IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

STATE OF OKLAHOMA ex rel. MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA Plaintiff / Appellee / Counter-Appellant, vs. JOHNSON & JOHNSON PHARMACEUTICALS, INC.; ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC. Defendants / Appellants / Counter-Appellees and PURDUE PHARMA L.P., THE PERDUE FREDERICK COMPANY; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC. Defendants.	)	Case No. 118,474

BRIEF *AMICUS CURIAE* OF GOLDWATER INSTITUTE IN SUPPORT OF DEFENDANTS/PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The Goldwater Institute ("GI") was established 30 years ago as a nonpartisan public policy and research foundation devoted to advancing the principles of limited government, individual freedom, and constitutional protections through litigation, research, policy briefings and advocacy. Through its Scharf-Norton Center for Constitutional Litigation, GI litigates and files *amicus* briefs when its or its clients' objectives are directly implicated. GI has appeared in this Court representing parties or as *amicus curiae* defending freedom of speech in medicine and addressing the constitutional problems with "public nuisance" lawsuits. *See, e.g.*, *Merck & Co. v. U.S. Dep't of Health & Human Servs.*, 962 F.3d 531 (D.C. Cir. 2020); *Hopi Tribe v. Ariz. Snowbowl Resort Ltd. P'ship*, 430 P.3d 362 (Ariz. 2018).

As part of its mission, GI has established its Truth in Medicine project, devoted to promoting the free flow of pharmaceutical information among manufacturers, physicians, and payers to achieve the best care for patients. GI has championed the Truth in Medicine Act, now law in Arizona and Tennessee, and GI scholars have published important scholarly research and analysis on the importance of free speech in medicine, *see, e.g.,* Naomi Lopez Bauman and Christina Sandefur, *Restoring Free Speech in Medicine* (Goldwater Institute, 2017);[1] Mark Flatten, *Gagged: Feds Use Criminal Charges, Threats to Silence Drugmakers* (Goldwater Institute, 2019),[2] as well as the way "public nuisance" lawsuits are abused in ways that violate the Constitution. *See* Timothy Sandefur, *The Right to Earn a Living* 239-45 (2010). GI believes its litigation experience and policy expertise will aid this Court in consideration of this case.

[1] https://goldwaterinstitute.org/wp-content/uploads/2017/06/Restoring-Free-Speech-in-Medicine-Policy-Paper.pdf
[2] https://goldwaterinstitute.org/wp-content/uploads/2019/02/Gagged-Report-2019-02-26-Flatten.pdf

INTRODUCTION AND SUMMARY OF ARGUMENT

The concept of "public nuisance" is so vague that there is *no* legal consensus on what the phrase actually means. Absent some objective limiting principle, the tort itself would become an unconstitutionally vague law against "bad behavior." To avoid that outcome, courts have cabined the concept by imposing objective standards that fit within the Constitution and give people sufficient warning of what actions are prohibited. But here, the trial court did the opposite. It found liability based on the defendants' speech—without distinguishing between who said what, or what speech was commercial or non-commercial, or what speech was misleading or only potentially misleading—and as a result, it exploited the vagueness of "public nuisance" to punish businesses that engaged in lawful acts. This violates both the freedom of speech and the principles of due process.

If left undisturbed, the decision below threatens legal predictability and economic stability in Oklahoma, and, as the Rhode Island Supreme Court has warned, it risks "open[ing] the courthouse doors to a flood of limitless [lawsuits] … against a wide and varied array of other commercial and manufacturing enterprises and activities … . 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 non-defective, lawful product or service, and a public nuisance claim would be conceived and a lawsuit born." *State v. Lead Indus. Ass'n*, 951 A.2d 428, 457 (R.I. 2008) (citations and quotation marks omitted).

But this case threatens more than economic harm: it risks depriving patients suffering from incurable pain of the medicines they need. Most shockingly, the trial court endorsed a proposition voiced by one witness who said "not everyone deserves pain medicine." Final

Judgment (FJ) at 21 ¶ 57. This inhumane proposition is contrary to Oklahoma public policy and should not guide the determination of this case. The judgment should be reversed.

ARGUMENT

I. Public nuisance is a dangerously vague concept and must be carefully limited.

A. Due process requires that the law be clear enough that people can know what is forbidden.

A basic element of the rule of law is that people must be able to know what is proscribed. If a law "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits," it violates the certainty requirement inherent in Due Process of Law. *Hill v. Colorado*, 530 U.S. 703, 732 (2000); *Combs v. State*, 536 P.2d 373, 375–76 (Okla. Crim. App. 1975). Of special importance is the legislature's obligation to "establish minimal guidelines to govern law enforcement" to avoid giving officials the "standardless" power to "pursue their personal predilections." *Edmondson v. Pearce*, 91 P.3d 605, 630 ¶48 (Okla. 2004) (citations and quotation marks omitted).

Although most cases involving the "constitutional requirement of definiteness," *Estep v. State*, 562 P.2d 905, 908 (Okla. Crim. App. 1977), have dealt with criminal statutes, the definiteness requirement also applies to civil matters that bear significant penalties, *Sessions v. Dimaya*, 138 S.Ct. 1204, 1212–13 (2018), and to common-law causes of action, including nuisance. For example, in *Grove Press Inc. v. City of Philadelphia*, 418 F.2d 82 (3d Cir. 1969), authorities tried to use the public nuisance doctrine to prohibit the showing of an allegedly obscene film. The court found that this violated the due process rule against vagueness. *Id.* at 87. Terms like "injury to the public" and "unreasonableness" were "too elastic and amorphous" to satisfy the requirement of definiteness, the court said; in fact, the court described public

nuisance as a "sprawling doctrine" that "sweep[s] in a great variety of conduct under a general and indefinite characterization." *Id*. at 88 (citation omitted).

