



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

Document split into multiple parts

PART A

STATE OF OKLAHOMA, ex rel.,)
MIKE HUNTER,)
ATTORNEY GENERAL OF OKLAHOMA,)

Plaintiff,)

vs.)

Case No. CJ-2017-816
Judge Thad Balkman

- (1) PURDUE PHARMA L.P.;)
- (2) PURDUE PHARMA, INC.;)
- (3) THE PURDUE FREDERICK COMPANY;)
- (4) TEVA PHARMACEUTICALS USA, INC.;)
- (5) CEPHALON, INC.;)
- (6) JOHNSON & JOHNSON;)
- (7) JANSSEN PHARMACEUTICALS, INC;)
- (8) ORTHO-MCNEIL-JANSSEN)
PHARMACEUTICALS, INC., n/k/a)
JANSSEN PHARMACEUTICALS;)
- (9) JANSSEN PHARMACEUTICA, INC.,)
n/k/a JANSSEN PHARMACEUTICALS, INC.;)
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,)
f/k/a ACTAVIS, INC., f/k/a WATSON)
PHARMACEUTICALS, INC.;)
- (11) WATSON LABORATORIES, INC.;)
- (12) ACTAVIS LLC; and)
- (13) ACTAVIS PHARMA, INC.,)
f/k/a WATSON PHARMA, INC.,)

Defendants.)

STATE OF OKLAHOMA } S.S.
CLEVELAND COUNTY }

FILED

MAY 23 2019

In the office of the
Court Clerk MARILYN WILLIAMS

PRETRIAL CONFERENCE ORDER

1. **APPEARANCES:**

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2. GENERAL STATEMENT OF FACTS:

A. The State's Factual Summary:

The State of Oklahoma contends the Defendant pharmaceutical manufacturers, the J&J Defendants and the Teva Defendants, and settling Defendant Purdue, caused an opioid public health crisis in the State of Oklahoma which constitutes a public nuisance. From 2011-2015, more than 2,100 Oklahomans died of an unintentional prescription opioid overdose. In 2015, over 326 million opioid pills were dispensed to Oklahoma residents, enough for every adult to have 110 pills. Oklahoma dispenses the most prescription fentanyl per capita. In 2017, 4.2% of babies born covered by SoonerCare were born with Neonatal Abstinence Syndrome (NAS). The State alleges it will take between approximately \$12.7 billion and \$17.5 billion dollars to abate the nuisance over a 20-to-30-year period. Defendants deployed their deceptive marketing campaign and oversupply mission (just as they intended) nationwide, including in Oklahoma, causing this opioid public nuisance in the State.

During the better part of the twentieth century, the American medical community exercised “narcotic conservatism”—meaning that opioid pain medicines were only used in the rarest of circumstances due to their highly addictive and deadly qualities. Specifically, opioids were primarily prescribed for palliative care and cancer patients or short-term for acute pain following surgery. In the 1980s and early 1990s, the first extended-release opioid products were launched. The two primary extended-release opioids released during this time were MS Contin (a morphine product made by Purdue) and Duragesic (a fentanyl patch made by Janssen). During this time in the 1980s and early 1990s, Janssen and Purdue marketed these opioids drugs for cancer pain—a relatively small market. As such, the introduction of these new extended-release products did not alter the medical community’s understanding of when to use opioids and did not change narcotic conservatism.

However, in 1996, Purdue released a new extended-release oxycodone product called OxyContin and, with it, a new marketing strategy. The FDA label stated OxyContin was indicated “for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.” At that time, narcotic conservatism still prevailed. However, Purdue sought to change the perception of opioids and began aggressively marketing OxyContin for chronic non-cancer pain, downplaying the risks of addiction and other negative side-effects and exaggerating its benefits for long-term, chronic use and everyday pain.

Soon thereafter, in 1997, Janssen deliberately changed its marketing strategy for Duragesic to the chronic non-cancer pain market, and an arms race began. Indeed, in 1996, Duragesic had been on the market for 6 years and had only been marketed for cancer pain.

In 2001, Cephalon (now owned by Teva) re-launched the fentanyl lollipop, Actiq, that it had purchased from a different pharmaceutical company. Actiq is so potent that it was only supposed to be used in opioid-tolerant cancer patients with “breakthrough” pain episodes. Immediately after launch, Cephalon too began promoting Actiq for use in non-cancer pain, such as headaches. Sales of all of Defendants’ opioid products—OxyContin, Duragesic, and Actiq—

increased rapidly.

To ensure their success, Defendants had to create a market for opioids where none had existed for decades (due to narcotic conservatism). Defendants employed what is referred to as the “classic problem/solution strategy.” Defendants primarily promoted their specific opioids and all opioids generally for chronic non-cancer pain through use of massive sales forces, speaker programs, continuing medical education (“CME”), branded marketing, and unbranded marketing. All of these methods were deployed nationwide and in Oklahoma. Through these methods, Defendants advocated for more widespread use of opioids generally, including by relying on Key Opinion Leaders (“KOLs”), such as Dr. Russell Portenoy and Scott Fishman, and agenda-driven professional societies, such as the American Pain Society, which are commonly referred to as “front groups.” All Defendants had financial ties to these paid KOLs and front groups. Defendants also created or co-opted so-called “patient advocacy” groups, such as the American Pain Foundation and Purdue’s “Partners Against Pain” which they also used as front groups. All Defendants utilized many of the same KOLs and front groups. In the early 2000s, Defendants and many of these same groups formed a single shadow organization that ultimately became known as the Pain Care Forum. The Pain Care Forum, created by Purdue at the inspiration of a KOL, operated as an informal group to disseminate information on issues related to the “problem” of pain and the “solution” of opioids and remove any barriers to access to these narcotics. J&J and Cephalon were day-one members.

