drug abusers" but also recognizes that "[p]reoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control."[95]

The State's experts clearly disagree with the FDA's decision to indicate opioids for the treatment of chronic non-cancer pain. And they remain free to continue trying to convince the

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[93] *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).

[94] 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*).

[95] 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*).

agency of their position's merits, with full assurance that the First Amendment protects their right to lobby the government for any policy they might prefer. *See supra* Section III.B.2.iii. But that disagreement cannot form the basis for tort liability: The FDA's rejection of Kolodny's petition proves that it would have rejected a similar manufacturer-initiated change to a drug label, and therefore precludes the State's public-nuisance claim. *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).

The State's experts can disagree with the FDA's decisions about the benefits and risks of certain opioid medications.[96] But because Janssen promoted its products in lock-step with their FDA-approved labels, that disagreement cannot be the basis for liability. Federal law preempts the State's theory that Janssen should not have promoted opioids for chronic non-cancer pain.

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

Federal obstacle-preemption rules also preclude holding Janssen liable for promotional statements about opioid medications consistent with their FDA-approved labeling.

The Supremacy Clause preempts state law where it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. The State's theory that Janssen can be held liable for promoting opioid medications consistent with their FDA-approved labeling poses exactly that sort of threat here. The FDA requires rigorous proof that a drug is safe and effective for the indications described in its labels, and authorizes advertising consistent with those labels, all with the goal of promoting public health by enabling access to safe and effective medications with net benefits for appropriate

[96] *See* June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 42:8-11 ("Highly addictive drugs should not be marketed the way we market other products.").

patients. Imposing billions of dollars of liability for FDA-authorized promotions that inform doctors about FDA-approved indications would throw that scheme into disarray.

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.

Congress mandates that no new drug can be marketed unless and until the FDA determines that the drug 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. § 355(d). As part of the approval process, the FDA must determine that a medical product is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling," and find that the benefits of using the product for those specific indications outweigh the product's risks. *Id.*; *see also, e.g.*, S. Rep. No. 87-1744, at 2891-92 (1962) (for especially risky drugs, "the determination of safety is ... considered by the [FDA] to be inseparable from consideration of the drug's effectiveness"); FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006) ("Under the [FDCA] and FDA regulations, the [FDA] makes approval decisions based ... on a comprehensive scientific evaluation of the product's risks and

benefits under the conditions of use prescribed, recommended, or suggested in the labeling."). This approval process involves a rigorous scientific evaluation, requiring consideration of not just "complex clinical issues ... but also important and practical public health issues." 71 Fed. Reg. at 3,934. In short, by approving a drug to be marketed for the indications stated in its approved labeling, the FDA has made an expert decision that the drug serves a net public benefit for those indications and specifically endorses its use for the listed indications.

The federal government's regulation of advertising for prescription drugs is likewise comprehensive. Federal law requires that the promotion of a prescription drug conform to its FDA-approved labeling. *See, e.g.*, *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013) (citing 21 C.F.R. §§ 201.100(d)(1), 202.1(e)(4)); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014). Congress also directs that the limited forms of advertising that do not qualify as "labeling"—for example, television or magazine ads—include a "true statement" about the drug, including its name, ingredient list, and a summary of its side effects and contraindications. 21 U.S.C. § 352(n).

With respect to promotions that qualify as labeling, such as detailing and brochures, FDA regulations require pharmaceutical manufacturers to "submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product." 21 C.F.R. § 314.81(b)(3). And as the FDA itself has explained, the FDA continually "monitors drug labeling and prescription drug advertising to help ensure that they provide accurate information about drug products." FDA, *Prescription Drug Product Labeling; Medication Guide Requirements*, 60 Fed. Reg. 44,182, 44,210 (Aug. 24, 1995). The FDA's regulation of marketing aims to "help[] people get the accurate, science-based

information they need to use medicines appropriately and improve their health," and to "protect the public health by ensuring that prescription drug information is truthful, balanced, and accurately communicated." FDA, *Background on Drug Advertising* (June 19, 2015)[97]; FDA, *Office of Prescription Drug Promotion: Mission* (July 25, 2018)[98]; *see also* FDA, *Consumer-Directed Promotion of Regulated Medical Products*, 70 Fed. Reg. 54,054, 54,056 (Sept. 13, 2005) (FDA marketing regulations seek "to protect public health by helping to ensure that the promotion of medical products directed to professionals and consumers is truthful, not misleading, and contains balanced risk and benefit information"); 60 Fed. Reg. at 44,210 (FDA's monitoring of labeling and advertising meant "to carry out the public health protection purposes of the [FDCA]").

A multi-billion dollar state law judgment against Janssen for promotional statements that tracked its medications' labeling—and thus satisfied federal requirements—would throw this scheme into disarray. The FDA's regulatory system aims to give doctors and the public access to information that the FDA has found to be accurate. Imposing massive state-law liability on Janssen for doing exactly that 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."). Basic preemption principles block states

[97] Available at https://www.fda.gov/drugs/prescription-drug-advertising/background-drug-advertising.

[98] Available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research/office-prescription-drug-promotion-opdp.

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

In addition to triggering federal preemption principles, the State's targeting of federally authorized conduct runs afoul of the Oklahoma nuisance statute's safe harbor. That provision commands that "[n]othing which is done or maintained under the express authority of a statute can be deemed a nuisance." 50 O.S. § 4. By its express terms, it precludes the State from holding Janssen liable for FDCA-authorized promotions of its medicines for their approved indications or Noramco's CSA-authorized API sales. In doing so, it vindicates Janssen's due process right to avoid punishment for conduct that was affirmatively authorized by federal law. *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.").

As explained, the CSA authorizes companies that receive the DEA's blessing to import specified quantities of raw poppy materials and purchase specified quantities of narcotic API. *See* 21 U.S.C. § 952; 21 C.F.R. § 1312.11. Noramco's and Tasmanian Alkaloids' sales under that detailed federal scheme thus occurred "under the express authority of a statute" and cannot "be deemed a nuisance." 50 O.S. § 4. Similarly, the FDCA's implementing regulations allow manufacturers to promote medications in conformity with their FDA-approved labels. *See* 21 C.F.R. §§ 201.100(d)(1), 202.1(e)(4). Accordingly, under the nuisance statute's safe harbor, promotional statements that tracked the FDA-approved labels of Janssen's medications—including statements that the medications were appropriate for treatment of chronic non-cancer pain—cannot form a basis of liability. *See, e.g.*, *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"); *Prohias v. AstraZeneca Pharm., L.P.*, 958 So.2d 1054, 1056 (Fla. Dist. Ct. App. 2007) (advertisements consistent with FDA label fall under safe harbor for acts "specifically permitted by federal law").

To be sure, as the State argued in opposition to Janssen's motion for summary judgment, statutory authorization to undertake a specific activity does not mean a business can operate in any manner it chooses. *See Reaves v. Territory*, 1903 OK 92, ¶¶ 8, 27, 74 P. 951, 954. But here, large portions of the State's case is targeted at the ***specific acts*** federal law authorized—raw material sales, API sales, and promotional statements mirroring Duragesic's and Nucynta ER's FDA-approved labels. That frontal assault on statutorily authorized conduct is precisely what the safe-harbor provision forbids. *See* 50 O.S. § 4.

IV. THE STATE HAS FAILED TO PROVE JANSSEN CAUSED THE OPIOID CRISIS

Janssen is also entitled to judgment because the State has presented no viable evidence of proximate or even but-for causation of the entire opioid epidemic. The State's causation theory, presented through its chief expert, Andrew Kolodny, begins with the logical fallacy that because opioid prescriptions and opioid abuse rose over the same time period, increased prescriptions—not criminal diversion, not enforcement failures, and not complex social forces—caused Oklahoma's opioid crisis.[99] And it makes no attempt to link Janssen's own products to those prescription increases—indeed, the State presented no evidence about the sales of Janssen's drugs at all. Instead, Kolodny provided a narrative in which various factors combined to make

[99] *See, e.g.*, June 11, 2019 Trial Tr. (Kolodny Test.) at 76:24-77:13, 96:23-97:5; June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 101:16-23; June 13, 2019 Trial Tr. (Kolodny Test.) at 21:14-23:13, 43:2-14; June 17, 2019 Trial Tr. (Kolodny Test.) at 38:22-24, 39:17-40:3; 44:12-17.

Janssen responsible for increased prescriptions of *all* opioids, including Noramco's sales of "opium and oxycodone to Purdue Pharma," "an unbranded campaign" using "front groups" and "professional groups," the use of the Pain Care Forum to "protect [Defendants'] stake in the opium supply into the United States," and "sales reps" who "downplayed the addiction potential of Duragesic" and "promoted their products aggressively" and "improperly."[100]

That narrative falls far short of the rigorous scientific evidence needed to prove the causes of a complex nationwide public-health problem. Kolodny's narrative did not purport to use any scientific method. He failed to explain how Janssen's promotion of its own seldom-prescribed drugs could cause a crisis of oxycodone and hydrocodone abuse. Nor did he offer any analysis to measure Janssen's impact on ***other manufacturers'*** sales. Indeed, he offered no way to measure the impact of Janssen's alleged conduct ***at all***—not even evidence that any statement by Janssen influenced a single Oklahoma doctor to write a single harmful prescription. He did not isolate Janssen's asserted role in the crisis from that of countless other potential causes. In the end, Kolodny spent days testifying that Janssen engaged in ***the kind*** of conduct that he believes caused increased opioid prescriptions. But neither he nor the State presented any sound method to establish that Janssen's actual conduct—an obscure brochure here, a donation to a lobbying effort or professional organization there—actually made a dent in a large market fed by countless other forces.

Having shirked its burden to measure the effects of Janssen's conduct, the State has left this Court no way to tease out the causal significance of the countless episodes on which Kolodny's opinion relies. His testimony that Noramco's and Tasmanian Alkaloids' sales of raw materials caused Oklahoma's opioid abuse crisis not only collides with multiple federal and

[100] June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 21:14-23:13.

state-law rules, *see supra* Section.D.3, but also ignores the existence of other raw-material manufacturers who might have sold Purdue and Teva their DEA-approved allotments of raw material even if Noramco had never existed. And his assertion that Janssen caused the crisis through organizations that he disparages as "front groups" relied on speculation that Janssen must have "influenced" third parties that by all appearances acted of their own volition and voiced sincerely held beliefs about pain treatment.

Kolodny's observational narrative testimony may have made for a good story—but it fell well short of the rigorous analysis required to mete out blame for a phenomenon as varied and complex as the opioid abuse crisis. Influences on prescription choices are complex, and increased prescriptions for a medicine can result from a host of factors besides unlawful marketing—including ***lawful*** marketing, changes in insurance reimbursement practices, and developments in scientific literature. *See infra* Section IV.A.2. For that reason, courts have consistently rejected far more scientific ***statistical*** causation evidence on the question whether unlawful pharmaceutical marketing caused increased prescriptions. Here, Kolodny does not even offer the statistics—he relies on a *historical narrative* to assert that Janssen caused *an entire public-health crisis*. If this Court finds Kolodny's unscientific say-so good enough to prove causation for a nationwide social problem, it will reach a conclusion with no precedent in any American court.

These fundamental defects on their own compel judgment for Janssen. But the State's failures go deeper. It has presented nothing but speculation to suggest that increased prescriptions were the actual cause of the opioid abuse crisis. That speculation commits the predictable blunder of confusing correlation with causation—i.e., it assumes that because prescriptions went up over the course of the crisis, the former must have caused the latter. This is

a logical fallacy, as courts uniformly recognize in rejecting such causation analysis. At the same time, the State ignores crucial independent causes such as illicit diversion, enforcement failures, and the societal and economic factors that led to exponential rises in alcohol, methamphetamine, benzodiazepine, and muscle-relaxant abuse over the same period.

The State has failed not just to establish that Janssen was a cause-in-fact of its injuries, but also that Janssen was a legal cause of the opioid abuse crisis. The trial evidence makes clear that multiple independent phenomena, including rampant criminal conduct, fed the crisis. And although the State seeks abatement payments covering 30 years of government programs, the notion that a sales representative's statements about Duragesic in the 1990s or an obscure brochure about pain treatment in 2008 caused someone to become addicted to heroin in 2035 stretches the idea of proximate cause past the breaking point.

Janssen's marketing of drugs that were not widely prescribed or abused did not cause Oklahoma's opioid abuse crisis. And unscientific expert say-so based on statements cherry-picked by a partisan State expert cannot change that conclusion.

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

The State and its experts,[101] including Kolodny, Mazloomdoost, Beaman, and White, offered no evidence to support a finding that anything Janssen did in any way caused Oklahoma's injuries. They neither offered a sound basis to measure the impact of Janssen's conduct, nor distinguished causation from correlation, nor addressed the many independent factors that propelled Oklahoma's opioid abuse crisis. Each of those failings requires judgment for Janssen, which was not a factual cause of Oklahoma's opioid abuse crisis.

[101] The State's experts are anti-opioid activists with strong opinions that happen to align with the State's interests in this litigation. As Janssen's pre-trial *Daubert* motions explained, their testimony bears none of the hallmarks of proper expert testimony under 12 O.S. § 2702.

1. The State Has Not Measured the Impact of Janssen's Alleged Conduct

Asserting that this "case isn't about [Janssen's] drug[s],"[102] the State declined to introduce ***any*** evidence about Duragesic's or Nucynta's sales in Oklahoma. It did nothing to show that those products registered as even a minor blip in the state's prescription-opioid market. Nor did the State offer any evidence that either drug was abused or diverted at significant rates, let alone on a scale capable of driving a statewide crisis. The State's limited selection of sales representative call notes promoting Janssen's drugs thus cannot support a finding of causation: The State has no proof they increased prescriptions of Janssen's own drugs, much less opioids as a class. Similar defects afflict the State's reliance on Janssen's limited unbranded promotions accompanying Nucynta's 2009 introduction. The State offered no credible, non-speculative basis to conclude that statements clipped from an obscure website or brochure in the late 2000s caused an opioid abuse crisis that, by the State's own calculation, was already nearing its peak.[103] *See McKellips v. Saint Francis Hosp., Inc.*, 1987 OK 69, 741 P.2d 467, 471 ("Absolute certainty [of causation] is not required, however, mere possibility or speculation is insufficient.").