Similarly, in *Grayned v. City of Rockford*, 408 U.S. 104 (1972), a protestor was convicted of violating a noise-abatement ordinance that prohibited the making of "any noise or diversion which disturbs or tends to disturb the peace or good order" of a nearby school campus. *Id*. at 108. The protestor claimed the law was unconstitutionally vague. While rejecting this claim, Justice Marshall explained that "a basic principle of due process" requires that the law "clearly define[]" its "prohibitions." *Id.*

As a matter of legal theory, it makes sense that the definiteness requirement would apply to public nuisance, because that tort occupies a vague twilight zone between criminal and civil law. At common law, it was a *criminal* theory. *Lead Indus. Ass'n*, 951 A.2d at 444. As recently as 1910, it was considered a criminal law concept in Oklahoma. *Stewart v. State*, 109 P. 243, 246 (Okla. Crim. App. 1910). Today it is generally considered civil—or "tort-like," *Nichols v. Mid-Continent Pipe Line Co*., 933 P.2d 272, 276 (Okla. 1996)—yet it still overlaps with criminal law, e.g., in *Connick v. Lucky Pierre's*, 331 So.2d 431 (La. 1976), in which a bar was accused of being a public nuisance because it was a place where prostitution was likely to occur. The Louisiana Supreme Court held that using public nuisance theory in this way transgressed the void-for-vagueness rule. *Id*. at 435. But even where civil law matters involve significant takings of liberty or property, due process requires clarity. *See Sessions*, 138 S.Ct. at 1212–13. The Supreme Court has applied the definiteness requirement to purportedly "civil" law causes of action, including public nuisance, that involve the imposition of monetary liability. Both *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Automotive*

Insurance Co. v. Campbell, 538 U.S. 408 (2003), held that due process limits the liability states may impose on defendants under common law tort theories.

As with statutes, common law claims must be guided by standards that allow people to know what is and is not sanctioned by law. This is especially—though not exclusively—true where, as in this case, the liability infringes on freedom of speech. *Grayned* and *Grove Press* were cases in which expression—a public protest in *Grayned* and a film in *Grove Press*—was characterized as a public nuisance by government officials. Likewise, in *Rubin v. City of Santa Monica*, 823 F.Supp. 709 (C.D. Cal. 1993), the plaintiffs challenged the constitutionality of an ordinance that required a permit whenever a group of 35 persons assembled in a city park. The ordinance declared that the license would not be granted if the assembly constituted a "public nuisance." *Id*. at 710. The court found this too ambiguous because the statute did not define "public nuisance." *Id*. at 713.

Some jurisdictions have ruled that a greater degree of vagueness is tolerable in the realm of business regulations than in other areas of the law, but Oklahoma has not adopted this rule. *See, e.g., Bonnell, Inc. v. Bd. of Adjustment of City of Oklahoma City*, 791 P.2d 107, 110 (Okla. App. 1989) (applying vagueness analysis to business regulation); *Woods Dev. Co. v. Meurer Abstract & Title Co*., 712 P.2d 30, 35 (Okla. 1985) (same). Even if it had, courts have made clear that "fair warning should be given to the world in language that the common world will understand" of what rules businesses must follow. *Arthur Andersen LLP v. United States*, 544 U.S. 696, 703 (2005) (citations omitted). And as Justice Gorsuch recently noted, there is "no good [reason]" for allowing vague civil laws—which carry severe penalties—while vigilantly policing against vagueness in other realms. *Sessions*, 138 S.Ct. at 1231 (Gorsuch, J., concurring).

B. Nobody knows what a public nuisance is.

"[N]o other tort is as vaguely defined or poorly understood as public nuisance." D.G. Gifford, *Public Nuisance as A Mass Products Liability Tort*, 71 U. Cin. L. Rev. 741, 774 (2003). The term "has meant all things to all people, and has been applied indiscriminately to everything from an alarming advertisement to a cockroach baked in a pie. There is general agreement that it is incapable of any exact or comprehensive definition." *Prosser and Keeton on Torts* § 86 at 616 (5th ed. 1984). The precedent regarding public nuisance has been described as a "'wilderness,'" H.G. Wood, *A Practical Treatise on the Law of Nuisances* iii (3d ed. 1893); an "'impenetrable jungle,'" Prosser and Keeton, *supra*; a "mystery," W.A. Seavey, *Nuisance: Contributory Negligence and Other Mysteries*, 65 Harv. L. Rev. 984, 984 (1952); a "legal garbage can," W.L. Prosser, *Nuisance Without Fault*, 20 Tex. L. Rev. 399, 410 (1942); and a "quagmire," J.E. Bryson & A. MacBeth, *Public Nuisance, The Restatement (Second) of Torts, and Environmental Law*, 2 Ecology L.Q. 241, 241 (1972). Justice Blackmun said that courts have "searche[d] in vain" for "anything resembling a principle in the common law of nuisance." *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1055 (1992) (Blackmun, J., dissenting).

Definitions in case law have often been unhelpful, typically amounting to little more than a prohibition on bad conduct. *See, e.g., Donaldson v. Cent. Ill. Pub. Serv. Co.*, 767 N.E.2d 314, 337 (Ill. 2002) (defining public nuisance as "the doing of or the failure to do something that injuriously affects the safety, health or morals of the public, or works some substantial annoyance, inconvenience or injury to the public." (citation omitted)). As the Fourth Circuit has put it, the public nuisance tort operates "at such a level of generality as to provide almost no standard of application." *N.C., ex rel. Cooper v. Tenn. Valley Auth.*, 615 F.3d 291, 302 (4th Cir.