Defendants’ marketing messages included the following: (1) there is widespread undertreatment of pain; (2) the risks of opioid use (*e.g.*, addiction, dependence, abuse, death, etc.) had previously been exaggerated when used properly for treating pain; and (3) there are benefits to long term opioid use for those suffering from chronic pain. Defendants stated, among other things, that the risk of addiction was a “myth,” “very rare,” “virtually non-existent,” and “less than 1%.” Defendants also supported and promulgated the idea that pain should be treated as the “5th Vital Sign,” a concept first created by the American Pain Society, in conjunction with the pharmaceutical industry. In reality, while Defendants have always known their narcotics carry a substantial risk of addiction, Defendants did not know and have never known the exact risk of addiction. Nonetheless, Defendants “targeted” Oklahoma prescribers and hammered them with these messages from all angles. In particular, Defendants largely targeted physicians who had received little to no training in pain management and addiction: family doctors, general practitioners, and primary care providers. Defendants also targeted consumers and the public at large to convince them that their pain was undertreated and to seek out opioid medications. Defendants (and in particular J&J) targeted children, the elderly, and veterans with their problem/solution messaging. Defendants misrepresented what they knew about their drugs and omitted material information in their messaging. The ultimate result was a paradigm shift away from narcotic conservatism.

Having created a quickly growing market for opioids, Defendants then pumped their prescriptions into the supply chain. Prescriptions of all opioids (*e.g.*, OxyContin, Duragesic, Ultram/Ultram ER, Actiq, etc.) dramatically increased in the two decades after 1996. To meet the rising demand, J&J’s subsidiary companies, Noramco and Tasmanian Alkaloids, became the primary suppliers of opioid active pharmaceutical ingredients (“APIs”), such as oxycodone (the opioid in OxyContin) and hydrocodone (Vicodin). These J&J subsidiaries provided APIs to

Purdue, Teva, and other opioid manufacturers. Noramco became the largest supplier of opioid APIs in the United States. Tasmanian Alkaloids patented a new poppy strain that was high in a material used to manufacture oxycodone. According to J&J, this was a “transformational” technology that “enabled the growth” of oxycodone in the United States. Without Tasmanian Alkaloids and Noramco, Purdue’s OxyContin could not have become the blockbuster drug it became.

The early success of branded opioids quickly spawned a massive generics market. Teva became the primary purveyor of generic opioids in the State of Oklahoma. And Defendants’ branded and unbranded marketing of opioids is inextricably tied to the marketing and success of generic opioids. Again, Defendants engaged in unbranded marketing for opioids generally—a tactic that benefitted the profit margins for all of their opioids—branded and generic and drove up the prescribing of all opioids. Teva has a distribution agreement with Purdue whereby Purdue granted Teva rights to sell generic Oxycontin. Both Actavis and Watson had similar distribution agreements with Purdue for selling generic OxyContin prior to Teva acquiring them. Watson also had an agreement with Purdue to sell generic MS Contin prior to Teva acquiring them. Purdue paid its own sales representatives bonuses for sales of Teva’s generics—and, in turn, Purdue earned a royalty payment from Teva for such sales. All the while, J&J was supplying both Teva and Purdue with opioid APIs.

Over this course of time, Defendants continued to release newer and stronger opioids. OxyContin scaled up to a 160mg dosage, which had to be pulled from the market because it was so dangerous. Purdue also released several other opioids, including Butrans and Hysingla. J&J released Nucynta and Nucynta ER. Cephalon released Fentora (a fentanyl lozenge). And, Teva made and still makes multiple doses of virtually every opioid known to man.

By causing a paradigm shift, Defendants’ actions ultimately led to liberal over-prescribing of opioids and, thus, an oversupply of opioids. In other words, the result of Defendants’ actions was the opioid crisis—a crisis of opioid addiction, abuse, overdose, and death. All of Defendants’ marketing strategies were carried out in Oklahoma, and the State and a considerable number of its residents have been harmed. Due to the oversupply of opioids caused by Defendants’ actions, the State must cope with widespread addiction, dependence, abuse, overdose, and death related primarily to prescription opioids, and to a lesser extent illicit opioids like heroin, for which Defendants created an appetite.

The overprescribing and oversupply that caused this crisis is not limited to just those prescriptions covered by the Oklahoma Medicaid program (which only covers approximately 20% of the State population) but includes *all* prescription opioids dispensed in the State. Indeed, Defendants targeted not just Oklahoma prescribers, but also major private insurers in the State and pharmacies in communities all over the State. Defendants primed the State of Oklahoma to be an ideal environment in which to pump their narcotics—and this opioid nuisance includes ALL of the opioids that found their way into Oklahomans’ medicine cabinets as a result of Defendants’ conduct. Defendants not only interfered with the rights, safety and health of Oklahomans, they also violated their own corporate codes of conduct by putting profits over patient safety and not holding their business partners to the standards they set for themselves. Both J&J and Teva have written codes of conduct that set standards (or pay lip service to standards) for all of their

employees (from the top down) and all of their business partners. Defendants blatantly violated their own stated standards by engaging in the acts and omissions alleged herein.

The result of Defendants' acts and omission in Oklahoma is the worst man-made public health crisis in its history that interferes with and endangers, among other things, the health, safety, and comfort of a considerable number of Oklahomans and renders Oklahomans insecure in their lives. This constitutes a single, indivisible injury. The proper remedy for this nuisance is a Court-ordered abatement. Defendants are jointly and severally liable for costs of any abatement awarded by the Court.

B. Teva and Actavis Generic Defendants'¹ Factual Summary

Millions of citizens suffer annually from chronic pain, including break-through pain. Opioid medicines are an essential tool in helping patients alleviate that suffering. While each prescribing decision is highly individualized, opioids help alleviate pain when used as directed by patients who are appropriately screened and monitored by their prescribing doctors. Opioids can reduce health costs, too, such as by ensuring that patients suffering from pain can return to work and do not have to be hospitalized. This is particularly true with the use of short-acting opioids to treat break-through pain. Because they come with risks, which have long been known to the medical community, opioids only can be prescribed by a licensed physician. The FDA has approved each of the opioid medicines manufactured by the Teva and Actavis Generic Defendants as safe and effective for their intended use. Each opioid medicine comes with a label that warns of the risks of that medicine, including the risk of addiction and abuse. Under Oklahoma law, each physician is obligated to be aware of these risks.