Unable to link any conduct by Janssen to Oklahoma's alleged injuries, the State presented a sweeping case suggesting that Janssen is responsible for statements by any doctor, any researcher, or any nonprofit organization with which it was affiliated in any way. As explained above, that case is at war with the First Amendment. More fundamentally, the State offered no sound evidence that Janssen caused those third parties' statements, let alone that the statements went on to instigate Oklahoma's opioid abuse crisis. The State's experts did not identify a single Oklahoma doctor who relied on any statement in any way linked to Janssen. Instead, they

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[102] June 3, 2019 (PM) Trial Tr. (Beckworth Arg.) at 53:22-23.

[103] *See* June 7, 2019 (AM) Trial Tr. (Nguyen Test.) at 96:23-97:5 (the "peak" of the opioid crisis was "2007 to 2014").

asserted in strikingly general terms that statements made as part of this alleged marketing campaign—misleading or not, associated with Janssen or not, disseminated in Oklahoma or not—caused the State's injuries. Their conclusory opinions offer no basis for finding that the specific statements the State attempts to trace to Janssen caused the opioid abuse crisis in Oklahoma.

Dr. Andrew Kolodny. A longtime anti-opioid crusader, Kolodny provided testimony that was observational at best and pure say-so at worst. He testified that J&J was "a major cause of" the opioid abuse crisis.[104] He even went so far as "to characterize them as the kingpin in our opioid crisis."[105] But Kolodny applied no identifiable method to determine whether Janssen or J&J caused Oklahoma's opioid abuse crisis. *See* 12 O.S. § 2702 (expert testimony must be "the product of reliable principles and methods"). He did not even purport to. He simply told a story in which Janssen (not Purdue, not Teva, and not illegal drug cartels) was the villain. Such narrative testimony—closer to a closing legal argument than expert opinion—is not valid causation evidence and cannot support judgment against Janssen. *See, e.g.*, *Christian v. Gray*, 2003 OK 10, ¶ 36, 65 P.3d 591, 607; *Pfizer Inc. v. Teva Pharm., USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006); *Advanced Med. Optics, Inc. v. Alcon, Inc.*, 2005 WL 782809, at *4 (D. Del. Apr. 7, 2005).

But Kolodny's testimony fails for other, equally glaring reasons. He based his causation opinion largely on Noramco's and Tasmanian Alkaloids' role supplying raw materials to

[104] June 13, 2019 Trial Tr. (PM) (Kolodny Test.) at 21:14-23:13.

[105] *Id.* at 21:14-23:13.

manufacturers of opioid medications, including Purdue.[106] That role, Kolodny insisted, makes J&J responsible for all other manufacturers' medicines: "[I]t was their opium that [Teva and Purdue] were selling and that other drug dealers or pharmaceutical companies were selling."[107] Putting aside that this theory ignores the federal and state-law protections detailed above, it also fails as simple but-for causation evidence because it does not account for numerous other companies who could have supplied—and often did supply—raw material even if Noramco and Tasmanian Alkaloids had never existed. Kolodny did not even try to engage those other companies or learn about their relationships with Purdue and other manufacturers.[108] But their existence precludes any conclusion that Noramco or Tasmanian Alkaloids was a but-for cause of Oklahoma's opioid abuse crisis.

Kolodny next testified that J&J promoted opioids generally by "funding front groups, patient groups meant to look like grassroots organizations that promoted opioids, funding professional groups that were promoting opioids," and by participating in organizations such as the Pain Care Forum, which Kolodny referred to as the "opioid mafia."[109] But Kolodny's observation that Janssen contributed to such groups and retained prominent doctors for sporadic consulting work is not proof that Janssen caused any particular statement by any group or doctor. And Kolodny's testimony about the impact of those third parties' statements—for example, his assertion that the APS and AAPM consensus statement was "one of the single most damaging

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[106] *Id.* at 21:16-21 ("It was Johnson & Johnson's opium that flooded – that flooded into the United States."); *id.* 22:1-12 ("Johnson & Johnson continued to sell opium and oxycodone to Purdue Pharma.").

[107] *Id.* at 21:16-21.

[108] June 17, 2019 Tri. Tr. (AM) (Kolodny Test.) at 82:24-86:11.

[109] June 13, 2019 Trial Tr. (PM) (Kolodny Test.) at 22:14-21.

documents when we look back at the history of our opioid crisis"[110]—represents exactly the sort of conclusory expert say-so that courts cannot rely on to find causation. *Christian*, 2003 OK 10, ¶ 36, 65 P.3d at 607 ("An expert's opinion on causation must be more than *ipse dixit*.").

Kolodny's bare assertion that Janssen caused the opioid abuse crisis by "directly promot[ing] their own opioids in ways that were improper"[111] was equally insufficient. In particular, Kolodny faulted Janssen for "downplay[ing] the addiction potential of Duragesic," "promot[ing] their products aggressively at a time when it was very clear that the United States was suffering from an epidemic of opioid addiction because of overprescribing," and "encourag[ing] doctors to prescribe their opioids for conditions where we shouldn't use them."[112] But whatever Kolodny's opinion of Janssen's marketing, the State offered not one shred of evidence to suggest that Janssen's products played any significant role in the Oklahoma opioid market—or its crisis of opioid abuse and misuse.[113] Much of the marketing the State criticizes

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[110] June 11, 2019 Trial Tr. (PM) (Kolodny Test.) at 27:11-16.

[111] June 13, 2019 Trial Tr. (PM) (Kolodny Test.) at 22:22-23:13.

[112] *Id.* at 21:9-23:13.

[113] *See, e.g.*, June 4, 2019 Trial Tr. (PM) (Deem-Eshleman Test.) at 17:19-18:10, 19:11-17 (Data from the Research Abuse Diversion Addiction Research ("RADARS") surveillance system confirms that Duragesic's abuse potential and abuse rates have been and remain low); Janssen Exs. 1027, 1046, 1177, 1203, 1228, 1232, 1247, 1269, 1295, 1323, 1324, 1336, 1337, 1352, 1354, 1378,1379, 1397, 1418, 1453, 1485, 1502, 1532, 1537, 1567, 1580, 1600, 1616, 1642, 1672, 1688, 1718, RADARS System Reports, Duragesic (2007-2014) (*admitted June 27, 2019*); Janssen Ex. 812, DUR Board Meeting Packet (July 8, 2003) (*admitted June 25, 2019*) (In the 2002 Duragesic "[u]tilization review," the University of Oklahoma College of Pharmacy concluded that "utilization, at this time, appears to be within acceptable parameters."); Janssen Exs. 1310, 1349, 1371, 1388, 1350, 1409, 1452, 1487, 1519, 1560, 1585, 1609, 1650, 1681, 1716, Nat'l Addictions Vigilance Interventions and Prevention Program ("NAVIPPRO"), Drug Abuse Surveillance Reports, Nucynta (2010-2015) (*admitted June 27, 2019*); June 14, 2019 (AM) Trial Tr. (Hoos Test.) at 88:10-23 ("Q. And you said he also prescribed you a pain patch? A. Yes. … Q. And you didn't become addicted [then]? A. [N]o, I mean, I didn't get addicted then, no."); June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 153:1-156:2 (Of the 14,1332 medical

urged doctors to use Duragesic, a drug with vastly lower abuse rates, ***instead*** of OxyContin, the drug the State has all along maintained sparked its crisis. Yet neither Kolodny nor any other State witness offered a coherent explanation for how Janssen caused the crisis by urging doctors to ***avoid*** prescribing the drug most widely abused and misused.[114] Nor did Kolodny coherently explain how the marketing of products containing fentanyl and tapentadol caused an opioid crisis driven primarily by oxycodone and hydrocodone.[115] Lacking any foundation in the evidence, Kolodny's assertion that promotion of Duragesic and Nucynta caused Oklahoma's opioid abuse crisis boils down to the impermissible say-so of an expert witness. *Christian*, 2003 OK 10, ¶ 36, 65 P.3d at 607.

Kolodny's opinion likewise cannot account for multiple, independent factors that may have contributed to overprescribing. Kolodny acknowledged, for instance, the role of Purdue's

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examiner reports produced by the State, only forty-eight mention Duragesic, and of those, twenty-three reports identified fentanyl as the sole cause of death.).

[114] *See* May 31, 2019 (AM) Trial Tr. (Deem-Eshleman) 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 on how Duragesic compared favorably to OxyContin and other oral opioids); *see also, e.g.*, June 25, 2019 (PM) Trial Tr. (White Test.) at 11:11-19:18, 19:23-30:4, 37:11-22 ("[T]his is an example of the oversupply problem in Oklahoma" (referencing medical examiner reports on OxyContin-related deaths and prescription claims data evincing OxyContin prescriptions *far* exceeding the recommended dose); Janssen Ex. 2941, Okla. Bur. of Narcotics Report (2009) (*admitted June 17, 2019*) (noting that OxyContin is frequently abused and commonly results in overdose deaths in Oklahoma); Janssen Ex. 802, DUR Board Meeting Packet (Mar. 2003) (*admitted June 25, 2019*) (DEA intelligence briefing on diversion of OxyContin providing that "[s]ince 1996 … DAWN data indicate an increasing number of emergency department mentions and deaths associated with oxycodone").

[115] *See, e.g.*, Janssen Ex. 3928, Okla. Dep't of Health, Fatal Unintentional Poisoning Surveillance System Slide Deck, at 9 (*admitted June 6, 2019*) (From 2007 to 2017, hydrocodone and oxycodone were the two prescription medications most commonly associated with unintentional poisoning death).

criminal misconduct,[116] the Joint Commission's "promotion of pain [as] the fifth vital sign,"[117] and the AAPM and APS consensus statement that, according to Kolodny, is "one of the single most damaging documents when we look back at the history of our opioid crisis."[118] Kolodny never even tried to account for the role these and other intervening causes played in Oklahoma's opioid abuse crisis. Instead, he relied on innuendo to attribute some or all of them to Janssen. By failing to separate those other factors from Janssen and J&J's own conduct, he made it impossible to find that Janssen's own conduct caused Oklahoma's injuries. *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)).

Each of these defects individually makes Kolodny's testimony insufficient as a matter of law to prove that Janssen caused Oklahoma's opioid abuse crisis. But Kolodny's opinion fails for another, independent reason: Kolodny not only sweeps in, but inextricably relies on third parties' protected speech about medicine, constitutionally shielded lobbying activities, and federally authorized API sales.[119] *See supra* Sections III.B-C. Kolodny made no effort to set apart these protected acts and provide a theory of causation from actionable conduct alone. Quite the

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[116] June 13, 2019 Trial Tr. (PM) (Kolodny Test.) at 21:22-22:12; *see also id.* at 31:13-17 (Despite DEA regulation and authorization, Kolodny believes that "Noramco should have stopped supplying active pharmaceutical ingredients to Purdue Pharma or one of its affiliates").

[117] June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 134:5-10 ("[T]he Joint Commission's ... promotion of pain [as] the fifth vital sign played an important role in encouraging aggressive prescribing of opioids.").

[118] June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 27:11-16.

[119] *See, e.g.*, June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 5:5-7:4, 21:14-23:13.

contrary, his causation opinion overwhelmingly relied on all of them.[120] For that reason, too, his speculation cannot support a finding that Janssen created Oklahoma's opioid-abuse epidemic.

Dr. Danesh Mazloomdoost. Mazloomdoost's testimony likewise did nothing to show causation. Mazloomdoost's theory is that "the opioid industry, including Johnson & Johnson, influenced physicians' prescribing habits," which "directly and indirectly caused … overprescribing," because it "directly and indirectly affected the mindset of the people prescribing," which in turn purportedly led to the opioid abuse crisis in Oklahoma.[121]

Despite those sweeping generalities, Mazloomdoost offered nothing concrete to connect Defendants to Oklahoma's injury. The most he could say was that increases in prescriptions were caused by "pharmaceutical manufacturers ***like*** Johnson & Johnson"[122]—never connecting any overprescribing, or any change in physicians' attitude, ***to*** Janssen or J&J. Not once did he even attempt to link ***any*** allegedly actionable conduct by Janssen to increased prescriptions.

Mazloomdoost admitted that in formulating his theory, he failed to consider all the information available to prescribing physicians, including FDA-approved product labels and the *Physicians' Desk Reference*.[123] "People don't read those things," he insisted.[124] If accepted, Mazloomdoost's position would make pharmaceutical companies liable for physicians' refusal to heed (or read) companies' warnings, which they are by law presumed to do. *See, e.g.*, *Exck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001) (applying Oklahoma law); *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1483 (E.D. Okla. 1997) (same).

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[120] *See id.*

[121] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 70:14-71:7, 72:17-20.

[122] *Id.* at 25:21-24 (emphasis added).

[123] June 6, 2019 (PM) Trial Tr. (Mazloomdoost Test.) at 96:23-98:9.

[124] *Id.* at 98:1.

Mazloomdoost did describe some examples of what he believed to be misconduct, but he identified no actionable misconduct by the Janssen Defendants and did not even try to explain how the third-party misconduct he identified caused the opioid abuse crisis in Oklahoma. For instance, Mazloomdoost purported to identify multiple misrepresentations in a brochure distributed at a 2002 CME,[125] but he admitted that Janssen could not "influence" the content of this CME,[126] and he could not identify a single word in the brochure that Janssen had written.[127] Similarly, Mazloomdoost claimed that the FDA's Risk Evaluation and Mitigation Strategies ("REMS") for opioids were "marginalized" by "a lot of these pharmaceutical companies, like Johnson & Johnson."[128] But the only example he identified—drug representatives laughing about REMS—***did not involve Janssen representatives***.[129]

Mazloomdoost also claimed to "know with certainty" that medical education in this country was "influenced by opioid industry bias,"[130] but pointed to no instance of Janssen or any other manufacturer drafting medical education materials.[131] His only specific example was that

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[125] *See* June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 48:12-53:1 (discussing State's Ex. 975, a CME program on opioid pharmacotherapy for chronic pain management).