2010). Oklahoma's statutory definition is no clearer; it prohibits any act that "annoys" others or "offends decency," among other things. 50 Okla. St. § 1.

Simply put, no lawyer can define public nuisance with certainty.

Judges and scholars have therefore labored to formulate an objective definition of the concept, to avoid the unconstitutionality that would otherwise result. Oklahoma courts, for instance, have observed that the determination of public nuisance requires "sound judgment and … common sense in each case," *McPherson v. First Presbyterian Church of Woodward*, 248 P. 561, 565 (Okla. 1926), and have rejected efforts to expand the tort to encompass, e.g., smoking in a private home, by requiring that an act be unlawful before it may be deemed a public nuisance. *Nuncio v. Rock Knoll Townhome Vill., Inc*., 389 P.3d 370, 374 (Okla. Civ. App. 2016).

Courts frequently employ "saving construction[s]" to avoid determining that a law is unconstitutional, particularly to avoid voidance for vagueness. *See, e.g., Cherokee News & Arcade, Inc. v. State*, 533 P.2d 624, 627 (Okla. Crim. App. 1974); *Skilling v. United States*, 561 U.S. 358, 411-12 (2010). The authors of the *Restatement (Second) of Torts* (1998) made an effort to define public nuisance as conduct "actionable under the principles controlling liability for negligent or reckless conduct or for abnormally dangerous activities." *Id*. at § 821B cmt. e. Such limits are important because "[t]he handful of principles governing the tort of public nuisance were never intended to govern any unreasonable harm that might result from human interaction, nor are they adequate for such a daunting task." Gifford, *supra*, at 833. And they prevent public nuisance from being exploited as a legal weapon against whatever activity a public official decides contributes to a bad state of affairs.

C. States have increasingly abused "public nuisance" due to its vagueness.

The danger of an overbroad definition of public nuisance is plain. Absent objective rules limiting liability, the concept can become a catch-all rule against whatever government officials, or even individual citizens, decide is bad behavior.

In several states, public officials have sued gun manufacturers on the theory that marketing firearms—even though perfectly lawful—is a public nuisance because it contributes to violence. In *James v. Arms Technology, Inc.*, 820 A.2d 27 (N.J. Super. Ct. App. Div. 2003), the court allowed such a suit to proceed on the grounds that gun makers "foster[ed] an illegal secondary gun market," *id*. at 52, and this caused the government to spend money to provide "governmental services." *Id*. at 33. The court found that simply selling firearms that people later used to commit crimes made the manufacturers participants in "an illegal, secondary market" for guns that harmed the public generally. *Id*. at 53 (citation omitted). *See also City of Cincinnati v. Beretta U.S.A. Corp*., 768 N.E.2d 1136, 1141–44 ¶¶ 7–16 (Ohio 2002) (allowing public nuisance case against gun-makers).

The California attorney general sued General Motors on a public nuisance theory, arguing that selling cars constituted a public nuisance, despite the fact that cars are legal, because cars contribute to environmental pollution. That case was dismissed, *People v. General Motors Corp*., No. C06-05755-MJJ, 2007 WL 2726871 (N.D. Cal., Sep. 17, 2007), but a similar case in the Fifth Circuit, brought by landowners who claimed that oil companies contributed to global warming and thereby worsened the effects of hurricanes—and that this led to the damage of their properties—was allowed to proceed. *Comer v. Murphy Oil USA*, 585 F.3d 855 (5th Cir. 2009), *appeal dismissed*, 607 F.3d 1049 (5th Cir. 2010). And the California Court of Appeal allowed plaintiffs to sue paint companies on a public nuisance theory for having sold lead paint (when it

was legal), on the grounds that homes that have since deteriorated now present environmental hazards. *People v. ConAgra Grocery Prods. Co*., 227 Cal.Rptr.3d 499 (App. 2017), *cert. denied*, 139 S.Ct. 377 (2018). There have even been efforts to sue McDonald's on the grounds that selling fast food is a "public nuisance" because it leads to obesity. *Pelman v. McDonald's Corp*., 396 F.3d 508 (2d Cir. 2005).

Such abuses led the Illinois and Rhode Island Supreme Courts to warn against expanding the public nuisance concept to impose liability on manufacturers for the misuse of products or general social harms caused by people over whom the defendants had no control. In *City of Chicago v. Beretta U.S.A. Corp*., 821 N.E.2d 1099, 1124–25 (Ill. 2004), the city sued gun makers for selling guns because they contributed to the problem of gun violence. The court rejected the argument. It began by noting that because "the concept [of public nuisance] 'elude[s] precise definition,'" *id.* at 1110, courts must insist upon objective proof of *causation* and *control*—that is, proof the defendant caused the harm and/or controlled the persons or things that caused the harm. *Id.* at 1127–32. To do otherwise would risk "impos[ing] public nuisance liability for the sale of a product that may be possessed legally by some persons, in some parts of the state." *id.* at 1121. Even more to the point, the Rhode Island Supreme Court warned against exploiting the vagueness of public nuisance in ways that would transform it into "'a monster that would devour in one gulp the entire law of tort.'" *Lead Indus. Ass'n*, 951 A.2d at 457 (citation omitted).

In this case, the vague contours of "public nuisance" are especially worrisome because, as explained in the next section, the acts complained of consist of speech. In cases where "public nuisance" intersects with speech, courts must be *especially* vigilant to ensure against vagueness. *Grove Press Inc., supra; Grayned, supra; People v. Sequoia Books, Inc*., 537 N.E.2d 302 (Ill. 1989). The decision below failed to address these concerns and therefore should be reversed.