Manufacturers do not approve, prescribe, distribute, dispense, or consume opioids. Nonetheless, in June of 2017, Plaintiff filed suit against several Purdue entities and a few other pharmaceutical manufacturers (collectively, "Defendants"), including the Teva and Actavis Generic Defendants, seeking to hold them responsible for all opioid misuse and addiction problems throughout Oklahoma. Notably, the State did not sue any prescribers, pill mills, distributors, pharmacies, patients, or third-party insurance companies. Nor did it sue numerous other opioid manufacturers. In fact, the State's theory fails to even account for the criminal acts of illegal drug manufacturers and others.

After years of litigation, the State has dismissed all claims and requests for relief except for a single public nuisance claim for abatement. With respect to that lone remaining claim, the State alleges that Defendants "falsely represented and/or omitted the risks of addiction and falsely touted the benefits of [its] opioids." (Pet. ¶ 53.) The State contends that Defendants' misrepresentations and omissions misled Oklahoma prescribers into writing harmful opioid prescriptions to Oklahoma citizens, thereby creating an opioid epidemic in Oklahoma in violation of 50 Okla. St. § 2. (Pet. ¶ 118-19.) The State "seeks to abate the public nuisance." (*Id.* ¶ 120.)

¹ Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Cephalon, Inc. ("Cephalon") are referred to collectively as the "Teva Defendants" and Watson Laboratories, Inc. ("Watson Labs"), Actavis LLC ("Actavis LLC"), and Actavis Pharma, Inc. ("Actavis Pharma") are referred to collectively the "Actavis Generic Defendants."

The State ignores that not all manufacturers—and not all opioids—are the same. The State has long argued that the opioid epidemic in Oklahoma started in 1996, as a result of the promotion of OxyContin by Purdue for long-term chronic pain. But the Teva and Actavis Generic Defendants are differently situated. They did not sell any opioid medicines in 1996, and they have not marketed any long-acting opioids. They also have long had corporate policies in place to prevent and address any such false or misleading marketing. Despite the State’s rhetoric, the Teva and Actavis Generic Defendants are simply not responsible for the opioid abuse epidemic in Oklahoma.

Actavis Generic Entities/Teva USA. The Actavis Generic Defendants have only sold generic medicines. Generic manufacturers compete on price and, given drug substitution laws (which allow pharmacists to substitute generic medicines for brand medicines at the pharmacy level), they do not market opioids to physicians. Consistent with their business model, the Actavis Generic Defendants never promoted their safety or efficacy. The State has identified no false or misleading marketing by any Actavis Generic Defendant—and there is none. They did nothing wrong.

Likewise, prior to 2011, Teva USA sold only generic medicines and never promoted their safety, efficacy, or therapeutic value. Indeed, while Teva USA sells generic opioid medicines, it has never marketed those generic opioids to physicians in Oklahoma or elsewhere. For this reason, there is simply no public nuisance claim that can be brought against Teva USA based upon its sale of generic medicines.

Cephalon/Teva USA.² Cephalon has only ever manufactured, sold, and marketed two unique opioid medicines—Actiq and Fentora. Those medicines account for well less than 1% percent of opioid prescriptions in Oklahoma. For example, the State estimates that, through its Medicaid Program, the State reimbursed for 2700 prescriptions of Actiq and Fentora after 1996 (out of 9 million total opioid prescriptions), and concedes that it has not identified a single Actiq or Fentora prescription that was medically inappropriate or unnecessary.

Actiq and Fentora are not used for long-term chronic pain. Instead, Actiq is a unique short-acting opioid medicine indicated for the “management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” The label for Actiq comes with numerous warnings of the risks involved, including a black-box warning that fully discloses the risks of abuse, addiction, overdose, and death. Cephalon did not start to market Actiq until 2001 and ceased promotion of Actiq in 2006. All branded marketing materials were submitted to and approved by the FDA prior to their use.

Fentora is also a short-acting opioid medicine indicated for the “management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” The label for Fentora comes with numerous warnings of risks involved, including a black-box warning that fully discloses its risks, including the risks of abuse, addiction, overdose, and death. Cephalon obtained approval from the FDA to market and sell Fentora in September 2006. Cephalon no longer promotes Fentora.

² As noted above, Teva USA only became affiliated with Cephalon in 2011.

Since their inception, both Actiq and Fentora have been subject to FDA-mandated risk management strategies to ensure doctors are aware of their risks and FDA-approved indications. Most recently, since the beginning of 2012, prescribers of Actiq and Fentora have been required to comply with the stringent requirements of the TIRF REMS Program—*before* writing a prescription for these medicines. This includes, among other things, passing a knowledge assessment about the risks and approved uses of Actiq and Fentora, reviewing the FDA-approved medication guides for Actiq and Fentora with the patient, and signing a patient-prescriber agreement that the prescriber understands and has counseled her patient about the risks and approved uses of Actiq and Fentora.

In addition to the FDA-mandated risk mitigation programs, Cephalon has always had policies in place to prevent the false or misleading marketing of its opioids medicines. Indeed, Cephalon has had internal policies governing, among other things, promotional activities, meals and gifts, speaker programs, and detailing and call activity. While Cephalon has provided funding to third-party organizations and sponsored medical education events, Cephalon policies prevented any influence by Cephalon over the content of those third-party publications and educational programs. Indeed, based upon the undisputed testimony in this case, those third-party organizations and speakers operated independently, and the Teva and Actavis Generic Defendants did not influence or dictate the content of their publications.