[126] *Id.* at 49:18-19.

[127] *Id.* at 107:9-108:3; *see also id.* at 105:13-16 (Mazloomdoost could not testify to any change in prescribing "specific to this brochure").

[128] *Id.* at 63:13-17.

[129] *Id.* at 63:17-24, 120:24-121:21; *see also* Janssen Ex. 1369, Nucynta ER Risk Evaluation and Mitigation Strategy (REMS) (*admitted June 6, 2019*); Janssen Ex. 2148, Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) (*admitted June 6, 2019*).

[130] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 44:7-45:15.

[131] *See, e.g.*, Portenoy Depo. Tr. at 331:6-19 (played May 29, 2019) (speakers control CME content, not pharmaceutical companies).

J&J funded a study on short-term outcomes from Duragesic,[132] but an anecdote about J&J's funding of a study does not make it responsible for the state of American medical education or the opioid abuse crisis.

Dr. Jason Beaman. Beaman offered the same opinion as Kolodny and Mazloomdoost: that Janssen caused Oklahoma's opioid abuse crisis because it "unleashed" a "misinformation campaign."[133] He testified simply that he "talked to physicians" and therefore knows they were influenced by manufacturers' information.[134] This mix of anecdote and conclusory say-so from an addiction doctor with no expertise in pharmaceutical marketing establishes nothing at all. *See, e.g.*, *Maben v. Lee*, 1953 OK 139, ¶ 14, 260 P.2d 1064, 1067 (admission of expert's causation testimony premised on hearsay was reversible error); *Christian*, 2003 OK 10, ¶ 36, 65 P.3d at 607 (expert *ipse dixit* is insufficient to establish causation).

Beaman's causation testimony not only lacked any supporting methodology, but it also repeatedly and fundamentally contradicted the record. He testified, for instance, that Oklahoma's opioid epidemic started in ***1996*** "as a consequence" of the "aggressive unbranded marketing campaign by the pharmaceutical manufacturers, including [J&J] and Janssen."[135] But the State has presented no evidence of any unbranded marketing by Janssen before ***2008***. And on at least four occasions, Beaman testified that manufacturers like Janssen falsely claimed the risk of addiction was low when opioids ***are*** "used for pain."[136] But the State has presented no evidence Janssen (or any other manufacturer) ever made such a claim.

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[132] June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 45:5–15.

[133] June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 68:22-71:12.

[134] *Id.*

[135] *Id.* at 171:6-12.

[136] *Id.* at 65:25-66:18, 80:1-15, 150:14-22, 166:2-167:10.

Beaman's also ignores the ample information Janssen ***did*** provide to physicians. Beaman maintained that manufacturers inappropriately "h[e]ld back the risks and benefits,"[137] but his testimony revealed his complete ignorance of even the most basic interactions between manufacturers and physicians. When confronted with Duragesic's label, he conceded that it adequately communicated the product's risks.[138] He also admitted that he did not know about the Risk Evaluation and Mitigation Strategies, the program Janssen implemented under FDA oversight to educate doctors about Nucynta's risks.[139] Conversations with a handful of physicians cannot overcome these basic gaps in his knowledge or make credible his opinion that Janssen caused Oklahoma's opioid abuse crisis.

Ms. Terri White. White formulated her causation opinion ***by observing the State's case-in-chief.***[140] Unsurprisingly, her opinion mirrored the theories advanced by Kolodny and the State's lawyers: Janssen's "false and misleading" marketing materials tricked physicians into overprescribing opioid medications, which caused a surge in opioid-related deaths, as demonstrated by (purported) CDC data.[141] And like Kolodny, her testimony reads more like a closing argument than expert opinion. She provided no identifiable methodology and failed to address the role played by countless rival causes. The conclusions she claimed to draw from a

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[137] *Id.* at 63:1-8.

[138] *Id.* at 105:1-107:21.

[139] *Id.* at 119:8-124:24.

[140] *See, e.g.*, June 25, 2019 (AM) Trial Tr. (White Test.) at 31:24-32:6 ("They did not tell us they were going to be sending this many -- 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." (emphasis added)); *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.").

[141] *See, e.g.*, June 25, 2019 (AM) Trial Tr. (White Test.) at 55:22-56:25, 62:10-63:5, 66:10-19; June 27, 2019 (PM) Trial Tr. (White Test.) at 25:20-26:16.

trial that she hopes will triple her agency's budget are not valid evidence that Janssen caused the opioid abuse crisis. Her outlandish suggestion that Janssen somehow caused Oklahoma's ***methamphetamine*** abuse crisis further underscores her partisanship and her causation opinion's lack of reliability.[142]

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In short, none of the State's experts identified a "reliable method for determining causation" from the specific documents or public statements the State attributes to Janssen. *Christian*, 2003 OK 10, ¶ 36, 65 P.3d at 607. And none identified any way to test or verify their assertions or measure causation—a statistical analysis, a formula, data, *anything*. *Cf. BancFirst v. Ford Motor Co.*, 2011 WL 2215014, at *4 (W.D. Okla. June 6, 2011) ("Rather than methodology, Medcalf offers simply the 'ipse dixit of the expert.'"), *aff'd*, 489 F. App'x 264 (10th Cir. 2012). Instead, each expert said that misleading pharmaceutical marketing—which, according to the State's definition, encompasses nearly every positive statement any medical organization has ever made about opioids—caused Oklahoma's opioid abuse crisis.[143]

Such bare opinions, unsupported by any method or scientific analysis, are no basis to rule for the State on the causation question here: Whether Janssen's allegedly unlawful conduct increased prescriptions of *all* opioids throughout Oklahoma. *City of New Haven v. Purdue*

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[142] *See* June 25, 2019 (PM) Trial Tr. (White Test.) at 80:18-87:3 ("[W]hen your addiction circuitry has already been turned on by a prescription drug and you can't get that and what is available and what is cheap is methamphetamine, you will absolutely see a rise in methamphetamine use .... [A]bsolutely the rise in methamphetamine use is correlated ... in the turning on of addiction circuitry due to prescription drugs and that's a really important point ....").

[143] The same is true of 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 Portenoy and he did not identify a single Janssen representation supporting his statement that Janssen had misused his work.

Pharma., LP, 2019 WL 423990, at *4 (Conn. Sup. Ct. Jan. 8, 2019); *see also Boyle v. ASAP Energy, Inc.*, 2017 OK 82, ¶ 38, 408 P.3d 183, 196 (expert evidence of causation must offer "more than subjective belief or unsupported speculation"); *Christian*, 2003 OK 10, 65 P.3d at 601-02 ("When an injury is of a nature requiring a skilled and professional person to determine cause and the extent thereof, the scientific question presented must necessarily be determined by testimony of skilled and professional persons."). Without a hint of scientific analysis, this testimony amounts to nothing more than unsupported say-so, which Oklahoma courts have always rejected. *Id.* at ¶ 36, 65 P.2d at 607 ("An expert's opinion on causation must be more than *ipse dixit*.").

2. The State's Purported Correlation Evidence Is Both Insufficient and Hopelessly Flawed

"[S]implistic" statistical evidence such as "correlation evidence" cannot establish causation on a question as complex as the effects of allegedly unlawful pharmaceutical marketing. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 96 (2d Cir. 2015). The State's evidence did not even rise to that standard. The State instead offered a litany of sources reflecting a loose temporal connection between increased marketing of opioids, increased sale of ***all manufacturers'*** opioids, and deaths involving ***all manufacturers'*** opioids. Renzi Stone, for instance, testified that as Janssen sales calls increased, so did sales of opioids generally, and as opioid sales increased, so did deaths related to prescription opioids.[144] Claire Nguyen, an epidemiologist in the Oklahoma State Department of

[144] June 10, 2019 (PM) Trial Tr. (Stone Test.) at 104:15-106:9.

Health, aptly summarized the State's theory: "as sales increased, the deaths increased."[145] That is classic correlation testimony; it cannot, as a matter of law, establish causation.

The State's actual evidence does not even establish correlation: There is at best only a crude temporal relationship between Janssen's alleged conduct and the trajectory of Oklahoma's opioid abuse crisis. Regardless, "mere correlation does not demonstrate causation." *Sergeants Benevolent*, 806 F.3d at 92 (citing *Brown v. Entm't Merchs. Ass'n*, 564 U.S. 786, 800 (2011)). That is a "statistical truism," *Nelson*, 2016 OK 69, ¶ 52, 376 P.3d at 228, one even Kolodny and White acknowledge.[146] A correlation shows that two phenomena might be related—not that one caused the other. Ice cream sales and crime both go up in the summer but that does not mean ice cream causes homicides.

Here, the State's observation of a loose temporal relationship between Duragesic marketing and increased opioid prescriptions cannot establish causation because it ignores a host of other factors that drove prescriptions—for example, the medical profession's emerging emphasis on pain treatment in the 1970s,[147] the FDA's approval of OxyContin in 1996,[148] and

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[145] June 7, 2019 (PM) Trial Tr. (Nguyen Test.) at 26:18-27:5. Notably, Nguyen expressly declined to offer an opinion "on what caused the increase in opioid-related mortality and morbidity." *Id.* at 26:18–27:5.

[146] June 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 105:13-17 ("Correlation and causation are not the same thing."); June 25, 2019 (PM) Trial Tr. (White Test.) at 86:24-87:3 ("Q. [Y]ou understand that correlation and causation are different things? A. That is correct. They are different things.").

[147] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 102:22-103:2; *see also* "The Interagency Committee on New Therapies for Pain and Discomfort: Report to the White House" at I-1 (May 1979).

[148] *See* Janssen Ex. 729, DUR Board Meeting Packet (Jul. 5, 2001) (OxyContin was released in 1996); 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 OxyContin and had limited OxContin's promotion of … we might not have an epidemic today.").

SoonerCare reimbursement practices favoring cheap, easily abused opioids.[149] *See also infra* Section V. The State's observation that increased prescriptions coincided with Oklahoma's crisis similarly elides countless other factors spurring opioid abuse and misuse and widespread unlawful diversion, an influx of illicitly trafficked street drugs, and shifting social and economic forces that caused skyrocketing abuse rates for other drugs over the same time period. *See infra* Section IV.B. With so many other variables lurking and unaccounted for, the "logic" that "the early necessarily causes the later … defies both common sense and time-honored principles of causation." *In re Death of Gray*, 2004 OK 63, ¶ 10 n.13, 100 P.3d 691, 700-01.

These failures of proof become even more problematic under the circumstances here. Oklahoma law recognizes that a "physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is ***his duty to inform himself*** of the qualities and characteristics of those products which he prescribes … and to exercise independent judgment, taking into account his knowledge of the patient as well as the product." *Edwards v. Basel Pharms.*, 1997 OK 22, ¶ 8, 933 P.2d 298, 300 (emphasis added). Accordingly, if prescription medicine is "properly labeled and carries the necessary instructions and warnings to fully apprize the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning." *Id.* Here, no one—not even the State's experts—disputes that the FDA-approved labels for Janssen's medicines "carried the necessary instructions and warnings to fully apprize" about the risks and benefits of opioid pain therapy.[150]

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[149] *See, e.g.*, Janssen Ex. 1515, DUR Board Meeting Packet (Feb. 2013) (*admitted June 26, 2019*), at 29-30 (explaining the State's tier formulary structure and the requirements for each formulary tier).

[150] *See, e.g.*, June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 105:1-107:21 (conceding that Duragesic's warning label, Janssen Ex. 2769, adequately communicates the risks of abuse, fatal

Id. Accordingly, the doctors who prescribed those medicines are "assume[d]" to "exercise the informed judgment thereby gained" in addition to their own "independent judgment." *Id.* The State's suggestion that Janssen's marketing was instead responsible for increased opioid prescriptions reads those doctors' informed judgment—and their awareness of risks that Janssen's labels prominently disclosed—out of the equation entirely.

As explained by the Second Circuit in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), "the nature of prescriptions…thwarts any attempt to show proximate cause through generalized proof." *Id.* at 135. Yet that is precisely what the State has attempted to do. The State and its experts ignore that doctors might not rely on a manufacturer's marketing claims at all, and even when doctors do so, they consider numerous other factors as well, including a "patient's diagnosis," "past and current medications being taken by the patient, the physician's own experience," and the "physician's knowledge regarding the [medication's] side effects." *Id.*; *see also id.* at 136 ("individual physicians prescribing [the drug] may have relied on [the] alleged misrepresentations to different degrees, or not at all").

Courts across the country have applied this reasoning in similar cases—including cases where plaintiffs offered more than temporal convergence and conclusory expert opinions.[151] In

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overdose, and diversion associated with Duragesic); June 14, 2019 (PM) Trial Tr. (Kolodny Test.) at 32:8 (conceding that Nucynta ER's warning label, Janssen Ex. 3736, warns about the risks associated with misusing or abusing Nucynta ER, including overdose and death).