II. Imposing liability based on persuasion is a violation of free speech.

In *In re Nat'l Prescription Opiate Litig*., No. 1:17-md-2804, 2019 WL 3737023, at *6 (N.D. Ohio June 13, 2019), the court laid aside the concerns about the vagueness of public nuisance expressed by *City of Chicago v. Beretta U.S.A. Corp*., and *Lead Indus. Ass'n* on the grounds that the plaintiffs in opioid marketing cases like this one allege not that the products were faulty, but that the defendants acted badly when marketing them. But this purported distinction fails because (a) gun cases like *City of Chicago v. Beretta U.S.A. Corp*. did, in fact, involve marketing; (b) the defendants' marketing here consisted of speech; and (c) the trial court failed to specify who said what and what speech was punishable and what was not. It therefore either imposed liability on constitutionally protected speech, or it imposed liability on some defendants for the acts or omissions of others. This is constitutionally unsustainable and will have harmful consequences.

A. The trial court erred in concluding that the speech in question is "commercial" and therefore non-protected.

The trial court concluded that the defendants' speech was "commercial in nature," and "therefore not protected speech under the First Amendment." FJ at 28 ¶ 15. This was reversible error for two reasons.

First, "commercial speech" does not mean all speech that has a commercial purpose; it specifically means speech that "does *no more than* propose a commercial transaction." *Bolger v. Youngs Drug Prod. Corp*., 463 U.S. 60, 66 (1983) (citations omitted; emphasis added). In fact, it is limited to speech proposing a commercial transaction *with the speaker*. *Roberts v. U.S. Jaycees*, 468 U.S. 609, 634 (1984) (O'Connor, J., concurring). Speech *about* commerce is not necessarily "commercial speech." Only speech that *solely* proposes a transaction is "commercial speech." *Bolger* made clear that courts must "examine[] [the speech in question] carefully to

ensure that speech deserving of greater constitutional protection is not inadvertently suppressed" by lumping commercial speech in with noncommercial speech. 463 U.S. at 66. In fact, that case concerned informational pamphlets about medicines, and found that even though they were created with a commercial motive and addressed one specific product, they were *not* commercial speech. *Id.*

Second, commercial speech *is* protected by the First Amendment. While it receives less protection than other types of speech, the Court has never suggested that it *lacks* constitutional protection. On the contrary, the Court has made clear that restrictions on commercial speech must "not [be] more extensive than is necessary to serve [the government's] interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

Yet the trial court swept all the speech upon which it predicated liability into the category of "commercial," which it characterized as wholly without constitutional protection. Thus it lumped together perfectly legal speech with speech it deemed misleading, disregarding constitutional standards. For example, it found that defendants helped fund a group that offered continuing medical education (CME) events regarding painkillers, FJ at 15 ¶ 39, and that "CME materials" for this program contained "misleading statements." *Id.* at 16 ¶ 41. But a CME cannot in *any* respect be deemed commercial speech, since it did not propose any commercial transactions at all. *See Bolger,* 463 U.S. at 66. And there was *no evidence* that speakers such as Johnson & Johnson had any control *whatsoever* over what was said at the CME program.

The trial court's blanket classification of all of the speech as commercial and disregard of who said what was legal error. If it was "legally or practically impossible" for the court "to separate out the commercial and noncommercial elements of [the] speech," then the court was obligated to treat the speech as a whole—and the whole "gets the benefit of the *higher* standard

of scrutiny applicable to *noncommercial* speech." *Jordan v. Jewel Food Stores, Inc.*, 743 F.3d 509, 521 (7th Cir. 2014) (emphasis added). *See also Reagan Nat'l Advert. of Austin, Inc. v. City of Austin*, No. 19-50354, 2020 WL 5015455 at *10 (5th Cir. Aug. 25, 2020) ("Where 'the component parts of a single speech are inextricably intertwined…we apply our test for fully protected expression.'" (citation omitted)). On the other hand, if the court *could* separate the speech into commercial and non-commercial elements, it was obligated to do so to protect the noncommercial speech. *Bolger*, 463 U.S. at 66.

Yet with a record encompassing speech by *thirteen* corporate defendants over the course of "at least" *thirty years*, FJ at 4 ¶ 4, the trial court made *no* specific findings about what precisely was false in the statements of multiple defendants. In some places it found that marketing materials were "later described" as false by the FDA, *id.* at 13 ¶ 31; elsewhere it asserted that the speech was *potentially* misleading[3] because defendants failed to give satisfactory emphasis to certain risks, or "overstate[d]" efficacy (e.g., *id.* at 17 ¶ 44, 19 ¶ 50); in other places it merely insinuated that speech was false—for example, FJ at 10 ¶ 19, where it found that defendants "promot[ed] … the concept that chronic pain was undertreated," but never found that chronic pain was *not* undertreated.

[3] The trial court failed to distinguish between *actually false* commercial speech and *potentially misleading* commercial speech, despite the fact that First Amendment jurisprudence requires such a distinction. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002). For instance, the court refers to the defendants "taking data out of context to deliver misleadingly incomplete impressions," FJ at 17 ¶ 44, and "downplay[ing] the risk of addiction and overstat[ing] the efficacy of opioids," *Id.* at 19 ¶ 50, which mean that the statements were not actually false, but could give the wrong impression. The Supreme Court has made clear that states may not ban or punish *potentially* misleading speech, because that would exceed the tailoring requirement of First Amendment law. *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 109-10 (1990).