Given these facts, it is clear that no prescriber in Oklahoma was misled by the Teva or Actavis Generic Defendants. Notably, the State has not identified a single false statement that the Teva or Actavis Generic Defendants made to a single prescriber in Oklahoma; a single Oklahoma doctor who was misled by anything that the Teva or Actavis Generic Defendants said or did; or a single patient who was harmed because of a false statement that the Teva or Actavis Generic Defendants made. The State certainly has not identified an “entire community” of Oklahoma patients who received harmful prescriptions because of some false statement by the Teva or Actavis Generic Defendants, as required for its public nuisance claim. Oklahoma doctors, in fact, will testify to the exact opposite—they were not misled by any such marketing whatsoever.³ As

³ The Teva and Actavis Generic Defendants have repeatedly been deprived of meaningful discovery throughout the duration of this case. The State’s refusal to provide relevant, non-privileged information is in contravention of its obligation under Oklahoma’s rules and these Defendants contend that the Court has erred in failing to correct the State’s discovery abuse.

numerous courts have recognized,⁴ the State's very theory against the Teva and Actavis Generic Defendants fails.⁵

To make matters worse, there are numerous independent actors that break the chain of causation against the Teva and Actavis Generic Defendants. At a minimum, for each opioid-related harm that the State seeks to abate, the chain of causation would include at least the following links:⁶

- **Link One:** Actavis and Teva Defendants manufacture the opioids;
- **Link Two:** The FDA approves the sale of the medicines and their labeling;
- **Link Three:** The DEA sets quota limits to ensure that there is no "oversupply" of opioid medicines in the market;
- **Link Four:** An Oklahoma prescriber receives marketing material for branded opioid medicines attributable to the Actavis and Teva Defendants and that marketing material is false or misleading in violation of an Oklahoma law;
- **Link Five:** Instead of exercising her own independent medical judgment, the Oklahoma prescriber writes a prescription for an opioid medicine to an Oklahoman because of an allegedly false statement made by the Actavis or Teva Defendants and without knowledge or an understanding of the risks of the medication as a learned intermediary, despite prominent and extensive labeling information provided on the medication—and, after 2012, despite the stringent TIRF REMS requirements;

⁴ See *Travelers Indem. Co. v. Cephalon, Inc.* ("Travelers P"), 32 F. Supp. 3d 538 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3d Cir. 2015) ("Travelers IP"); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.* ("Carpenters"), No. 13-7167, 2014 WL 2115498 (E.D. Pa. May 21, 2014); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.* ("CREB IP"), No. 09-3418, 2010 WL 1257790 (D.N.J. Mar. 29, 2010); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.* ("CREB P"), No. 09-3418, 2009 WL 3245485 (D.N.J. Oct. 7, 2009); see also *City of Chi. v. Purdue Pharma, LP*, No. 14 C 4361, 2015 WL 2208423 (N.D. Ill. May 8, 2015).

⁵ The State has represented to the Court that it intends to rely on North Dakota law in support of its claim of public nuisance pursuant to Oklahoma law. But, contrary to the State's interpretation of North Dakota's nuisance law, a North Dakota court recently held the exact opposite in a nearly identical opioid case: "No North Dakota court has extended the public nuisance statutes to cases involving the sale of goods." *State of North Dakota v. Purdue Pharma*, Case No. 08-2018-cv-01300 (Order 5/10/19) (dismissing nearly identical claims, including public nuisance claim, because manufacturer of opioids has no control over the product once it enters the market).

⁶ This causal chain is not exhaustive and merely provides some of the elements and various actors involved in the manufacture, sale, prescription, distribution, and diversion of opioid medicines.

- **Link Six:** Reimbursement policies by managed care organizations, like insurance companies, do not cause the Oklahoma prescriber to write the opioid prescription;
- **Link Seven:** The patient chooses to fill the medically inappropriate prescription without any knowledge about the risks of the medication;
- **Link Eight:** A distributor sells opioids to the pharmacy, without flagging the sale as suspicious;
- **Link Nine:** The pharmacist first decides whether to substitute a generic medicine for a branded medicine and then dispenses the medically unnecessary opioid prescription, without informing the patient about the risks or deeming the prescription to be medically unnecessary;
- **Link Ten:** The Oklahoma Health Care Administration does not deem the opioid prescription to be medically necessary (and appropriate) by reimbursing for it (which it did for over 9 million opioid prescriptions after 1996);
- **Link Eleven:** The patient, or someone who illegally obtained the opioid from the patient, misuses, abuses, and/or becomes addicted to opioids due to the allegedly fraudulently-induced prescription, as opposed to other factors or other medically appropriate prescriptions;
- **Link Twelve:** The patient or someone else who illegally diverted the opioid medicine suffers physical or other harm as a result of the medically unnecessary prescription, as opposed to numerous other factors or circumstances.

Given this tortured chain of causation, the Teva Defendants cannot be held responsible for the discretionary and fact-intensive decision-making of, among others, distributors, pharmacies, illegal pill mills, patients, the FDA, DEA, and the State itself.

In fact, rather than blaming the Teva and Actavis Generic Defendants, the State should be examining its own actions and inaction—which directly contributed to the opioid abuse problem in Oklahoma. For example, the State waited years before it imposed any reimbursement limits on Actiq and Fentora prescriptions, and continues to reimburse for opioid prescriptions for chronic pain today, thereby influencing what gets prescribed and dispensed to patients. The State also failed, among other things, to implement an effective prescription drug monitoring program, pass effective and timely legislation cracking down on pill mills, or otherwise effectively address diversion of opioid medicines. The State also failed to take steps to reduce the number of opioid deaths, such as by making it easier for citizens to obtain medically-assisted treatment for opioid use disorder.

Given the absence of any proof of wrongdoing by the Teva and Actavis Generic Defendants, the State contends that they should be responsible for the acts of other Defendants. But the State cannot show that the Teva and Actavis Generic Defendants worked—much less

conspired—with any Defendant to falsely market opioids in Oklahoma. The Defendants are competitors in a competitive industry, and there never has been any agreement involving the Teva and Actavis Generic Defendants and any other Defendant to engage in any false marketing or any other wrongful act. Likewise, the State cannot try to invoke a joint and several liability theory merely because the State has made no effort to try to apportion the harm it suffered by Defendant (or any other cause). The absence of any proof against the Teva and Actavis Generic Defendants is a reason why they are not liable—not a basis for joint and several liability.