[151] *See e.g.*, *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1280-81 (S.D. Fla. 2009) ("Doctors are presumed to go beyond [the] advertising ….Loss calculation necessarily would require an analysis of whether or not a particular physician ever received or relied on … allegedly fraudulent statements, and whether or not a physician, knowing the risk … would still have used [the drug] during an operation."); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *7 (N.D. Cal. Aug. 2, 2012) ("Because 'at least some doctors were not misled by Defendants' alleged misrepresentations … general proof of but-for causation is impossible.'" (quoting *Eli Lilly*, 620 F.3d at 135)); *In re Vioxx Prod. Liab. Litig.*, 2010 WL 11570867, at *7 (E.D. La. Mar. 31, 2010) ("In this case … it is not sufficient for

each case, a plaintiff claimed that a manufacturer's fraudulent marketing caused physicians to write improper or excessive prescriptions. And in each case, the court ruled that the plaintiff cannot establish causation without an "inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit." *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008). Without such an inquiry, courts cannot "determine what damages were caused by [the manufacturer's] alleged fraudulent conduct" as opposed to other factors. *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 2010 WL 3119499, at *7 (S.D. Ill. Aug. 5, 2010).[152]

The State knows these cases well. They are the reason, long before this trial started, it promised a "statistical" model to prove "how many doctors bought into" Janssen's marketing.[153] But rather than provide one, the State staked its case on conclusory speculation that if Janssen marketed opioids while opioid prescriptions and abuse rose, Janssen must have caused those

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Plaintiff to generally assert that Merck's misrepresentations led to the prescription of Vioxx. Each decision by each doctor and each patient was different.").

[152] Only a single court has departed from this consensus and allowed plaintiffs to prove increased prescriptions in the aggregate (rather than individually)—but that exception only further exposes the State's shortcomings. In *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 30 (1st Cir. 2013), the First Circuit held that an economist's regression analysis—a statistical technique for estimating relationships between variables—adequately measured the number of prescriptions caused by Pfizer's off-label promotion of its drug Neurontin. But that analysis showed a strong correlation between a manufacturer's promotions of a single drug for specific uses, and prescriptions of that same drug for those uses. *Id.* Here, the State offers no such analysis, even though its claim—which seeks to connect Janssen's marketing statements to other manufacturers' products, illegal drug sales, and diversion by non-parties—is exponentially more ambitious than the one-drug analysis in *Neurontin*. And, in any case, courts have since questioned the sufficiency of *Neurontin*-style regression analysis even in the narrow single-drug, single-manufacturer context. *See, e.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 577-78 (7th Cir. 2017) (Easterbrook, J.) (questioning whether regression analysis can measure effects of a drug's promotion and noting that *Neurontin* had been rejected by other federal circuit courts).

[153] Dec. 5, 2017 Hr'g Tr. at 136:6-137:7.

rises. That theory lacks the "scientific validity" required "[w]hen an injury is of a nature requiring a skilled and professional person to determine cause and extent thereof." *Christian*, 2003 OK 10, ¶¶ 7, 20, 65 P.3d at 597, 601. The fallacy of "correlation equals causation" is no basis for imposing billions of dollars of liability for an exceedingly complex social problem.

3. *The State Has Not Addressed Any Other Factors That Could Have Contributed to the Increased Numbers of Prescriptions or to the Opioid Abuse Crisis*

The State's experts also failed to address ***any*** of the countless factors (other than marketing) that could have driven opioid prescriptions and the opioid abuse crisis. The FDA's approval of a new generation of oral extended-release opioids, including OxyContin; lawful promotional activities by other manufacturers, and the medical community's increased emphasis on treating chronic pain (which began before Duragesic hit the market in 1990)[154] easily could have driven opioid prescription rates even if Janssen had never uttered a single word. Yet the State's experts make no effort to account for these factors.

Similarly, in assuming that increased prescriptions caused the opioid abuse crisis, they again ignored various forces that could have driven abuse, including rampant illegal diversion of prescription drugs, including opioids—which state agencies recognized as a major public-health issue as early as the 1990s.[155] *See infra* Section V. They failed to account for the fact that addicts may be more comfortable stealing FDA-approved prescription medications such as OxyContin than turning to the streets for dangerous, illicitly manufactured heroin that could be laced with any number of unknown drugs. They ignored broader social and economic factors that caused

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[154] May 30, 2019 (PM) Trial Tr. (Deem-Eshleman Test.) at 60:9-61:4 (stating that "more chronic pain ...was being diagnosed and treated" between 1988 and 1999).

[155] *See, e.g.*, June 7, 2019 (AM) Trial Tr. (Nguyen Test.) at 107:22-110:19 (describing various types of drug diversion that took place in Oklahoma).

abuse rates for all drugs—including alcohol, benzodiazepines, muscle relaxants, methamphetamine, and cocaine—to skyrocket over the same period.[156] And they offered no opinion on policy failures by the State that exacerbated the epidemic.[157]

Ignoring the opioid abuse crisis's complex and varied roots, the State's experts instead pointed to a single factor—Janssen's marketing—and asserted without explanation that it was the cause of the opioid crisis. Because their testimony failed to account for ***any*** other factor, it did not show that Janssen's marketing caused the State's injuries. *See, e.g.*, *Hall*, 248 F. Supp. 3d at 1193 ("'expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes'" renders causation testimony inadmissible).

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.

Here, the limited acts ***by Janssen*** on which the State actually presented evidence exhibit no "natural and continuous" connection to the opioid abuse crisis. *Id.* No unbroken chain connects, for example, sales representatives' promotions of the Duragesic fentanyl patch to a

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[156] *See, e.g.*, State Ex. 1569, Emily Piercefield, et al., *Increase in Unintentional Medication Overdose Deaths Oklahoma, 1994-2006*, 39 Am. J. Prev. Med. 357, 1 (2010) (*admitted June 7, 2019*).

[157] *See, e.g.*, June 7, 2019 (PM) Trial Tr. (Nguyen Test.) at 5:14-6:21 (conceding the State failed to track unintentional poisoning deaths to deter doctor shopping for five years after gaining access to the PMP database); June 18, 2019 (AM) Trial Tr. (Mendell Test.) at 66:22-67:1, 89:3-10 (checking PMP data just twice annually does not meet best practices); *id.* at 67:2-19 (conceding that Oklahoma has failed to implement the 2016 CDC prescribing guidelines, which would significantly impact prescribing practices).

crisis fueled predominantly by illegally diverted oxycodone and hydrocodone.[158] Much less is there any proximate connection between Janssen's attempts to promote Duragesic ***as an alternative*** to OxyContin and a crisis in which Duragesic played no role and OxyContin played an outsized one.[159] Nor, for that matter, is there a "natural and continuous" connection between a handful of unbranded promotions in the late 2000s and a crisis that had already reached full swing.[160] The link between this smattering of evidence about Janssen's own conduct and the State's injuries is not only highly speculative, but also runs through a long list of independent causes having nothing to do with Janssen.

Those independent causes include the medical community's increased emphasis on treating chronic pain, including with opioids—a trend that began in the 1970s and continued in

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[158] *See, e.g.*, June 7, 2019 (AM) Trial Tr. (Nguyen Test.) at 107:22-110:19 (describing various types of drug diversion that have occurred in Oklahoma); Janssen Ex. 802, DUR Board Meeting Packet (Mar. 2003) (*admitted June 25, 2019*) (DEA intelligence briefing on diversion providing that "[s]ince 1996 … DAWN data indicate an increasing number of emergency department mentions and deaths associated with oxycodone"); Janssen Ex. 3928, Okla. Dep't of Health, Fatal Unintentional Poisoning Surveillance System Slide Deck at 9 (*admitted June 25, 2019*) (From 2007 to 2017, hydrocodone and oxycodone were the two prescription medications most commonly associated with unintentional poisoning deaths).

[159] *See* May 31, 2019 (AM) Trial Tr. (K. Deem-Eshleman) 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 (Janssen call notes describe discussions between sales representatives and physicians on how Duragesic compared favorably to OxyContin and other oral opioids); *see also, e.g.*, Janssen Ex. 2941, Okla. Bur. of Narcotics Report (2009) at 3 (*admitted June 17, 2019*) (noting that OxyContin is frequently abused and commonly results in overdose deaths in Oklahoma).

[160] *See, e.g.*, June 17, 2019 (AM) Trial Tr. (Kolodny Test.) at 51:3-16 (conceding that Janssen's unbranded marketing that took place after January 2008 could not have caused the increase in opioid deaths that occurred before 2008); June 7, 2019 (AM) Trial Tr. (Nguyen Test.) at 96:23-97:5 (the "peak" of the opioid crisis was "2007 to 2014").

the 1980s, before Janssen had even begun marketing Duragesic.[161] They also include the FDA's approval of OxyContin in 1996 and the widespread diversion of oxycodone and hydrocodone that followed, which the State recognized as a chief catalyst of abuse and misuse by the early to mid-2000s.[162] They include the introduction of cheap heroin and illegal fentanyl by international drug-trafficking cartels in the late 2000s.[163] And they include lapses by federal and Oklahoma policymakers, who, however well-motivated, made choices that facilitated diversion, while missing out on valuable opportunities to control excessively large prescriptions prone to diversion, curb doctor shopping, and deter other abuses. *See infra* Section V. Given these independent and fundamental forces driving Oklahoma's opioid abuse crisis, the notion that a handful of alleged missteps by Janssen caused the State's injury in "natural and continuous sequence" strains credulity.

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[161] *See* June 27, 2019 (AM) Trial Tr. (Moskovitz Test.) at 102:22-103:2; *see also* "The Interagency Committee on New Therapies for Pain and Discomfort: Report to the White House" at I-1 (May 1979).

[162] *See* Janssen Ex. 734, DUR Board 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, DUR Board Meeting Tr. (Mar. 8, 2006) at 29 (*admitted June 26, 2019*) (Board member Dr. Brent Bell and Dr. Hal Vorse acknowledging that OxyContin diversion had become a serious problem in Oklahoma); Janssen Ex. 456, DUR Board Meeting Packet (May 14, 2008) at 8 (*admitted June 7, 2019*) (M. Woodward of the Oklahoma Bureau of Narcotics stating that "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 OxyContin and had limited … Purdue Pharma's promotion of OxyContin, we might not have an epidemic today.").

[163] *See* Portenoy Depo. Tr. at 383:16-384:16 (played May 29, 2019) ("My understanding now is that … the importing of illicit fentanyl is part of the public health problem we now have, particularly with respect to the continuing rise in opioid mortality."); June 18, 2019 (PM) Trial Tr. (Pfeifer Test.) at 107:3-5 (acknowledging that illicit fentanyl often comes from China or Mexico).

The State's legally deficient causation evidence is all the more glaring given that the State seeks damages from Janssen to address harms that will not materialize for many years, if at all. The State seeks to have Janssen pay for every dollar allegedly needed to prevent any and all opioid addiction for the next 30 years. It seeks to have Janssen pay to treat individuals who are not addicted today, even ones who are not yet born. But Janssen stopped promoting Duragesic in 2008 and its Nucynta products in 2015.[164] A supposed misstatement about Duragesic in 1999 does not have a remotely "proximate" connection with an individual who becomes addicted to OxyContin in 2035. The State certainly has offered no evidence connecting such remote injuries to any conduct of Janssen's, now or in the past.

The evidence showed that the State's injuries were inflicted by a wide range of causes that had nothing to do with Janssen, and that attenuation will grow only more apparent over the next three decades. Proximate cause limitations exist precisely to foreclose this type of remote, limitless liability. *See, e.g., Holmes v. Sec. Investor Protection Corp.*, 503 U.S. 258, 268-70 (1992) (proximate cause is a "central element[]" that ensures "some direct relation between the injury asserted and the injurious conduct alleged" and "reflects ideas of what justice demands" (quotation omitted)); *Graham v. Keuchel*, 1993 OK 6, ¶ 13, 847 P.2d 342, 350 ("Lapse of time … may cause the duty to prevent harm to another, threatened by the original actor's negligent conduct, to shift from that actor to [a] third person. When this happens the third person's failure to prevent the threatened harm may be a supervening cause.").

Causation is a cornerstone of tort law, and 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

[164] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 44:21-46:3.

from imposing tort liability without the traditional "common law protection[s]" essential to guard against the "arbitrary deprivation of property." *Oberg*, 512 U.S. at 430-32. Both cause-in-fact and legal cause are bedrock safeguards against arbitrary judgments. It is "textbook tort law" that an action is not even "regarded as *a* cause of an event" if but-for causation is not satisfied. *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 347 (2013) (emphasis added) (quoting Prosser and Keeton, The Law of Torts 265 (5th ed. 1984)). And legal cause, which many jurisdictions refer to as "proximate cause," is the traditional, *see, e.g.*, *Holmes*, 503 U.S. at 268-70—indeed, the "necessary," *Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 838 (1996)—method for foreclosing liability where "the link has become too tenuous—that what is claimed to be consequence is only fortuity," *id.* (quotation omitted).

The State's unbounded interpretation of nuisance law, coupled with its attempt to impose joint and several liability, makes those protections all the more vital in this case. Allowing the State to single out one of dozens of potential defendants and force it to pay for myriad consequences of a public-health crisis that it had no measurable part in creating would be "excessive and disproportionate," *id.* at 455-56 (applying similar requirement under the Excessive Fines Clause), in the extreme. The Due Process Clause forecloses the imposition of liability in this case because the State cannot prove either traditional element of causation.

V. THE STATE'S CONTRIBUTIONS TO THE OPIOID CRISIS ENTITLE JANSSEN TO JUDGEMENT

Though the State now argues that opioid medications have always been dangerous products that should be prescribed only with the strictest care and supervision, it has come to that opinion only recently. For more than a decade, and through the vast majority of Oklahoma's opioid crisis, State regulators, health care officials, and even the Attorney General's office believed in the same scientific consensus that led Janssen and other companies to manufacture

and market opioid medications: that these drugs, despite their risks, could safely and effectively treat chronic non-cancer pain. And to that end, the State took numerous actions that made it easier—and either delayed or failed to take actions to make it harder—for Oklahomans to obtain prescriptions for opioid medications. It handed down only minor penalties for doctors that overprescribed or overdispensed opioids, it rejected recommendations for additional scrutiny of certain opioid prescriptions, and in 2016—the year before the State initiated this litigation—it *eased* restrictions on OxyContin. Although these actions and inactions no doubt played some role in the State's current crisis, the State has offered no evidence to apportion its own contributions versus those it attributes to Janssen. Without such evidence, the State cannot recover anything from Janssen, and the Court should enter judgment for Janssen.