This lack of precision is totally incompatible with free speech jurisprudence. The consequence is a vague ruling that chills legitimate speech and will worsen outcomes for patients.

Consider just a few examples:

1) The court concluded that the defendants tried to "convinc[e] physicians that undertreated pain was harming patients," and "promot[ed] … the concept that chronic pain was undertreated," FJ at 10 ¶ 19, but made *no* finding that undertreated pain does *not* actually harm patients, or that chronic pain is *not* undertreated. In other words, the court implies that there is something untrue and deceptive about the assertion—without ever finding that it is actually false.

In reality, it is *not* false: **chronic pain *is* undertreated in the United States**, meaning countless Americans are needlessly suffering, unable to obtain medicines to alleviate their agony. *See, e.g.*, M. Coggins, *Undertreating Pain,* Today's Geriatric Medicine, Mar./Apr. 2014[4]; O. Bassat, et al., *Chronic Pain is Underestimated and Undertreated in Dialysis Patients: A Retrospective Case Study*, Hemodialysis International, Feb. 2019[5]; R. Piana, *U.S. Cancer Patients Still Plagued by Undertreated Pain,* Cancer Network, June 1, 2008.[6]

Responsible physicians nationwide have warned that the crackdown on pain prescribing is already causing doctors to withhold medicine from suffering patients. *See* K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. Kan. L. Rev. 961, 973–77 (2019). The American Medical Association (AMA) recently criticized the Centers for Disease Control (CDC) for issuing rules to restrict pain prescriptions, noting "the lack of evidence that these limits have improved outcomes

[4] https://www.todaysgeriatricmedicine.com/archive/032414p8.shtml
[5] https://onlinelibrary.wiley.com/doi/abs/10.1111/hdi.12736
[6] https://www.cancernetwork.com/view/us-cancer-patients-still-plagued-undertreated-pain

for patients." *AMA Urges CDC to Revise Opioid Prescribing Guideline,* June 18, 2020.[7] The AMA found that restrictions like those offered by the CDC "have increased stigma for patients with pain and have resulted in legitimate pain care being denied to patients." *Id.*

In any event, the speech by which the defendants sought to "convince" and "promote" ideas was at least a blend of commercial and noncommercial speech—and at most a blend of true and *potentially* misleading speech—and the trial court made no effort to distinguish between these things.

2) Nor is "promotion" or "convincing" people of things unlawful—even if the things the speaker is trying to promote or convince people of turns out later to be untrue. The trial court made ***no* finding that specific defendants *knowingly* sought to convince people of untrue things** for private gain—a finding that would have supported a conclusion of fraud or false advertising. On the contrary, it found that the scientific studies and marketing materials in question were "*later* described as false and misleading by the FDA," FJ at 13 ¶ 31, a finding the court was able to fit within the vague contours of the concept of "public nuisance."

Similarly, the decision below repeatedly insinuated that the phenomenon of "pseudoaddiction" was manufactured as a deceptive marketing device, when in reality it is a genuine theory the medical community is still evaluating.[8] Although "the concept *may* have

[7] https://www.ama-assn.org/press-center/press-releases/ama-urges-cdc-revise-opioid-prescribing-guideline

[8] *Addiction* is defined as compulsive use (or engagement in an activity, i.e., gambling, eating) despite negative consequences. *See* American Society of Addiction Medicine, *Definition of Addiction*, https://www.asam.org/Quality-Science/definition-of-addiction. *Pseudoaddiction* refers to the way a person suffering from pain, and desperate to obtain pain medicine, will act duplicitously to obtain it, or otherwise behave like an addict, but do not experience the compulsive behavior or "negative consequences." D.E. Weissman & J.D. Haddox, *Opioid Pseudoaddiction—An Iatrogenic Syndrome,* 36 Pain 363 (1989), https://pubmed.ncbi.nlm.nih.gov/2710565/. Both concepts incorporate normative presuppositions. *See* J. Ballantyne, et al., *Bonica's Management of Pain* 419 (4th ed. 2012).

fallen out of favor," in light of later developments, L. Kofi et al., *Ethics at the Intersection of Chronic Pain and Substance Use, in* D. Buchman & K. Davis, *Pain Neuroethics and Bioethics* 138 (2018) (emphasis added), it has not been squarely rejected, let alone proven to be a form of deceptive marketing. As recently as 2004, it was deemed "an important step forward in pain management," S. Passik & K. Kirsch, *Assessing Aberrant Drug-Taking Behaviors in the Patient with Chronic Pain,* 8 Current Pain & Headache Reports 289, 291 (2004), and is still endorsed by the American Society of Addiction Medicine. *See* American Pain Society, *Definitions Related to the Use of Opioids for the Treatment of Pain*.[9] There is nothing deceptive or unlawful about the scientific community proposing, discussing, studying, and even later rejecting a medical or psychological hypothesis. Yet the trial court concludes that defendants and others broke the law by "suggest[ing] pain is undertreated and doctors should prescribe more opioids"—without finding that these things were factually untrue or negligently stated. FJ at 15 ¶ 37.

3) In other words, the trial court **characterized legitimate scientific discourse as deceptive**. It predicated liability, for example, on the "Consensus Statement"—a public expression of an opinion—which "suggest[ed] that pain is undertreated and doctors should prescribe more opioids." *Id*. But the publication of such consensus statements is a normal part of the scientific method. Even if a public statement of a scientific belief turns out to be incorrect, that is not proof of impropriety.[10] Penalizing people after the fact for honest public statements of scientific belief—even if later repudiated—risks chilling scientific discourse and hampering the

[9] https://www.naabt.org/documents/APS_consensus_document.pdf

[10] As one philosopher put it, science is the process of "making mistakes in public. Making mistakes for all to see, in the hopes of getting the others to help with the corrections." D. Dennett, *Darwin's Dangerous Idea* 380 (1995).

development of new medical treatments.[11] And given that **the Consensus Statement cannot by any means be characterized as "commercial speech"**—it proposed no commercial transactions, nor was it "related solely to the economic interests of the speaker and its audience," *Central Hudson*, 447 U.S. at 561—the chilling effect of the trial court's ruling cannot be disregarded.