Nor does the State’s “abatement” plan make any sense. The State cannot seek “abatement” relief against the Teva and Actavis Generic Defendants in this case for the simple reason that there is no public nuisance (*i.e.*, false marketing) to abate. The Actavis Generic Defendants do not market their generic medicines, and the Teva Defendants stopped marketing their only two branded opioid medicines. Notably, the State’s so-called abatement plan is not linked to any false marketing by the Teva and Actavis Generic Defendants—the alleged public nuisance. Instead, the State’s “abatement” plan is a thinly-veiled and improper attempt to obtain damages for the opioid abuse crisis, without any link to the Teva or Actavis Generic Defendants.

In short, there is no legal or evidentiary basis for the State’s public nuisance claim against the Teva and Actavis Generic Defendants. The State’s theory of public nuisance is neither supported by statute or Oklahoma case law interpreting Oklahoma’s nuisance statute. It would be a gross violation of due process to impose any liability on the Teva and Actavis Generic Defendants for a public nuisance claim or under any other legal theory.

C. Janssen Defendants’ Factual Summary:

Decades ago, doctors, researchers, and federal regulators recognized that untreated pain represented a public-health issue that had gone largely unaddressed by then-available treatment options. They began to view prescription opioids as a safe and effective treatment option for certain pain patients. In 1977, at the White House’s request, the federal government created the Interagency Committee on New Therapies for Pain and Discomfort. That Committee—which included representatives from the FDA, DEA, Department of Health, Education, and Welfare, and Department of Justice—found a need for new opioid medications to address untreated pain.

In response, ALZA Corporation and Janssen developed Duragesic, a prescription transdermal patch that administers a controlled dose of pharmaceutical fentanyl through a patient’s skin over 72 hours. The FDA approved Duragesic in 1990. At all times, the indication found in its FDA-approved labeling included chronic pain; the indication was never limited to cancer pain.

At all relevant times, Duragesic was indicated by the FDA for “management of persistent, moderate to severe chronic pain that ... requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means.”⁷

⁷ In 2013—five years after Janssen stopped promoting Duragesic—the FDA revised the indication of all long-acting opioids to “pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” This change became effective in revised labeling approved in 2014.

(Duragesic label, approved Feb. 2005.) Duragesic provides relief to patients suffering from severe chronic pain.

Over the next decades, several other long-acting prescription opioids were introduced (e.g., OxyContin, Opana ER). By the turn of the century, some of these opioids began to come under public and government scrutiny for issues involving abuse, misuse, and diversion, including through reports of pill mills and doctor shopping. Duragesic was not one of these opioids. Duragesic is different—it is a patch, not a pill. By design, Duragesic patches are more difficult and risky to abuse than pills such as OxyContin and Vicodin: users cannot, for example, crush or snort them. In addition to the abuse-deterrent architecture of the patch, Janssen promoted Duragesic responsibly. All opioids carry a risk of addiction, abuse, and misuse, and Duragesic’s FDA-approved label warned about these risks. The State’s own witnesses agree they learned as much in medical and pharmacy school. Janssen also warned about these risks in promotional and FDA-approved Risk Evaluation and Mitigation Strategy (“REMS”) materials and educated doctors about the importance of proper patient selection, counseling, and monitoring. Janssen’s pharmacovigilance, post-market surveillance, and other safety review programs consistently showed that Duragesic had among the lowest rates of abuse, misuse, diversion, and addiction of any opioid. Janssen stopped marketing Duragesic in 2008.

In the early 2000s, Janssen began developing two other opioid products—Nucynta and Nucynta ER—in response to the continued need for safe and effective opioids to treat chronic pain. The FDA approved Nucynta, a short-acting prescription opioid pill, and Janssen began marketing it in 2009. The FDA later approved Nucynta ER, an extended-release version and Janssen began marketing it in 2011. Janssen developed its Nucynta products with the specific goal of minimizing their potential for abuse. In both versions, Janssen used an active ingredient—tapentadol—designed to have a second, non-opioid, pain relief mechanism, and reports from post-marketing indicated that patients experienced less euphoria than with drugs like oxycodone. And for Nucynta ER, Janssen used a tamper-resistant formulation that protected the pills from being broken, crushed, or otherwise modified to be abused. As with Duragesic, the FDA-approved labels for Nucynta and Nucynta ER warned of the risks of addiction, and Janssen also warned about these risks in promotional materials, REMS, and educational outreach to doctors. Like Duragesic, Nucynta and Nucynta ER had low rates of abuse, misuse, addiction, and diversion compared to other prescription opioid medications. Janssen sold the Nucynta product line in 2015 and stopped marketing it at that time.

Taken together, Janssen’s prescription opioids made up a small fraction of opioid prescriptions in Oklahoma. The State’s own expert found that of a sample of opioid prescriptions—which he testified represented prescriptions submitted for reimbursement by Oklahoma’s Medicaid program between 1996 and 2017—only **0.28** percent were for Duragesic, Nucynta, and Nucynta ER. Neither Duragesic nor Nucynta was prescribed—let alone abused, or illegally diverted—to such an extent that they could have been a cause of a public-health crisis in Oklahoma. To the extent the State’s opioid problems stem from prescription opioids, those problems arose primarily from the abuse and illegal diversion of oxycodone (e.g., OxyContin, Percocet) and hydrocodone (e.g., Vicodin), products Janssen did not make or promote.

In the early 2000s, Oklahoma authorities recognized overprescription and diversion of OxyContin as a mounting policy challenge. The Oklahoma Drug Utilization Review Board (“DURB”) expressed concern about doctors prescribing OxyContin to a growing pool of patients, often at quantities well beyond the drug’s twice-daily indications. DURB repeatedly examined policies adopted by other states to curb opioid abuse and diversion, including prior-authorization requirements and 30-day limits per prescription. Such recommendations were either slowly implemented or not enacted at all.