Under Oklahoma law, 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. In *Walters*, landowners brought a nuisance suit alleging that oil companies had dumped refuse into a stream running through the plaintiffs' property. *Id.*, ¶ 1, 204 P. at 906. But the plaintiffs themselves had contributed to that pollution by allowing their tenant, another oil company, to dump similar refuse that mixed with defendants' waste and "caused the pollution and damage complained of." *Id.*, ¶ 2, 204 P. at 907. The Supreme Court held that because the plaintiffs had contributed to the nuisance, they must apportion damages between themselves and the defendants if they wanted to hold defendants liable. Specifically, the court ruled that the plaintiffs must "produce evidence which will enable the court to separate the amount of damage inflicted by the group of defendants sued from the amount of damages resulting from the acts of the tenant," and that without such evidence, "*the plaintiff will not be entitled to recover from the*

defendants sued." *Id.*, ¶ 4, 204 P. at 908 (emphasis added). This requirement makes sense: Without it, plaintiffs would be able to extract money from defendants "not only for [defendants'] own acts, but for the acts of plaintiffs[.]" *Id.*; *see also City of Weatherford v. Luton*, 1941 OK 305, ¶ 5, 117 P.2d 765, 767 (plaintiff's contribution to nuisance "would not defeat his right to recover *for so much of the damage as was fairly attributable to the wrong of the [defendant]*" (quotation omitted) (emphasis added)).

Here, the State must account for how its own actions and decisions factored into the opioid abuse crisis. It has failed to do so and has bristled at the notion that its own actions played any role at all. But the record shows that State officials and agencies took steps—perhaps well-meaning ones—that exacerbated the crisis. And they failed to take other actions that would foreseeably have stanched the very oversupply problem the State alleges.

The State eased access to opioid medications. Through the 2000s, and as recently as 2016, Oklahoma agencies and officials took steps to ensure that doctors could freely prescribe certain opioids and that patients could fill those prescriptions without additional State oversight. Those actions made opioids more readily available in Oklahoma—and were designed to do just that. Materials prepared for Oklahoma's Drug Utilization Review Board ("DURB")[165] meetings suggest that, in 2000, the State *removed* duration limits that restricted Medicaid from

[165] The DURB is required under federal Medicaid guidelines and is "responsible for the development, implementation and assessment of retrospective and prospective drug utilization programs under the direction of the" Oklahoma Health Care Authority. 63 O.S. § 5030.1(A). The DURB makes "recommendations to the [Health Care] Authority regarding existing, proposed and emergency rules governing retrospective and prospective drug utilization programs." *Id.* § 5030.1(F). The State has presented no evidence that the Authority has ever rejected a DURB recommendation related to narcotic analgesics. June 26, 2019 (AM) Trial Tr. (White Test.) at 46:23-47:1 ("Q. Are you aware of a single recommendation related to narcotic analgesics ever made by the Drug Utilization Review Board that was rejected by the Health Care Authority? A. Related to narcotic analgesics only? I don't know.").

reimbursing prescriptions for more than a 30-day supply of commonly prescribed and abused opioids, including hydrocodone and oxycodone.[166] That, in turn, made it difficult for physicians to adequately monitor their patients' reaction to opioid therapy and allowed patients to obtain a staggering number of opioid pills from a single prescription. By 2003,[167] the number of OxyContin prescriptions in Oklahoma had skyrocketed[168] and State data showed an increase in deaths associated with the drug's active ingredient, oxycodone. [169] Indeed, DURB reviewed evidence of certain patients being prescribed and dispensed, a single prescription for more than 500 pills of OxyContin.[170] It reviewed other states' responses to OxyContin misuse and abuse, including requiring that patients get State authorization before filling any OxyContin

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[166] Janssen Ex. 710 at 54, DURB Packet (Feb. 8, 2001) (*admitted June 25, 2019*); June 25, 2019 (PM) Trial Tr. (White Test.) at 29:6-11.

[167] By 2001, the State had learned that OxyContin usage had "nearly doubled every year" since the drug's release in 1996 and that OxyContin had received "national attention due to the abuse that [was] being reported." Janssen Ex. 729, DURB Packet (Jul. 10, 2001) at 71-72 (*admitted June 26, 2019*). At least as early as 2002, the State knew that OxyContin "[t]ablets [were] crushed and ingested, snorted, or injected to circumvent controlled release mechanism and obtain full dose immediately." Janssen Ex. 2455, DURB Packet (May 14, 2002) (*admitted June 25, 2019*) at 45-46. The State had data in 2002 showing that between 2001 and 2002 there were thousands of OxyContin Medicaid claims for quantities that would provide users over two tablets per day, *id.* at 46, even though OxyContin was only indicated for twice daily use. Janssen Ex. 729, DURB Packet (Jul. 10, 2001) at 71 (*admitted June 26, 2019*); June 25, 2019 (PM) Trial Tr. (White Test.) at 13:11-21.

[168] At this time, the State had Medicaid data showing that from 2001-2002 to 2003-2004, the total number of persons receiving OxyContin increased 12.7 percent, total claims increased 18.4 percent, and total units prescribed increased 26.8 percent. Janssen Ex. 812, DURB Packet (Jul. 8, 2003) at 67 (*admitted June 25, 2019*); June 25, 2019 (PM) Trial Tr. (White Test.) at 58:13-61:2.

[169] Janssen Ex. 802, DURB Packet (Mar. 11, 2003) at 74 (*admitted June 25, 2019*) (DEA brief including in March 11, 2003 DURB meeting packet noting that DAWN data "indicate an increasing number of emergency department mentions and deaths associated with oxycodone").

[170] Janssen Ex. 2455, DURB Packet (May 14, 2002) (*admitted* June 25, 2019) at 46 (showing 3,381 claims for 69-120 tablets, 460 claims for 122-186 tablets, 144 claims for 200-280 tablets, 49 claims for 300 to 360 tablets, 19 claims for 420 to 480 tablets, and 2 claims for 500 to 560 tablets).

prescription. But the DURB twice rejected that recommendation.[171] The Oklahoma Attorney General's office lobbied against placing quantity limits on OxyContin, claiming it would have a "chilling effect" on pain treatment.[172]

The State also actively encouraged doctors to prescribe immediate-release opioids—including hydrocodone and oxycodone products such as Lortab, Vicodin, Percocet, and Norco—by placing them on the least-restricted tier of its three-tiered Medicaid formulary. SoonerCare, Oklahoma's Medicaid program, covered prescriptions for these Tier 1 drugs, often for 10 or more pills a day, without any prior authorization from the Health Care Authority.[173] But SoonerCare did require prior authorization for pricier Tier 2 and Tier 3 drugs, including Janssen's Duragesic and Nucynta products. SoonerCare would not cover those drugs unless patients jumped through several hoops, often including a 30-day trial with a lower-tier medication.[174] This tier system, imposed in 2008, had a predictable effect: Prescriptions for Tier 2 and Tier 3 drugs went down,[175] while prescriptions for less-restricted (but more frequently

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[171] In January 2003, the DURB voted "not to include Oxycontin for prior authorization." *Id.* at 16. In August 2003, when the DURB again considered whether Oklahoma Medicaid should place controls on OxyContin utilization, it failed to do so. *See* Janssen Ex. 815, DURB Packet (Aug. 12, 2003) at 64 (*admitted June 25, 2019*) (proposing seven potential options to "put controls on OxyContin utilization" ranging from requiring prior authorization on all OxyContin prescriptions to placing no restrictions on OxyContin use).

[172] Janssen Ex. 1522, DUR Packet for 2/11/2003 (*admitted June 25, 2019*) at 11-12 (summarizing DUR Board vote on SoonerCare formulary change requests for January 2003).

[173] *See* June 26, 2019 (AM) Trial Tr. (White Test.) at 74:2-15 (immediate-release opioids were placed into Tier 1); Janssen Ex. 1515, DUR Packet for 2/13/2013 at 29-30 (*admitted June 26, 2019*) (February 2013 DURB meeting materials showing that "Tier-1 products are covered with no prior authorization necessary").

[174] Janssen Ex. 1515, DUR Packet for 2/13/2013 at 29 (*admitted June 26, 2019*) (explaining the authorization requirements for each formulary tier).

[175] *Id.* at 30, 32 (showing that, after imposition of these controls in 2008, claims for extended-release drugs—all of which were Tier 2 or Tier 3 drugs—*decreased* from a peak of 3,000-3,500 per month to 2,000-2,500 per month).

abused and diverted) Tier 1 drugs jumped.[176] The State initially placed all extended-release opioid medications, including OxyContin, in Tier 2 and Tier 3. But in 2014, it agreed to "partner" with Purdue and by 2016 placed OxyContin in Tier 1—notwithstanding the State's characterization of Purdue as a criminal in this litigation—after Purdue offered the State a supplemental rebate, making the drug cheaper.[177]

The State delayed action to curb overprescribing and "doctor shopping." As the State took steps to ensure easy access to certain opioid medications, it also failed to take steps to curb overprescribing and diversion, despite having ample evidence of both. The State knew for years that hydrocodone and oxycodone were being abused and diverted, resulting in overdose deaths;[178] that doctors often prescribed (and SoonerCare often reimbursed) more than the maximum two-tablet daily dose of OxyContin;[179] and that many Oklahomans were "doctor shopping," seeking opioid prescriptions from several physicians at a time. Yet the State did not

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[176] *Id.* at 30, 32 (showing that, after imposition of these controls in 2008, claims for immediate-release drugs *increased* from a level between approximately 30,000-35,000 claims per month to 40,000-45,000 claims per month).

[177] Janssen Ex. 3757, November 21, 2014 email from K. Wade of the Oklahoma Health Care Authority to A. Zanetti of Purdue (*admitted June 26,* 2019) at 4 (noting that the Health Care Authority appreciated Purdue's "effort to offer additional rebates and partner with the state of Oklahoma"); Janssen Ex. 344, August 15, 2016 Dear Pharmacist Letter from SoonerCare (*admitted June 13, 2019*) (noting that OxyContin 10mg, 15mg, and 20mg strengths "are Tier-1 and available without prior authorization").

[178] Janssen Ex. 217, Email from D. Waiver to P. McNeil at 6 (*admitted June 25, 2019*) (September 22, 2006 OBN strategic plan for fiscal years 2008 to 2012 noting that "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.").

[179] Janssen Ex. 2455, DUR Packet for 5/14/2002 at 46 (*admitted* June 25, 2019) (showing 3,381 claims for 69-120 tablets, 460 claims for 122-186 tablets, 144 claims for 200-280 tablets, 49 claims for 300 to 360 tablets, 19 claims for 420 to 480 tablets, and 2 claims for 500 to 560 tablets).

meaningfully crack down on overprescribers or use existing State systems to spot doctor shoppers.

Until 2015, nearly two decades after the State-identified beginning of the opioid crisis, the State allowed physicians to prescribe narcotics without consulting its prescription monitoring program ("PMP")—a system designed to monitor prescriptions for controlled substances to reduce diversion. But State officials knew as early as 2008, seven years earlier, that the PMP could identify, and indeed *had identified*, "very alarming" statistics on "doctor shopping." And at this time, the State had data showing that 1,930 patients had obtained prescriptions for controlled substances from *five or more* doctors from July to September 2007.[180] "[The data] also show[ed] [Oklahoma] dispense[d] nearly 104 million doses of Hydrocodone per month—that's about 30 pills for every man, woman and child in Oklahoma each month."[181] Had the State not waited until 2015 to make the PMP mandatory, it could have suppressed doctor shopping and combated the widespread diversion of opioid medications.

Evidence at trial also demonstrated that the State has done little to prevent or discourage physicians and other healthcare providers from overprescribing. For example, the OBN found that Dr. Mickey Tyrrell committed prescribing violations or failed to maintain proper records of controlled substances prescribed to a particular patient who eventually died of an overdose. The OBN concluded that Tyrrell violated OBN's registration rules and the law.[182] But it did not revoke his prescribing privileges or suspend his license; instead, it fined him a mere $8,000 and

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[180] Janssen Ex. 637, Email re: OBNDD Prescription Drug Abuse Data at 10 (*admitted June 26, 2019*).

[181] *Id.* at 1. Fentanyl appeared nowhere on the list of frequently prescribed narcotics. *Id.* at 10.

[182] Janssen Ex. 600, *OBNDD v. Tyrrell* at 1-2 (*admitted June 26, 2019*).

suspended his prescribing privileges for just a month.[183] As another example, OBN suspended the license of voting DURB member and pharmacist James Swaim in 2004 because he failed to report that he filled fraudulent prescriptions for tens of thousands of opioids that were all "prescribed" by a doctor who did not exist.[184] OBN suspended his license for just 28 days, and Swaim—who had previously voted not to require prior authorization for OxyContin—remained on the DURB.[185] The State also waited years to take any action against known "pill mill" doctors like Harvey Jenkins,[186] Ronald Myers,[187] and Tamerlane Rosza.[188]

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[183] *Id.*

[184] June 26, 2019 (AM) Trial Tr. (White Test.) at 14:24-17:13.

[185] *See id.*

[186] The State had disciplined Jenkins in 2011 for abusing or excessively using opioids that he prescribed to himself. June 26, 2019 (AM) Trial Tr. (White Test.) at 83:25-84:9. But the State did not revoke his prescribing privileges at this time. Instead, the State spent years investigating Jenkins who appeared to be operating a pill mill. *See generally* Janssen Ex. 298, Final Order / State of Oklahoma v. Dr. Harvey Jenkins (*admitted June 26, 2019*). Only in 2015 did the State finally revoke his OBN registration, prevent him from reapplying for a new one for two years, and fine him $36,000. *See id.* at 24.