Relatedly, the trial court therefore **punished defendants for freedom of association**—for example, penalizing them for helping fund organizations such as the National Pain Education Council. FJ at 15 ¶ 39. But as courts have repeatedly made clear, the choice to subsidize an organization is protected by the First Amendment, *NAACP v. Alabama. ex rel. Patterson*, 357 U.S. 449, 460–61 (1958), and this cannot be waved away as merely "commercial," unprotected speech. If this decision is allowed to stand, it is easy to foresee cases against petroleum companies for funding research into global warming which is later found to be politically unacceptable. Indeed, such lawsuits have already begun. *See, e.g.*, *California v. BP P.L.C.*, No. C 17-06011 WHA, 2018 WL 1064293, at *4 (N.D. Cal. Feb. 27, 2018).

4) The trial court found that the defendants created a nuisance by "deceptively minimizing risks," making efficacy claims "without substantial evidence," and "promoting unapproved uses" of medicines. FJ at 17 ¶ 44. But this latter action—**promoting unapproved uses—is perfectly legal.** In *Amarin Pharma, Inc. v. U.S. FDA*, 119 F.Supp.3d 196, 237 (S.D.N.Y. 2015), and *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012), federal courts

[11] The court found it significant that some members of the committee that drafted the statement "had a financial relationship" with the defendants, FJ at 15 ¶ 36, and that defendants contributed money to the American Pain Society and the American Academy of Pain Medicine, but it is perfectly ordinary for industry to financially support scientific organizations relating to that industry. These organizations were and are legitimate, independent entities. *See* C. Clark, *American Pain Society Seeks OK to Call it Quits*, Medpage Today, May 24, 2019, https://www.medpagetoday.com/painmanagement/painmanagement/80054

held that the truthful communication of information about "off-label" use (i.e., unapproved uses) of legal medicines is protected First Amendment speech. In other words, the trial court failed to distinguish between truthful, constitutionally protected speech and untruthful or non-protected speech, and indiscriminately labeled all of the speech "deceptive" and therefore a nuisance.

5) Moreover, the trial court's terminology fails to distinguish between actual misrepresentations, which the government may prosecute, and **the mere failure of the defendants to advertise or market medicines in ways today's prosecutors would prefer**. For instance, the court found that defendants "repeatedly used [scientific studies] in deceptive ways to support misleading claims that downplay[ed] the risk of addiction and overstate[d] the efficacy of opioids." FJ at 19 ¶ 50. What constitutes "downplaying" or "overstating," however, is left unexplained. How much emphasis *should* the defendants have placed on the risk of addiction? There is no standard in either statutory or common law. Instead, the decision here imposes *post hoc* liability on a business for falling below a purely subjective standard—and this is accomplished due to the vagueness of the "public nuisance" tort.

6) The trial court characterizes humane, even morally imperative decisions as nefarious. Through insinuation and implication, it concluded that defendants' speech harmed the public—even where that speech was true and important. For example, it predicated liability on finding that defendants "used the phrase, 'pain as the "fifth vital sign"' to influence doctors to liberally prescribe opioids." FJ at 21 ¶ 56. Yet *persuasion* is constitutionally protected speech—even within the commercial context—and there is nothing inaccurate about the phrase "pain as the fifth vital sign." On the contrary, the phrase refers to the idea that physicians should be as focused on treating pain as they are on treating a patient's difficulty with breathing, cardiac problems, etc. This is a legitimate and humane attitude—quite the opposite of the **shockingly**

inhumane, even cruel, idea expressed in the words the trial court quoted approvingly: **"Not everyone deserves pain medicine."** *Id.* at 21 ¶ 57.

B. The trial court failed to differentiate between acts and actors so that it attributed speech to entities not responsible for that speech, and punished lawful speech along with unlawful speech.

In addition to lumping non-commercial and commercial speech, and lawful speech with what it characterized as deceptive speech, the trial court also made no effort to specify who said what.

For example, it found that "[d]efendants" in general "ran a website called Prescribe Responsibly," to promote information about pseudoaddiction, *Id.* at 11 ¶ 22, but Janssen Pharmaceuticals alone was responsible for that website (as stated on the website itself), and other defendants had no connection with it. Likewise, the court found that "defendants' marketing materials" cited "the Porter and Jick letter" in ways that "downplay[ed]" the risk of addiction, *id.* at 19 ¶ 50, yet while it is generally agreed that Purdue used this letter for marketing purposes, the court made no finding other defendants did so.

But *causation* is required by basic principles of tort law. *Steed v. Bain-Holloway*, 356 P.3d 62, 68 ¶ 21 (Okla. Civ. App. 2015). While causation in public nuisance cases is sometimes complex, one rule is plain: "Regardless of which test of causation is used, the plaintiff must identify the actual defendant who caused the harm." R.C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. Rev. 565, 596 (2019). Even in the broadest public nuisance decisions, such as those involving lead paint, courts have insisted upon proof of causation. *See, e.g., City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 116 (Mo. 2007); *ConAgra Grocery Prod.*

Co., 227 Cal.Rptr.3d at 543. Without specific attribution of fault,[12] it is contrary to law to find a party liable. Indeed, absent a causation finding, a nuisance lawsuit resembles "the creation of a social program more than the resolution of a particular dispute." M.L. Richards, *Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation*, 54 U. Rich. L. Rev. 405, 457 (2020) (citation omitted).