The State likewise took no action to address the other driver of its crisis: hydrocodone. Hydrocodone, or generic Vicodin, was generally not used to treat chronic pain until an extended-release formulation was introduced in 2013, so it could not have been encompassed by the marketing that the State alleges here. By 2001, Americans abused hydrocodone more than any other prescription drug, according to a State expert. Hydrocodone was by far the most prescribed pain killer overall, and Oklahoma Medicaid reimbursed for more hydrocodone than for any other drug—including drugs used to treat common conditions such as high blood pressure, diabetes, and arthritis. DURB recognized that hydrocodone had not only become widely available, but could be easily diverted, with surplus pills from dental visits or surgeries abused by family members or sold. Hydrocodone also proved as deadly, if not more so, than oxycodone, with the two drugs frequently alternating from year to year as the State’s leading cause of opioid-overdose deaths. Yet the State encouraged doctors to prescribe hydrocodone over safer alternatives, which cost a few dollars more per pill.

Oklahoma agencies recognized that illicit diversion, not valid prescriptions, drove oxycodone and hydrocodone abuse—that “most of these folks are not getting [the drugs] from their physician.” Still, for years, the State took no action to address this issue. DURB considered, but never implemented, anti-diversion strategies developed by the DEA, FDA, and other states. The State also waited until the end of 2015 to require doctors to consult its Prescription Drug Monitoring Program—a system created a quarter-century earlier, in 1989. The system allows doctors and pharmacies to identify “doctor shoppers,” i.e., patients who gather prescriptions from multiple physicians. Once the State required prescribing physicians to consult the system to identify drug seekers, opioid prescriptions fell.

In addition, the State’s allegations ignore that street drugs—subject to no FDA regulation or medical oversight—have largely driven Oklahoma’s opioid problem. Criminal traffickers from Mexico, Colombia, and China smuggle these illegal substances, including heroin, fentanyl, carfentanil, and counterfeit pills, into the United States and distribute them across the country. Methamphetamine has overtaken all opioids as a public-health challenge in Oklahoma. These street drugs have become significant drivers of addiction and overdose deaths.

From 1979 through 2016, Janssen and J&J participated in the highly regulated business of manufacturing raw materials for use in opioid medications. During that period, Noramco was a Janssen subsidiary headquartered in Delaware that sold active pharmaceutical ingredients (“APIs”) to manufacturers of various FDA-approved medications including a number of Schedule II opioids. Noramco did not manufacture or market the finished opioid medications. Noramco’s business was limited to manufacturing medical grade pharmaceutical ingredients in amounts authorized and closely regulated by the federal government, an essential role in our medical

system. Over roughly the same period, Tasmanian Alkaloids was a J&J subsidiary manufacturing the narcotic raw material that Noramco used to make opioid APIs. The federal government had exclusive and pervasive oversight of both companies' sales. In particular, the DEA specifically approved the amount of API that Noramco manufactured and sold each year; and it specifically authorized each of Noramco's customers to buy the amount of API they purchased. Noramco operated independently of Janssen's broader pharmaceutical business.

After opioid abuse had already become problematic in Oklahoma, Janssen created the "unbranded" educational materials that the State's lawyers question. Created around the time the FDA approved Nucynta, these educational materials provided general information to patients and doctors. They did not promote specific opioid products or advocate for opioid use. Janssen sought to maximize the educational value of these unbranded programs by conducting research to identify unmet educational needs. When these unbranded materials discussed opioids, they presented prescription opioids as but one treatment option, alongside alternatives such as Nonsteroidal Anti-Inflammatory Drugs, herbal remedies, physical therapy, and massage. The unbranded materials also presented opioids' risks and benefits and explained responsible prescribing practices.

Like hospitals, pharmacies, health insurers, and other drug manufacturers, Janssen has funded and supported advocacy groups that share information, offer educational programs, lobby for their constituents, raise public awareness about medical conditions, and promote treatment methods. Such advocacy groups—from the American Cancer Society to the March of Dimes—advance the nation's medical priorities. They ask healthcare and pharmaceutical industries for financial support. As the medical profession began devoting attention to pain treatment in the 1970s, a number of such groups emerged to advocate for greater awareness and improved treatment of pain. Those organizations solicited funding from drug companies, including Janssen, which has long pursued a wide range of pain-treatment therapies. Janssen supported the goals of some of these groups. Janssen provided financial support but the organizations advanced their own outreach, advocacy, or organizational efforts.

Janssen likewise sought out and maintained relationships with key opinion leaders ("KOLs"), a common and important practice in the pharmaceutical industry. To develop quality products and market them effectively, pharmaceutical developers need the kind of deep, on-the-ground experience that only highly qualified, high-prescribing doctors can provide. Those doctors are in the best position to observe a medication's effects, to explain doctor and patient preferences, to advise on product development and marketing, and to share their expertise with other doctors. KOLs provide pharmaceutical manufacturers with valuable insight, and pharmaceutical manufacturers in turn compensate KOLs for their time, just as they would compensate any consultant. KOLs in this case have testified that the compensation they received from opioid manufacturers did not influence the content of their presentations.

Contrary to the State's claims, Janssen and J&J did not market opioids to children. In fact, Janssen took steps to educate adolescents about the risks of prescription opioid abuse and misuse. For example, with its "Smart Moves, Smart Choices" program, Janssen sought to curb prescription drug abuse. To maximize the program's impact, Janssen tailored it to teenagers—an audience affected by higher rates of prescription drug abuse—and focused outreach on geographic areas with high abuse rates, including a model program in Oklahoma.

Because Janssen’s promotion of Duragesic and Nucynta did not cause the State’s asserted injuries, the State cannot recover from Janssen. And it certainly cannot do so through its proposed “abatement” remedy. The State’s proposal will not eliminate or nullify the opioids crisis; the proposal extends for 20 to 30 years and addresses issues unrelated to claims in this case. It amounts to a long-term government-spending plan devised by a court, violating fundamental separation-of-powers principles. The State’s own failures contributed to the epidemic. Therefore, Janssen cannot be jointly and severally liable for any such remedy. Joint liability would be drastically disproportionate to Janssen’s peripheral role in the Oklahoma opioid market, and the State’s alleged injuries are apportionable by reference to Janssen’s tiny market share and low abuse rates of its prescription opioid medications.