[187] The State had begun investigating Myers for improper prescribing behavior at least as early as 2007, when he prescribed an undercover investigator prescription opioids within 7 minutes of meeting her and without her providing him any medical records. Janssen Ex. 218, Okla. Bureau of Narcotics ACISS Investigative Supplemental at 6-9(*admitted June 25, 2019*). In 2013, the DEA was investigating Myers. Janssen Ex. 595, *OBNDD v. Ron Myers* at 6 (*admitted June 25,* 2019). From January 2013 to June 2014, Myers prescribed over 4.6 million dosage units of controlled dangerous substances. *Id.* at 8. And from 2010 to 2013, there were at least 8 to 10 patients of Myers's clinic who died of overdoses. *Id.* at 10. Yet it took the State until April 2015 to revoke Myers's OBN registration, prohibit him from reapplying for a new one for a year, and fine him $25,000. *Id.* at 24-25.

[188] As early as 1999, Rosza had been investigated for prescribing large amounts of controlled dangerous substances. Janssen Ex. 598, *OBNDD v. Rosza* at 11 (*admitted June 26, 2019*). In the mid-2000s, she started prescribing large amounts of promethazine with codeine and oxycodone, known in combination as the party drug "lean." *Id.* at 12. Her prescribing practices were so notorious that Rosza was known at this time as the "Queen of Lean." *Id.* She was also known as a doctor "to go to for easy access to controlled drug prescriptions," *id.* at 13, and was in the "top 1% of prescribers for all controlled drugs," *id.* at 17. Despite decades of warning signs of

Oklahoma has taken recently taken steps to curb opioid diversion and abuse, a commendable effort given the scale of those problems in the State and the toll they have taken on Oklahomans. But the State's recent efforts do not change the factual record of the past two decades. The State encouraged doctors to prescribe certain opioids, rejected calls for heightened scrutiny of opioid prescriptions, and failed to act on worrying statistics compiled by its own agencies.

The State's policies, then, have facilitated access to opioid medications in large quantities and with inadequate oversight, in ways that contributed to opioid abuse and misuse in Oklahoma. That is no surprise: As the FDA just recently underscored, opioids are valuable but risky medicines that pose difficult policy choices with no easy answers. But even if the State's lapses were well intended, to recover from Janssen, it 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 appears to deny all responsibility. Under *Walters*, that lack of evidence is fatal to its ability to recover from Janssen. The State might object to that result, but it was the State that chose to litigate responsibility for the opioid abuse crisis using an 1890 statute designed to address property-based disputes. That decision precludes the State from holding Janssen liable for a supposed nuisance that its own conduct aggravated.

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

Having failed to prove that Janssen caused it any injury whatsoever, the State cannot plug that hole by foisting liability on Janssen for conduct by Purdue, Teva, or any other manufacturer.

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improper prescribing, the State waited until 2015 to revoke Rosza's OBN registration and prohibit her from reapplying for a new one for three years. *Id.* at 27.

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. The State has made neither showing, and its attempt to impose liability drastically disproportionate to Janssen's alleged misconduct violates fundamental due process protections under federal and Oklahoma law.

A. The State Has Failed to Establish an Indivisible Injury

Throughout this case, the State has maintained Janssen must pay for the whole opioid abuse crisis because that crisis constitutes an indivisible injury. The State is wrong. In more than a century of joint and several liability cases, Oklahoma courts have found injuries indivisible in exactly four circumstances, none of which is present here: (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. Each of those injuries is ***conceptually*** indivisible—there is no way to tease them out into their constituent parts or allocate blame for them among different defendants. In other words, they are not "theoretically 'capable of apportionment.'" *United States v. NCR Corp.*, 688 F.3d 833, 838 (7th Cir. 2012).

The harms the State's trial evidence depicted fall "far[] afield" from those scenarios. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 101 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009). The State's primary evidence about Janssen's marketing consisted of call notes—informal notes of sales representatives' contacts with providers—to assert that

individual Janssen sales representatives influenced individual Oklahoma practitioners.[189] Craig Box, whose son died of a drug overdose, testified about the personal impact of that loss.[190] Others testified about their experiences with opioid use disorder.[191] The State's evidence, in other words, described individual doctors who allegedly misunderstood the safety and efficacy of opioid medications, and individual Oklahomans that the State claims suffered injury as a result. That is not a commingled stream or singular physical injury: it is a collection of separate harms, each with its own cause. Janssen's responsibility (or lack thereof) for any patient's addiction can be determined—not just theoretically, but practically—using ordinary causation principles that courts routinely apply in product liability cases. *See, e.g.*, *Timmons v. Purdue Pharma Co.*, 2006 WL 263602, at *4 (M.D. Fla. Feb. 2, 2006) (granting summary judgment for lack of causation on failure-to-warn and fraud claims alleging that inadequate warnings caused plaintiff's opioid addiction). Indeed, Courts have ***always required*** that sort of individualized proof in pharmaceutical-marketing cases. *See infra* Section IV.A.

Such evidence readily lends itself to an individualized analysis of individual harms: Did any Janssen sales representative's statement recorded in a call note cause a doctor to write an improper prescription that harmed an Oklahoma resident? Each individual injury has identifiable causes. And a claim that simply bundles such individual harms together is the definition of a divisible injury that can—and must—be apportioned. *See* Restatement (Second) of Torts § 433A

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[189] *See generally*, State Exs. 2481-2492, Select Janssen Call Notes (predominantly between 2000-2004); May 31, 2019 (PM) Trial Tr. (Deem-Eshleman) at 72:14-25 (discussing two call notes suggesting sales representatives sought to influence physician prescribing); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 48:7-19 (claiming Janssen sales representatives left doctors with "one-sided information").

[190] *See* May 29, 2019 (AM) Trial Tr. (Box Test.) at 12:6-14:21.

[191] *See* June 7, 2019 (AM) Trial Tr. (McGregor Test.) at 10:12-17; 13:6-14:21, 16:20-24, 19:3-8, 22:17-25, 32:21-24, 36:2-38:17; June 14, 2019 (AM) Trial Tr. (Hoos Test.) at 66:12-69:25.

("Damages are to be apportioned among two or more causes where … there are distinct harms.").

The State's refusal to present the individualized proof that would address those questions—or even to deliver the statistical analysis it promised earlier in the litigation—does not somehow transform its divisible injury into an indivisible one: Divisibility does not turn on a plaintiff's selection of evidence but on whether it suffered a "single injury." *Delaney*, 1944 OK 51, ¶ 6, 145 P.2d at 938. Nor does the State's choice to fashion a claim encompassing ***so many*** distinct harms that an individualized causation analysis would be difficult and time-consuming make its injuries indivisible. *See Cayuga Indian Nation of N.Y. 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"). Holding that the practical burdens created by the staggering size of the State's claim somehow compel joint and several liability would perversely reward the State for bringing sprawling suits too large to prove by conventional means. The State cannot first take away Janssen's individualized causation defenses and then exploit that maneuver to impose joint and several liability. In assessing the State's evidence, the Court should consider only those individual harms, if any, for which Janssen bears specific liability—it cannot shift blame for Purdue's, Teva's, or anyone else's conduct to Janssen.

B. The State Has Offered No Evidence of Concerted Conduct

The State has also failed to show the other potential ground for imposing joint and several liability, that Janssen operated in concert with those who caused the opioid crisis.

Even if it were legally to focus just on the manufacturers themselves, the State has offered no evidence of concerted conduct. Janssen is not Purdue. Janssen is not Teva. And the

State cannot use conduct by those other companies to fill the yawning gaps in its case against Janssen. The State's Petition did not allege a single concerted action between Janssen and those companies. At trial, after full discovery, the State presented no evidence remotely suggesting any relevant agreement between them. Instead, it presented evidence only of ordinary business dealings and advocacy activities. With no agreement to speak of, and only run-of-the-mill conduct to connect these independent actors, the State cannot hold Janssen liable for Purdue's and Teva's actions.

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 nothing of the sort. Noramco's sales of API to other manufacturers cannot qualify as "tortious acts" at all, *id.*, as federal regulators affirmatively authorized them and federal law preempts state-tort liability for them. *See supra* Sections III.C. And that aside, "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.); *see also United States v. Gee*, 226 F.3d 885, 893-94 (7th Cir. 2000) (mere buyer-seller relationship insufficient to establish agreement to commit unlawful act needed to find conspiracy); *United States v. Lennick*, 18 F.3d 814, 818-19 (9th Cir. 1994) (same). If sales of raw material alone sufficed to establish concerted action, all component suppliers would face broad liability for their customers' torts—an unjust outcome that the law rightly rejects. *See Swift*, 2013 OK CIV APP 88, ¶ 22, 310 P.3d at 1133

("Inappropriate 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.").

The State likewise cannot infer an unlawful agreement between Janssen and Purdue based on membership in trade and advocacy groups. *See, e.g.*, *NAACP*, 458 U.S. at 920 (holding that "[c]ivil liability may not be imposed merely because an individual belonged to a group, some members of which committed [wrongful] acts"). Attending trade association meetings, an activity conducted by countless companies, "provides no indication of conspiracy." *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"); *In re Asbestos Sch. Litig.*, 46 F.3d at 1287 (Alito, J.) (rejecting argument that defendant's membership in trade organization that allegedly disseminated misleading information about asbestos meant that defendant should be considered part of civil conspiracy and thus liable).

Joint lobbying efforts by the Pain Care Forum, too, amount to ordinary—and constitutionally protected—business conduct. *See, e.g.*, *Pennington*, 381 U.S. at 670 ("[j]oint efforts to influence public officials" are "not illegal, either standing alone or as part of a broader scheme"). Joint participation in such protected conduct cannot support tort liability. *See, e.g.*, *Snyder*, 562 U.S. at 460 (if allegedly tortious conduct is protected by the First Amendment, plaintiff "cannot recover for civil conspiracy based on those torts"); *Gaylord Entm't Co.*, 1998 OK 30, ¶ 42, 958 P.2d at 149 ("A conspiracy to carry on activity that is lawful and shielded by fundamental law cannot be deemed tortious.").

Finally, that Janssen and other drug manufacturers sometimes employed the same key opinion leaders or donated to the same advocacy groups again amounts to ordinary business conduct, not a tortious agreement.[192] If the State hopes to establish an unlawful agreement, "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007); *see also Theatre Enters., Inc. v. Paramount Film Distrib. Corp.*, 346 U.S. 537, 541 (1954) (even "consciously parallel" behavior, standing alone, is insufficient to prove conspiracy); *Salehpoor v. Shahinpoor*, 358 F.3d 782, 789 (10th Cir. 2004) (parallel action not enough to prove agreement); *Dill v. Rader*, 1978 OK 78, ¶ 8, 583 P.2d 496, 499 ("disconnected circumstances ... consistent with lawful purposes ... are insufficient to establish a conspiracy"). Rather, parallel conduct by competitors is "not only compatible with, but indeed [i]s more likely explained by, lawful, unchoreographed free-market behavior." *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009).

The State has presented materials about Purdue and Teva at trial not to demonstrate any tortious agreement, but to distract from a fatal flaw: The State cannot show that Janssen *itself* caused its injuries. Given the State's failure to present evidence of any actionable conduct by Janssen, the Court must enter judgment in Janssen's favor. No amount of evidence about other manufacturers can change that conclusion.

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

The State seeks a radical expansion of joint and several liability that would both defy Oklahoma law, and violate the Due Process Clause of the Fourteenth Amendment, which

[192] *See, e.g.*, June 12, 2019 (PM) Trial Tr. (Kolodny Test.) at 72:16-73:12 (testifying that Janssen "employed the same tactics [as] Purdue"); June 11, 2019 (PM) Trial Tr. (Kolodny Test.) at 50:18-51:12 (asserting that Purdue made comments "consistent" with Janssen's marketing).

"prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor." *Campbell*, 538 U.S. at 416. If Janssen is forced to pay every penny purportedly needed to address the opioid abuse crisis over the next three decades, its liability will be vastly disproportionate to its alleged fault. Making an individual defendant responsible for remedying a massive, multivariate, social problem that even the State alleges it only partly caused 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 Clause forbids this result.

While joint and several liability is a well-established part of the law, its application has always been confined to very particular circumstances, such as where defendants are acting in concert or multiple defendants are each the proximate cause of a single injury. *See, .e.g.*, *Kirkpatrick v. Chrysler Corp.*, 1996 OK 136, 920 P.2d 122, 126 (1996). The potential contributors to the nuisance alleged by the State here include (but are not limited to) individual treating physicians, including some acting with intentional criminality, medical schools who allegedly failed to properly teach medical students about pain management, individuals who passed their prescriptions to others illegally, and even the State's own policies. The State has not alleged that Janssen acted in concert with all of these tortfeasors and has failed to establish that they all proximately contributed to a single injury. If sprawling social problems, caused in substantial part by criminal action and the actions of the state itself, can be a "single injury," then so long as a single deep-pocketed defendant played even the smallest causal role in some part of the social problem, the State could recover all of the costs associated with the entire social problem from a single defendant.