One consequence of this lack of specificity is that it makes *tailoring* impossible. Some kind of tailoring is required of *any* limitation on speech, including in the public nuisance context.[13] Exactly which degree of tailoring is required depends on how the speech is categorized—limits on "political" speech must be narrowly tailored, *Ariz. Free Enter. Club's Freedom Club PAC v. Bennett*, 564 U.S. 721, 734 (2011); limits on commercial speech must be "not more extensive than is necessary," *Central Hudson*, 447 U.S. at 566; limits on expressive actions must be "no greater than is essential." *United States v. O'Brien*, 391 U.S. 367, 376-77 (1968). But given the lack of specificity in the trial court's findings, there is simply no way to reconcile the judgment with the tailoring requirement of *any* speech category. The decision therefore penalizes plainly commercial speech (actual advertisements), along with *potentially* misleading *non*-commercial speech (such as the Consensus Statement), and true and

[12] Some states use the theory of "enterprise liability" in place of a showing of causation, but this Court rejected that theory in *Case v. Fibreboard Corp.*, 743 P.2d 1062, 1067 (Okla. 1987), and its reasons for doing so are even more strongly present here: it violates basic principles of law to impose liability "devoid of considerations of actual causation." *Id.* Even if enterprise liability were the law in Oklahoma, it would not apply here, because it applies only where it is certain *that* the defendants contributed to the harm, but unclear *how much* each contributed. In other words, it applies only where the defendants "jointly controlled the risk." *Sindell v. Abbott Labs.*, 26 Cal.3d 588, 608 (1980). But here, the trial court made no findings that the defendants jointly controlled the risk. It simply asserted that "[d]efendants, acting in concert with others, embarked on a [marketing] campaign" that encouraged the prescription of painkillers, FJ at 9 ¶ 17, a finding far too ambiguous to support a conclusion of joint control.

[13] *Near v. Minnesota ex rel. Olson*, 283 U.S. 697 (1931), was a public nuisance case.

constitutionally protected speech (such as the promotion of "off-label" uses). That alone requires reversal.

Perhaps the case closest to this is *Sequoia Books, supra*. That was a public nuisance obscenity case in which the defendants were convicted of selling obscene materials at their bookstore, and were then enjoined from using the building *at all*, including for selling *non*-obscene materials. 537 N.E.2d at 304. The court found this unconstitutional. Even assuming that the obscene materials were rightly deemed a public nuisance, the court declared it could not go further and restrict *non*-nuisance speech: "since sellers of obscene materials are often, as in this case, also sellers of protected speech, regulations which affect them must be carefully scrutinized in order that the proscription of the obscene does not unduly affect the distribution of protected expression," it explained. *Id.* at 309. "Similar concerns would be raised by a statute which closed an entire newspaper on the basis of individual instances of unprotected libelous falsehoods which had appeared within its pages." *Id.* The court therefore applied the *O'Brien* test, which includes a tailoring requirement: "'the incidental restriction on alleged First Amendment freedoms [must be] no greater than is essential to the furtherance of [the state's] interest.'" *Id*. at 307 (quoting *O'Brien*, 391 U.S. at 376-77).

In this case, the trial court made no effort at tailoring its analysis, or at differentiating between what speech was commercial and what was not, or which speech was lawful and which was not, or who said what. It simply asserted that all the speech at issue was commercial, FJ at 28 ¶ 14, and that all of it was misleading. *Id.* at 19 ¶ 50. Thus its liability finding has the same consequence as an injunction closing an entire bookstore based on some obscenity sales, or shutting a newspaper based on individual instances of libelous falsehoods: it sweeps in legitimate speech as well as unlawful speech. What exactly *can* a drug-maker say under this judgment

without risking future punishment? What can a petroleum company say about the environmental impact of its products? What can a gun-maker say about the sale of firearms? It is impossible to determine.

This was a failure of *causation* analysis. And as this Court has said, public policy "does not justify the abrogation of the rights of a potential defendant to have a causative link proven." *Case*, 743 P.2d at 1067. One reason such an abrogation violates public policy is that the medicines in question here have important, life-sustaining benefits, and this liability finding threatens *worse* outcomes for patients, as discussed in the next section.

III. Everyone *does* deserve pain medicine.

The trial court quoted with approval the words of one witness who summarized the premise on which the trial court operated: "Not everyone deserves pain medicine." FJ at 21 ¶ 57.[14] Yet this proposition is contrary to sound public policy. Indeed, it shocks the conscience and should not guide this Court in evaluating this case. It is not the state's role to determine who "deserves" pain medicine, and this Court should, at a minimum, presume that people in pain "deserve" the freedom to decide, in consultation with their physicians, whether or not to take medicines to alleviate their pain. While all medicines involve risks, including the risk of addiction, the *patient*, not the state, should make the choice.

As bioethicist Jessica Flannigan writes, patients are in the best position to make decisions about their lives, because they primarily experience the benefits of wise choices and suffer the penalties of bad ones, and because individuals have different priorities that cannot be adequately measured by others who presume to decide who does or does not "deserve" medicine. J.

[14] The witness was not expressing his own views, but the court quoted his words as articulating the principle that it did endorse.

Flannigan, *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicine* 11 (2017). Paternalism violates the principle of equality by presuming that some people are entitled to make decisions for the lives of others, *id.* at 19, and in practice those others are often biased, particularly against minority groups whose needs may not be known to the majority who impose the paternalistic standard. *Id.* at 21.