3. THE STATE’S CONTENTIONS:

Grounds for Recovery

Public Nuisance

The State’s “General Statement of Facts” above is incorporated here. Defendants engaged in a widespread marketing campaign and made false representations to healthcare providers and/or omitted material facts regarding the risks, efficacy, and medical necessity of opioids. Defendants did this through multiple channels, including sales representatives, speakers programs, CMEs, KOLs, front groups, patient advocacy groups, branded marketing and unbranded marketing.

Defendants stated, among other things, that the risk of addiction was a “myth,” “very rare,” “virtually non-existent,” and “less than 1%.” Defendants also supported and promulgated the idea that pain should be treated as the “5th Vital Sign.” By way of further example, Defendants promoted the false concept of “pseudoaddiction,” which Defendants used to convince prescribers that classic signs of addiction were actually signs of under-treated pain and should be treated with *more* opioid use. Defendants also overstated the benefits and efficacy of opioids and demonized safer alternatives. Defendants encouraged prescribers, including prescribers in Oklahoma to prescribe opioids for every day pain, rather than just for acute pain, cancer pain and palliative care. Defendants “targeted” Oklahoma prescribers and hammered these messages from all angles.

**Applicable Statute, Ordinance,
Common Law Rule**

Okla. Stat. tit. 50, §§ 1, 2, 8

Okla. Stat. tit. 23, § 15

Defendants acknowledge there is a direct correlation between Defendants’ marketing strategies for branded medications and Defendants’ profits for sales of such medications. Defendants acknowledge there is a direct correlation between sales of branded medication and sales of generic medication.

Defendants’ conduct constitutes a public nuisance—the opioid crisis in Oklahoma. The opioid crisis is an indivisible injury. Defendants each contributed, and are jointly and severally liable for, the public nuisance for which the State is entitled to the remedy of abatement.

Damages Or Relief Sought By The State

Applicable Statute, Ordinance, Common Law Rule

Abatement of Public Nuisance

Okla. Stat. tit. 50, § 8

The State’s plan to abate the public nuisance includes six major categories: (1) addiction prevention, treatment and recovery services; (2) overdose prevention and response; (3) medical education; (4) neonatal abstinence syndrome assessment and treatment; (5) data surveillance, reporting and research, and (6) funding for investigatory and regulatory actions related to the opioid crisis.

The net present value of the costs of the State’s abatement plan is \$12,667,819,392 for the 20-year period 2019-2038, \$15,193,102,533 for the 25-year period 2019-2043, and \$17,527,761,537 for the 30-year period 2019-2048.

4. DEFENDANTS’ CONTENTIONS:

A. Teva and Actavis Generic Defendants

No.	Grounds	Authority ⁸
1	The State Cannot Prove The Elements Of Its Claim By Clear And Convincing Evidence.	Okla. Stat. tit. 50, § 2; <i>Burlington N. & Santa Fe Ry. Co. v. Grant</i> , 505 F.3d 1013, 1022–23 (10th Cir. 2007)

⁸ The citations listed below are not meant to be an exhaustive list of all applicable statutes and case law but provide the Court with bases for concluding that the Teva and Actavis Generic Defendants cannot be held liable for causing a public nuisance in the State of Oklahoma.

2	The State cannot prove its public nuisance claim by clear and convincing evidence or by any other standard of proof.	Okla. Stat. tit. 50, § 2 <i>State of North Dakota v. Purdue Pharma, Case No. 08-2018-cv-01300</i> (Order 5/10/19) (dismissing nearly identical claims, including public nuisance claim, because manufacturer of opioids has no control over the product once it enters the market); <i>Burlington N. & Santa Fe Ry. Co. v. Grant</i> , 505 F.3d 1013, 1022–23 (10th Cir. 2007) (discussing abatement and establishing that the burden of proof under Oklahoma law for injunctive relief is clear and convincing evidence).
3	The Teva and Actavis Generic Defendants Did Not Cause The Opioid Epidemic And The State Cannot Satisfy Its Burden To Prove Causation.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation); <i>Travelers Indem. Co. v. Cephalon, Inc.</i> (“ <i>Travelers P</i> ”), 32 F. Supp. 3d 538 (E.D. Pa. 2014), aff’d, 620 F. App’x 82 (3rd Cir. 2015) (“ <i>Travelers IP</i> ”); <i>Ind./Ky./Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.</i> (“ <i>Carpenters</i> ”), No. 13-7167, 2014 WL 2115498 (E.D. Pa. May 21, 2014); <i>Cent. Reg’l Emps. Ben. Fund v. Cephalon, Inc.</i> (“ <i>CREB IP</i> ”), No. 09-3418 MLC, 2010 WL 1257790 (D.N.J. Mar. 29, 2010); <i>Cent. Reg’l Emps. Ben. Fund v. Cephalon, Inc.</i> (“ <i>CREB P</i> ”), No. 09-3418 MLC, 2009 WL 3245485 (D.N.J. Oct. 7, 2009); cf. <i>City of New Haven v. Purdue Pharma, L.P.</i> , A.3d, Dkt. No. X07-HHD-CV-17-608134-S (Conn. Super. Ct. Jan. 8, 2019);