Common-law courts were comfortable with joint and several liability because they expected that a small group of tortfeasors could allocate responsibility for the impact of a tort themselves, through a series of contribution and other actions. *See* Restatement (Third) of Torts: Apportionment Liab. §§ 22-23 (2000); Restatement (Second) of Torts 433B cmt. e (1965) (cases "all have involved a small number of tortfeasors, such as two or three"). But if Janssen is held responsible for the cost of the State of Oklahoma's entire abatement program, it has no meaningful prospect of contribution—no legal criteria exist to resolve contribution disputes between pharmaceutical manufacturers and dozens of pill-mill operators, drug distributors, and pharmacy owners over responsibility for a massive social crisis. That is so because the common law has never recognized tort liability—much less joint and several liability—for such sprawling and varied harms. The State's attempt to impose such a novel form of liability "wholly disproportioned to the offense," *BMW*, 517 U.S. at 575, violates basic due process protections, and the Court should reject it accordingly.[193]

[193] Imposition of excessive and disproportionate tort liability under the circumstances of this case would also violate the Eighth Amendment's prohibition on excessive fines. *See 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 *Browning–Ferris Industries of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257 (1989), the Supreme Court concluded that the Excessive Fines Clause does not limit damages awarded "to a private party in a civil suit when the government neither has prosecuted the action nor has any right to receive a share of the damages." *Austin v. United States*, 509 U.S. 602, 606 (1993). But here, despite being labeled a "civil" proceeding, this case is being prosecuted by the State, and the State stands to reap a windfall in damages. The Supreme Court has made clear that no matter the label (e.g., civil or criminal), the "Excessive Fines Clause limits the government's power to extract payments, whether in cash or in kind, as punishment for some offense." *Id.* at 609-10; *see also 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, and, conversely, that both punitive and remedial goals may be served by criminal penalties."). Damages and fines, moreover, pose a special risk because they "may be employed in a measure out of accord with the penal goals of retribution and deterrence, for fines are a source of revenue, while other forms of punishment cost a State money." *Timbs*, 139 S.Ct. at 689 (quoting *Harmelin v. Michigan*, 501 U.S. 957, 979, n.9 (1991)); *see also Harmelin*, 501 U.S. at 979 n.9

VII. THE STATE HAS FAILED TO PROVE ITS ENTITLEMENT TO ITS SOLE REQUESTED REMEDY

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

The Court must also enter judgment for Janssen because Oklahoma law does not authorize the only remedy the State seeks. The Oklahoma nuisance statute provides the State with just a single remedy: "abat[ing]" the "public nuisance." 50 O.S. § 11. The statute likewise makes plain that the "nuisance" the State can "abate" is the defendant's *conduct*—not the allegedly resulting harms: "A nuisance consists in unlawfully *doing an act, or omitting to perform a duty*." *Id.* § 1 (emphasis added). But here, the State's presentation at trial has confirmed that it does not seek to abate any "act" or "omi[ssion]" by Janssen. If it did, it could seek only to enjoin Janssen from its allegedly misleading marketing of opioid medications—a moot point, as Janssen stopped promoting opioid products altogether in 2015.[194] Instead, as its evidentiary presentation has made clear, the State aims to "abate the opioid epidemic"[195]—that

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(Scalia, J.) ("it makes sense to scrutinize governmental action more closely when the State stands to benefit"). Thus, where a State uses a civil suit to exact recompense and retribution from a party that far exceeds the actual harm caused by that party, the State's action violates both the Due Process and Excessive Fines Clauses of the U.S. Constitution.

[194] June 4, 2019 (AM) Trial Tr. (Deem-Eshleman Test.) at 44:21-46:3.

[195] *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 13, 2019 (PM) Trial Tr. (Kolodny Test.) at 21:5-7 (agreeing that "th[e] effects" in Oklahoma are what the State and Kolodny have "referred to as the opioid epidemic or crisis"); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 84:5-9 (testifying that the abatement plan is needed "[t]o fight this epidemic"); 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 (AM) Trial Tr. (White Test.) at 111:17-112:2 (claiming that "to abate the opioid crisis, we need to go back to the pre-'96 levels" of opioid prescriptions); 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").

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 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.

As Janssen's summary judgment motion and trial brief both explained in detail, Oklahoma law gives the State a single civil remedy in a public nuisance suit: abatement of the nuisance itself. In more than a century of Oklahoma public-nuisance cases, no court has ever granted the State any civil remedy other than abatement. To the contrary, public entities consistently request—and courts consistently grant—only injunctive relief to abate the nuisance itself. *See, e.g.*, *State ex rel. Field v. Hess*, 1975 OK 123, ¶¶ 1-3, 540 P.2d 1165, 1167; *Curlee v. State ex rel. Edmondson*, 1957 OK 72, ¶¶ 1-4, 309 P.2d 1064, 1064-65; *State ex rel. Whetsel v. Wood*, 1952 OK 175, ¶¶ 1-3, 248 P.2d 612, 613; *State ex rel. King v. McCurdy*, 1935 OK 412, ¶¶ 1-2, 43 P.2d 124, 124; *State ex rel. King v. Friar*, 1933 OK 501, ¶¶ 1-4, 25 P.2d 620, 621.

Here, the State ignores this well-settled precedent and seeks to abate an injury, not a nuisance. Oklahoma law distinguishes between a nuisance and its consequences. A "nuisance consists in unlawfully doing an act, or omitting to perform a duty." 50 O.S. § 1. By contrast, "'[d]amage' or 'injury', as ordinarily used in nuisance cases is the *result* of the nuisance." *Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 36. Put another way, "[n]uisance is a wrong, and damage is the result." *Oklahoma City v. Page*, 1931 OK 764, ¶ 10, 6 P.2d 1033, 1036; *see also Magnolia Petroleum Co. v. Wright*, 1926 OK 196, ¶ 3, 254 P. 41, 42 (government body's 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"

(emphases added)); *Atchison, Topeka & Santa Fe Ry. Co.*, 1928 OK 256, ¶ 10, 266 P. at 776 ("The defendant might abate its nuisance, but could not, by so doing, restore plaintiff's premises.").

This distinction between nuisance and injury precludes the State's requested remedy. The State can demand only that Janssen stop particular unlawful activity or start performing some particular duty, yet it has not done so. And for good reason: Janssen stopped promoting opioids in 2015, when it divested its Nucynta franchise. *See supra* Section IV.B. Thus, no "act or omission" remains for the State to abate. 50 O.S. § 1. Instead, the State advances an "abatement plan," demanding that Janssen pay for a grab bag of proposed programs that the State promises will target the opioid abuse crisis over the next 30 years.[196] Even the State's experts admit that this plan does not ask Janssen to do or stop doing anything.[197]

This brazen demand for cash exposes the State's "abatement plan" for what it really is: a straightforward attempt to recover nuisance damages—damages Oklahoma law does not permit the State to seek.[198] But the "damage" or "injury" that is "the *result* of the nuisance," is *not* a

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[196] *See generally* State Ex. 4734, Abatement Plan (*identified* June 25, 2019); *see also, e.g.*, June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 5:8-51:14 (opining about array of programs in State's proposed abatement plan); June 21, 2019 (AM) Trial Tr. (Hawkins Test.) at 5:24-61:19 (same); June 20, 2019 (PM) Trial Tr. (Hawkins Test.) at 118:11-122:15 (testifying about treatment services aspect of plan); June 20, 2019 (AM) Trial Tr. (Croff Test.) at 37:16-111:10 (describing various programs in plan); June 17, 2019 (PM) Trial Tr. (Beaman Test.) at 83:17-23 (testifying about medical education and other components of plan); June 6, 2019 (AM) Trial Tr. (Mazloomdoost Test.) at 25:6-13 (asserting that, to abate Oklahoma's opioid epidemic, the State will need to "chang[e] the culture of medicine" via a "concerted national effort").

[197] *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.").

[198] If this Court disagrees and concludes that the State's demand for cash payments represents nuisance abatement, the State would be required to establish its entitlement to relief by clear and convincing evidence. *See, e.g.*, *Edwards v. Bd. of Cty. Comm'rs of Canadian Cty.*, 2015 OK 58, ¶12, 378 P.3d 54, 59 ("the right to injunctive relief must be established by clear and convincing

nuisance. *Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 36. Thus, the State's demand for monetary recovery to address its alleged injuries amounts to a demand for damages, not the abatement of a "public nuisance." 50 O.S. § 11; *see also, e.g.*, *Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1029 (10th Cir. 2007) (applying Oklahoma law) ("one aspect of damages the victim of a temporary nuisance can recover is the cost of restoring the land to its former condition" (quotation marks omitted)); *Briscoe*, 1985 OK 43, ¶ 13, 702 P.2d at 37 ("costs of restoring the temporary abatable injury to the well site" are "damages"); *Thompson v. Andover Oil Co.*, 1984 OK CIV APP 51, ¶19, 691 P.2d 77, 83 ("Damages adjudged in an action predicated on a nuisance theory may include clean-up costs" (quotation marks omitted)). Because Janssen no longer promotes opioids, nothing remains for the State to abate—and because Oklahoma law allows the State to seek abatement only, nothing remains for the State to ask for.

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

The State requests a remedy unavailable not only under Oklahoma law but also in a bench trial—yet another reason this Court should grant judgment for Janssen on the State's public-nuisance claim. 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...."). "Where the Constitution provides that the right of trial by jury shall be inviolate, legislation must be both construed and strictly observed vigilantly in favor of the right." *Seymour v. Swart*, 1989 OK 9 ¶ 5, 695 P.2d 509, 511.

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evidence and the nature of the injury must not be nominal, theoretical, or speculative"). For the reasons explained throughout this brief, the State has not done so.

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. Far from being incidental, a cash recovery is the State's only aim.

To be sure, Oklahoma courts addressing *proper* nuisance-abatement actions have held that "[a] trial by jury is not required in suits brought for an injunction to suppress and abate a public nuisance." *Balch ex rel. Grisby. State*, 1917 OK 142, ¶ 3, 164 P. 776, 777. But, again, 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. *See supra* Section III.A; *Post v. Kingdom Hall of Jehovah's Witnesses*, 1955 OK 127, ¶ 3, 283 P.2d 528, 529 ("A court will not entertain an action to enjoin a party from doing that which he has already done."). Rather, the only "abatement" remedy the State seeks is a massive payment to create an array of government programs, *see supra* Sections III.A and VII.A, 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. That decision relied on *Oklahoma City v. Stewart*, 1919 OK 303, 184 P. 779, a nuisance suit where the water from a municipal storm system flooded the plaintiffs' land, *id.*, ¶ 1, 184 P. at 779. The Court affirmed a jury instruction allowing them to recover "the amount in money that it would take ***to repair the damages*** caused by the defendant," explaining that the instruction only "permit[ted] to recover only ***the actual damages suffered***." *Id.*, ¶ 8, 184 P. at 780 (emphasis added). Most recently, in *Briscoe v. Harper Oil Co.*, 1985 OK 43, 702 P.2d 33, the Supreme Court explained that, "'Damage' or 'injury,' as ordinarily used in nuisance cases is the ***result of***

the nuisance." *Id.*, ¶ 9, 702 P.2d at 36 (emphasis added). And money spent to abate such injuries is not abatement of a ***nuisance*** at all—it is the abatement of ***damages***. *See, e.g., id.* ("[D]amages adjudged in an action predicated on a nuisance theory may include temporary … injury to land.... Temporary damages … are by definition abatable.").

Unlike the State, the plaintiffs in those cases were entitled to collect damages to repair their injuries because Oklahoma law authorizes a "private person" to recover damages for "a public nuisance if it is specially injurious to himself." 50 O.S. § 10. More important, the plaintiffs in all three cases collected damages to restore their property ***only after a trial by jury***. *See Page*, 1931 OK 764, ¶ 26, 6 P.2d at 1039-40; *Stewart*, 1919 OK 303, ¶ 1, 184 P. at 779; *Briscoe*, 1985 OK 43, ¶ 9, 702 P.2d at 33. The State, like those plaintiffs, seeks to redress injuries it alleges Janssen caused. That is a demand for damages. *See Page*, 1931 OK 764, ¶ 10, 12, 6 P.2d at 1036 ("Nuisance is a wrong, and damage is the result."). Both federal and Oklahoma constitutional requirements foreclose it from proceeding without a jury. *See* Okla. Const. art. II, § 19; U.S. Const. amend. VII; *see also* 12 O.S. § 556.

Most clearly demonstrating that the State seeks no more than money damages are the billions of dollars of the abatement plan dedicated to services already funded by Medicaid and private insurance. For Oklahomans who already receive such services, those payments will change little—they represent only a cash transfer from Janssen to the State.

Jessica Hawkins admitted that Medicaid and private insurance already subsidize:

- Non-opioid pain therapies, for which the State demands $2.4 billion.[199]

[199] 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 &

- Screening, Brief Intervention, and Referral to Treatment services, for which the State demands $1.3 billion.[200]

- Prenatal screening services, for which the State demands $171 million.[201]

- Neonatal treatment services, for which the State demands $507 million.[202]

- Transportation services, for which the State demands $144 million.[203]

- Addiction treatment services for which the State demands $6.5 billion.[204]

In the end, about $11.1 billion of the $17.8 billion plan would pay for services that Medicaid and private insurance already cover. And that is to say nothing of the many additional elements of the

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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).

[200] 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).

[201] 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).

[202] 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.").

[203] 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).

[204] 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).

plan that that State or federal programs other than Medicaid currently fund.[205] In short, the overwhelming majority of the plan's elements contemplate little change in the status quo, but just a massive cash transfer from one party to another. That is damages; not equitable relief.

Indeed, Oklahoma law categorically bars the Attorney General from seeking any monetary recovery ***other*** than damages. The very same Oklahoma law that authorizes him to "initiate … any action in which the interests of the state … are at issue" also commands him to pay "into the State Treasury, immediately upon its receipt, all monies [he] receive[s] … belonging to the State." 74 O.S. § 18b(A)(11). That law controls any award in this case. And once such an award reaches the treasury, nothing can stop the legislature from appropriating the payday however it sees fit—not even the legislature itself, which must appropriate one year at a time, and cannot bind future legislatures to a 30-year abatement plan. *See* Okla. Const. art. X, § 23. An unconditional cash transfer to the treasury—the only form of monetary award the Attorney General can pursue—is not any kind of equitable relief. This Court cannot award it outside a jury trial.

[205] *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 (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).

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. In its opening argument, the State claimed that "only this Court has the power to look forward to fix this. You're the only one."[206] That gets it exactly backwards: Authorizing and funding decades of government spending programs to address daunting social problems is the work of legislatures—not courts. That is true not just under Oklahoma's Constitution, but in every state and the federal government: No American court is authorized to enact the kind of freewheeling policy prospectus that the State confuses for nuisance abatement.

Oklahoma's Constitution expressly divides government powers among three branches and strictly separates those powers. Okla. Const. art. IV, § 1. The Constitution provides that "the Legislative, Executive, and Judicial departments of government shall be separate and distinct," and no branch "shall exercise the powers properly belonging to either of the others." *Id.* 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 legislative power extends to "all rightful subjects of legislation," Okla. Const. art. V, § 36, including policies "to protect and serve the public health," *Cryan v. State*, 1978 OK 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 reserves these authorities 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.