Patient autonomy, in fact, is the announced public policy of Oklahoma. In 2015, the legislature adopted the Right to Try Act, 63 Okla. St. § 3091.1 *et seq*, which provides that patients have the right to decide whether to take medicines that have received basic safety approval from the FDA even where those medicines have not been approved for public sale.

Obviously patients have the right to demand that information about medicines be truthful. But the judgment here goes far beyond vindicating that principle and penalizes all defendants indiscriminately, for truthful statements as well as for dishonest ones, and for statements that were true, but potentially misleading. And the consequences could be horrendous.

Patients suffering chronic pain are routinely denied medicine today, frequently due to physicians' fear of being punished for it. *See* B. Moldovan, *'Opiophobia' Past and Present,* Practical Pain Management, Jan. 2012[15] (citing "[f]ear of disciplinary sanctions or legal action" as the leading reason doctors deny patients medicine). The Department of Health and Human Services recently reported that the "stigma" associated with opioid therapy "serve[s] as a significant barrier to effective treatment of chronic pain," Pain Management Best Practices Inter-Agency Task Force, *Pain Management Best Practices* 56 (2019),[16] and that rules or guidelines

[15] https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/opiophobia-past-present
[16] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

that "only promote and prioritize minimizing opioid administration run the risk of undertreating pain." *Id.* at 17.

Undertreatment is a life-and-death matter for countless patients who believe their only alternative to endless suffering—when denied appropriate medication by physicians afraid to prescribe—is suicide. Dineen, *supra,* at 1007. Although restrictions on prescribing implemented since 2013 have had "at best, a modest impact" on drug abuse, *supra* at 974, there is strong evidence that they have harmed innocent patients who suffer incurable pain, including by driving them to kill themselves. *Id.* at 1004–06. The medical community knows suicide is a risk of failing to treat pain; "the percentage of people who died by suicide and had evidence of chronic pain increased from 7.4% in 2003 to 10.2% in 2014," and the suicide rate of patients suffering from chronic pain is five times the suicide rate among those receiving opioid treatment for pain. *Pain Management Best Practices, supra,* at 12. Yet as Dineen observes, "[t]he most universally ignored category of misprescribing is *underprescribing*," which "may be a serious contributor to overall morbidity and mortality, for example by contributing to suicides or unintentional poisonings." *Supra* at 1001 (emphasis added). (Suicide by chronic pain sufferers is frequently inadvertent, as desperate patients take whatever medicine they can get their hands on to ease their pain. *Id.* at 1008.)

To withhold pain medication from patients in agony is the *opposite* of appropriate medical care, yet today's legal environment punishes doctors for, or deters them from, giving patients the medicine they need, and it stigmatizes patients with chronic pain who report being "dismissed, discounted, and ignored by clinicians," and who are treated as "essentially invisible" by politicians and policy makers, "except as an object of blame and suspicion." *Id.* at 1001-02.

Proper treatment of pain can prevent suicide. "[T]hose asking for assisted suicide almost always change their mind once we have their pain under control," reported Kathleen Foley, chief of pain service at Memorial Sloan-Kettering Cancer Center. P. Wilkes, *The Next Pro-Lifers*, New York Times Magazine, July 21, 1996.[17] But government policy—and the trial court in this case—still focuses exclusively on penalizing, stigmatizing, and preventing the prescription of needed painkillers, regardless of these preventable consequences. And policy discussions typically ignore the question of undertreatment. Dineen, *supra* at 1007-09. The trial court ignored it as well.

Doctors nationwide already fear giving medicine to suffering patients. R. Lawhern, *Stop Persecuting Doctors for Legitimately Prescribing Opioids for Chronic Pain*, Stat News, June 28, 2019.[18] "There is enormous pressure to limit the prescribing of opioids in noncancer pain patients today," writes the president of the American Academy of Pain Medicine. "At the same time, our society has little comprehension of the nightmare experienced by people who live every day with chronic pain … . As a result, patients are caught in the crossfire between law enforcement efforts and physicians who have fewer, and less effective, tools available to treat patients whose pain approaches levels unimaginable by most people." L. Webster, *Pain and Suicide: The Other Side of the Opioid Story*, 15 Pain Medicine 345 (2014). The Department of Health and Human Services even notes a "rising trend of health care professionals opting out of treating pain" entirely. *Pain Management Best Practices*, *supra* at 12.

The trial court's ruling will only worsen a growing trend of withholding pain-alleviating medicines from patients who need them. By punishing companies without specific findings of

[17] https://www.nytimes.com/1996/07/21/magazine/the-next-pro-lifers.html
[18] https://www.statnews.com/2019/06/28/stop-persecuting-doctors-legitimately-prescribing-opioids-chronic-pain/

wrongdoing, failing to apply the constitutionally-mandated free speech analysis, and endorsing the morally reprehensible idea that "not everyone deserves pain medicine," the decision below worsens outcomes for Oklahomans suffering incurable pain and violates the standards of tort law and the Constitution.

CONCLUSION

The judgment should be *reversed.*

Respectfully submitted this 14th day of October 2020,

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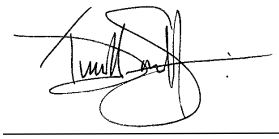

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I hereby certify that a true and correct copy of this filing was mailed this 14th day of October, 2020 by depositing it in the U.S. Mail, postage prepaid and/or by electronic mail to the following:

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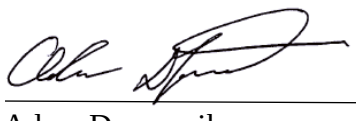

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