[206] May 28, 2019 (AM) Trial Tr. (State Opening) at 69:10-11.

The Oklahoma Supreme Court's decision in *Oklahoma Education Association* illustrates the point. The plaintiffs there alleged that the State's funding of public education was inadequate to satisfy Oklahoma students' constitutional right to an adequate education. 2007 OK 30, ¶¶ 3-4, 158 P.3d at 1061-62. As relief, they sought an order directing the Legislature "to design, formulate, adopt, properly and adequately fund, and maintain a comprehensive system of educational funding." *Id.*, ¶ 5, 158 P.3d at 1062. The Supreme Court affirmed the dismissal of the suit with prejudice on separation-of-powers grounds. As the Court explained, the plaintiffs were "attempting to circumvent the legislative process by having th[e] Court interfere with and control the Legislature's domain of making fiscal-policy decisions and of setting ... policy." *Id.*, ¶ 25, 158 P.3d at 1066. And while the education-policy issues before it were "immeasurabl[y] ... importan[t]," the Court was "constitutionally prohibited" from granting the plaintiffs relief because it "would require th[e] Court to invade the Legislature's power to determine policy" and "override the constitutional restrictions placed on [the Court's] judicial authority." *Id.*, ¶¶ 25, 27, 158 P.3d at 1066.

This case presents an even more egregious violation of separation-of-powers rules. The State's abatement plan encompasses no fewer than 37 line items,[207] many of which include multiple sub-items; it asks this Court to fund all of them, at Janssen's expense, for decades into the future. It proposes disseminating the Screening, Brief Intervention and Referral to Treatment ("SBIRT") practice to 2,157 Oklahoma primary care and emergency practices, at a cost of $1.3 billion over 30 years.[208] It seeks $2.4 billion in funding for pain treatments from acupuncture to

[207] State Ex. 4734, Abatement Plan, Ex. 1, at 8 (*admitted June 24, 2019*).

[208] *Id.*, Ex. S-1, at 22.

yoga to chiropractic care to steroids.[209] It asks for $435 million to fund "community-based coalition[s] for prevention services,"[210] and another $298 million to "[e]stablish ... an academic addiction medicine department attending to addiction disorders, providing education and utilizing a comprehensive approach to behavioral health."[211] And much, much more. All told, its catalog of spending programs would have this Court authorize over $700 million in government expenditures ***every year*** from now until 2048, at a total cost of $17.8 billion.[212]

The plan resembles no judicial remedy ever issued by an American court. It is, from beginning to end, an appropriations bill, submitted to the Court rather than the floor of the Oklahoma legislature. But under the Oklahoma Constitution, the wisdom and necessity of a state agency's request to triple its annual budget is committed to the legislature. *See Okla. Educ. Ass'n*, 2007 OK 30, ¶ 20, 158 P.3d at 1065 ("The state's policy-making power is vested exclusively in the Legislature" and "includes ... fiscal policy"). This Court cannot authorize new spending programs or dictate how they will be funded without trespassing on the legislature's domain. *See, e.g., 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....").

Recognizing these basic separation-of-power limitations, courts around the country have held that courts cannot even ***award tort damages*** to compensate government entities for

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[209] *Id.*, Ex. S-1, at 24-25.

[210] *Id.*, Ex. S-1, at 30.

[211] *Id.*, Ex. S-1, at 45.

[212] *Id.*, Ex. S-1, at 11.

expenditures made in the performance of governmental functions. *See, e.g.*, *District of Columbia v. Air Fla., Inc.*, 750 F.2d 1077, 1080-81 (D.C. Cir. 1984); *State v. Black Hills Power, Inc.*, 354 P.3d 83, 85-87 (Wyo. 2015); *Town of Freetown v. New Bedford Wholesale Tire, Inc.*, 423 N.E.2d 997, 997-98 (Mass. 1981); *Walker Cty. v. Tri-State Crematory*, 643 S.E.2d 324, 327-28 (Ga. Ct. App. 2007); *Penelas v. Arms Tech., Inc.*, 1999 WL 1204353, at *2 (Fla. Cir. Ct. Dec. 13, 1999); *Bd. of Supervisors of Fairfax Cty. v. U.S. Home Corp.*, 1989 WL 646518, at *1-2 (Va. Cir. Ct. Aug. 14, 1989). Those cases recognize that "the question of whether the costs of providing the public service should be spread among all taxpayers or reallocated in some other manner necessarily implicates fiscal policy, and, therefore, falls within the special purview of the legislature, not [the courts]." *Walker Cty.*, 643 S.E.2d at 328.

The State's abatement plan encroaches on legislative authority more egregiously still, creating a raft of government initiatives out of whole cloth and financing them for decades into the future. If the Oklahoma legislature agrees that those programs are necessary and appropriate, it has the power to authorize and fund them. This Court does not.

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

The State's abatement plan is untenable for another reason: not even the State believes that its $17.8 billion wish list of proposed programs will "abate" the opioid abuse crisis. Rather, the abatement plan is the epitome of runaway government spending, a bureaucracy untethered from evidence-based metrics that will enjoy guaranteed funding, year after year, for a generation to come. No responsible legislator would endorse such a scheme, and no court should either.

To be clear, the Oklahoma nuisance statute does not actually allow the State to "abate" harms or injuries, such as the opioid abuse crisis. It can abate only the *conduct* that constitutes the public nuisance. *See supra* Section III.A. Regardless, the State has offered no proof that its

$17.8 billion abatement plan is necessary or sufficient to eliminate or even reduce the crisis itself. The State, instead, offers a laundry list of programs and services but no coherent explanation for how they will eliminate the crisis or what benchmarks will be used to measure their efficacy. Without any credible evidence that the abatement plan will abate anything, the Court must enter judgment for Janssen.

Abatement means "[t]he act of eliminating or nullifying." Black's Law Dictionary (11th ed. 2019). Under the common law, 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); *see In re Lead Paint Litig.*, 924 A.2d 484, 498 (N.J. 2007) ("the public entity, as the modern representative of the sovereign in public nuisance litigation, has only the right to abate"). For decades, Oklahoma caselaw has embodied this principle: Public entities consistently request injunctive relief that "eliminat[es] or nullif[ies]" the entirety of the offending conduct. *See, e.g.*, *Hess*, 1975 OK 123, ¶¶ 1-3, 540 P.2d at 1167, 1171 (injunction barring bookstore from displaying obscene materials); *Curlee*, 1957 OK 72, ¶¶ 1-4, 309 P.2d at 1064-65 (injunction barring hotel tenants from violating liquor laws on premises); *McCurdy*, 1935 OK 412, ¶¶ 1-2, 43 P.2d at 124-25 (injunction barring defendant from operating gas station on a public highway).

The catalog of government programs the State seeks here does not remotely resemble those injunctive remedies—and the State has presented no credible evidence it will "eliminat[e] or nullify[]" the opioid abuse crisis. The plan sets out the policy agenda of two Oklahoma Department of Mental Health and Substance Abuse Services administrators—Jessica Hawkins and Terri White—who propose a breathtaking range of government services, from a health information exchange to specialized drug courts to $2 billion for pain therapies like yoga,

physical therapy, and meditation.[213] *See supra* Section VII.C. Many of those programs go far beyond opioids.[214]

But the State failed to provide any evidence that its plan will nullify or eliminate its alleged injuries. To the contrary, the plan's annual funding structure assumes it will be *ineffective*. The State demands Janssen pay for the same services at approximately the same inflation-adjusted level—between $727,219,744 and $789,186,743 annually—every year from 2020 to 2048.[215] That demand assumes that ***nothing*** will improve: If the plan actually abated the problem of opioid abuse, that problem would not require the same level of funding in 30 years as it does in year two.[216] For example, Hawkins's testimony about the costs of addressing neonatal abstinence syndrome presupposes that the plan will never reduce the rate of children born with the condition.[217] Much of that sustained spending reflects the reality that huge swaths of the plan are not especially focused on opioid abuse—Hawkins admitted, for instance, that that the plan's

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[213] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 71:18-73:19; June 20, 2019 (PM) Trial Tr. (Hawkins Test.) at 106:5-9.

[214] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 80:11-13 (acknowledging that proposed screening program would encompass not only opioid medications but also other drugs and alcohol); June 20, 2019 (AM) Trial Tr. (Croff Test.) at 47:4-13 (agreeing that the university behavioral health programming in the State's abatement plan would extend to substances beyond opioids).

[215] *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).

[216] The first year of the plan will cost $870 million, which includes some first-year implementation costs. June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 58:17-23, 60:2-4.

[217] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 14:1-18 (cost of an "ordinary NAS birth" is estimated to be $63,200, and Hawkins multiplied that by an estimated 300 NAS births per year for 30 years to get total cost); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 28:22-29:10, 64:6-66:17 (acknowledging the future damages estimate for NAS is based on the assumption that the opioid nuisance is permanent and cannot be abated, and that that estimate matches the abatement cost calculation for NAS programming).

funding for extra school counselors would remain for all 30 years "even if opioid use or misuse among school kids in Oklahoma returned to pre-1996 levels."[218] But there is similarly "no plan reduction" for the requested naloxone distribution and education services,[219] the costs of grief-support services will not decrease no matter the reduction in opioid-related deaths,[220] and costs for treatment services (at $5.8 billion, the plan's most expensive component) will not decline.[221] It defies logic and common sense to suggest that the plan will abate the opioid abuse crisis but that, at the same time, the crisis will require the same massive and costly government interventions in 30 years.

The State also fails to offer any coherent explanation for how it will measure the abatement plan's efficacy. The reason is plain: it has no way to do so. As Hawkins admitted, "[t]here is not an evaluation plan yet to accompany this abatement plan."[222] While the State claims that it "*expects* to see outcomes in certain areas," it admittedly has no means to measure those outcomes.[223] And while the State's purported experts contend that the plan's goal is to

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[218] *Id.* at 96:8-19 (Hawkins agrees that the extra counselors put in place will remain for all 30 years of the plan at Janssen's expense "even if opioid use or misuse among school kids in Oklahoma returned to pre-1996 levels").

[219] June 24, 2019 (PM) Trial Tr. (Hawkins Test.) at 31:11-32:14.

[220] *Id.* at 43:5-11 ("The services do not go down over the 30 years. They are required.").

[221] *Id.* at 71:10-22 ("Q. And there's no reduction in the level of services over time because we take it right out to get to that 20-year total of $4.1 billion. Correct? A. Yes. Q. And $5 billion over 25 years. Correct? A. Yes. Q. And $5.8 billion over 30 years. Right? A. Yes.").

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

[223] *Id.* (emphasis added); *see also id.* at 68:16-25 ("So I'll reiterate that we do not yet have an evaluation plan for the full abatement plan. What would have to occur … is that each of these components of the plan would have to have an implementation and evaluation plan established for them. …But there are multiple outcomes that could be measures. I have not been part of the process of developing an actual evaluation plan where those are yet defined.").

return to "pre-1996 levels,"[224] some do not identify which "pre-1996 levels" the plan would measure and others do not know what those pre-1996 levels are.[225] If the purported experts who designed the abatement cannot explain what it is supposed to achieve, there is little reason to put faith in their 30-year projections. In fact, the State is not even sure the plan can work in that time. White has suggested that the abatement plan must be in place for "*over* 30 years."[226] Hawkins waffled on the issue—testifying both that she has "confidence" the abatement plan will achieve its goals in 30 years[227] and that it will take "*at least* 30 years" to abate the crisis.[228]

The abatement plan represents runaway bureaucratic ambition, unchecked by legislative and executive constraints that typically impose accountability on government programs. It relies on the say-so of State employees who could not explain what they mean by abatement, and equivocated on whether the plan will work within its prescribed timeframe. That is not proof of "abatement" by a preponderance of the evidence. And it is no basis to make Janssen pay billions of dollars to the State.

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[224] *Id.* at 67:22-24 ("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.").

[225] June 26, 2019 (AM) Trial Tr. (White Test.) at 111:1-16 (White testifying that everyone should "agree we should go back to pre-'96 [supply] levels, and that those are numbers we could use. Do I have those numbers sitting here? I don't[.]"); June 24, 2019 (AM) Trial Tr. (Hawkins Test.) at 72:4-14 (Hawkins testifying that "we can return to pre-1996 levels" of high-school misuse of painkillers, but admitting that she has not studied what those levels are).

[226] June 26, 2019 (PM) Trial Tr. (White Test.) at 129:19-130:1 (emphasis added).

[227] June 21, 2019 (PM) Trial Tr. (Hawkins Test.) at 67:22-24 ("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.").

[228] *Id.* 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.").

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 3, 2019

Respectfully submitted,

By: _____

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CERTIFICATE OF MAILING

Pursuant to OKLA. STAT. tit. 12, § 2005(D) and agreement with the other parties, this is to certify on July 3, 2019, a true and correct copy of the above and foregoing has been served via email to the following:

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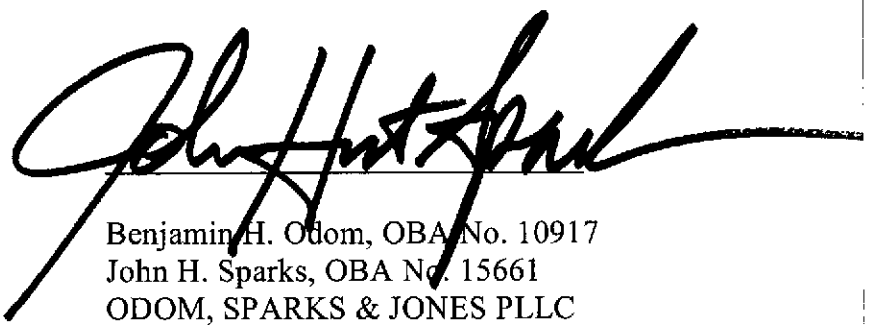

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