		<i>Delaware v. Purdue Pharma L.P.</i> , No. N18C-01-223, 2019 WL 446382, at *12–13 (Del. Super. Ct. Feb. 4, 2019) (refusing “to recognize a public nuisance claim for products”).
4	The State offers no causation analysis linking any marketing of opioid medicines by the Teva or Actavis Generic Defendants to any opioid prescriptions written by Oklahoma prescribers.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
5	There is no evidence linking any marketing of opioid medicines by the Teva or Actavis Generic Defendants to any opioid prescriptions written by Oklahoma prescribers.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
6	The State offers no causation analysis linking any marketing of opioid medicines by the Teva or Actavis Defendants to any harm allegedly experienced by any Oklahoman (including, but not limited to overdose death or other overdose, becoming addicted to opioids or other illegal drugs, requiring treatment for Opioid Use Disorder or being convicted of a crime).	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
7	There is no evidence linking any marketing of opioid medicines by the Teva or Actavis Defendants to any harm allegedly experienced by any Oklahoman (including, but not limited to overdose death or other overdose, becoming addicted to opioids or other illegal drugs, requiring treatment for Opioid Use Disorder or being convicted of a crime).	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
8	The Actavis Generic Defendants sold generic medicines and did not market or promote the safety or efficacy of any of those opioid medicines, much less to any doctors in Oklahoma	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
9	Prior to 2011, Teva USA sold generic medicines and did not market or promote the safety or efficacy of any of those opioid medicines, much less to any doctors in Oklahoma.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
10	The State cannot show that any marketing, including any allegedly false marketing, of any opioid medicine influenced or otherwise caused any Oklahoma prescriber to write a harmful opioid prescription to any Oklahoma resident—much less	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)

	harmed an entire community.	
11	The State cannot show that any marketing, including any allegedly false marketing, of any opioid medicine manufactured or sold by the Teva and Actavis Generic Defendants influenced or otherwise caused any Oklahoma prescriber to write a harmful opioid prescription to any Oklahoma resident—much less harmed an entire community.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation)
12	The State cannot establish proximate causation.	Okla. Stat. tit. 50, §§ 1–2 (requiring causation) <i>See, e.g., Woodward v. Kinchen</i> , 1968 OK 152, 446 P.2d 375, 377–78 (“[L]iability cannot be predicated on a prior and remote cause which merely furnishes the condition for an injury resulting from an intervening, unrelated and efficient cause.”); <i>Lexmark Int’l, Inc. v. Static Control Components, Inc.</i> , 572 U.S. 118, 132 (2014) (common-law proximate causation principles are incorporated into statutes).
13	The independent decision-making of medical professionals, who are learned intermediaries, and other independent actors, including the FDA, DEA, distributors, pharmacies, pill mills, patients, the State, pharmacy-benefit managers, and insurers, broke any possible chain of causation and preclude a finding that the Actavis or Teva Defendants are responsible for any harm.	Okla. Stat. tit. 50, § 1–2 (causation requirement) <i>Tortorelli v. Mercy Health Ctr., Inc.</i> , 2010 OK CIV APP 105, ¶ 26, 242 P.3d 549, 560 (“[a] major underlying assumption of the learned intermediary doctrine is that a product has properties rendering it dangerous so as to require a doctor’s prescription or order for its use”); <i>Butler</i> , 1994 OK CIV APP 22, 871 P.2d at 446 (proximate cause exists only if conduct causes injury “in a natural and

		continuous sequence, unbroken by any independent cause”).
14	The criminal conduct of others, including illegal actions by pharmacies, doctors, patients, drug dealers, and other third parties breaks any possible chain of causation, such that the Teva and Actavis Generic Defendants cannot be held liable.	Okla. Stat. tit. 50, § 1 (causation requirement) <i>See, e.g., Prince v. B.F. Ascher Co.</i> , 2004 OK CIV APP 39, ¶ 20, 90 P.3d 1020, 1028 (there is no duty to “anticipate and prevent the intentional or criminal acts of a third party”).
15	The State has repeatedly taken the position that the Purdue Defendants caused the harm that forms the basis for the State’s remain claim.	Okla. Stat. tit. 50, § 1–2 (causation requirement) <i>See also</i> 12/5/17 Hearing Tr., at 31:21–32:21 (Beckworth, B.)
16	The State fails to account for the fact that the State, through its acts and omissions, was responsible for creating opioid-related problems in Oklahoma and the harm about which it complains.	Okla. Stat. tit. 50, §§ 1–2 (causation requirement)
17	The State’s Claim Improperly Seeks To Expand Oklahoma’s Law of Public Nuisance.	Okla. Stat. tit. 50, §§ 1–2; <i>N.C. Corff P’ship, Ltd. v. OXY USA, Inc.</i> , 929 P.2d 288, 293–96; <i>Meinders v. Johnson</i> , 134 P.3d 858, 860, 867–68 (Okla. Civ. App. 2005)
18	Public nuisance law in Oklahoma is limited to addressing interference with the use and enjoyment of real property.	Okla. Stat. tit. 50, § 1 (definition of nuisance); Okla. Stat. tit. 50, § 2 (definition of public nuisance) <i>See, e.g., N.C. Corff P’ship, Ltd. v. OXY USA, Inc.</i> , 929 P.2d 288, 293–96 (Okla. Civ. App. 1996); (groundwater pollution from oil and gas wells); <i>Meinders v. Johnson</i> , 134 P.3d 858, 860, 867–68 (Okla. Civ. App. 2005) (sub-surface pollution from mineral exploration).
19	The State cannot cloak its products-based claim as	Okla. Stat. tit. 50, § 1

	a tort action.	(definition of nuisance) <i>See. e.g., State v. Lead Indus., Ass'n, Inc.</i> , 951 A.2d 428, 456 (R.I. 2008). <i>See also</i> Restatement (Third) of Torts: Liability for Economic Harm § 8 TD No. 2 cmt. g (2014).
20	No Oklahoma court has ever recognized a claim for public nuisance on the basis of false marketing of a product.	Okla. Stat. tit. 50, § 1 (definition of nuisance)
21	The State's Claim Fails Because It Cannot Prove The Teva And Actavis Generic Defendants Committed An "Unlawful Act" That Caused A Public Nuisance.	Okla. Stat. tit. 50, § 1 (requiring an unlawful act)
22	Under Oklahoma law, "[a] nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission . . . [a]nnoys, injures or endangers the comfort, repose, health, or safety of others . . .".	Okla. Stat. tit. 50, § 1 (requiring an unlawful act)
23	The State cannot show an unlawful act or omission that caused the alleged annoyance, injury, or endangerment.	Okla. Stat. tit. 50, § 1 (requiring an unlawful act) <i>See., e.g., Nuncio v. Rock Knoll Townhome Vill., Inc.</i> , 2016 OK CIV APP 83, ¶ 8, 389 P.3d 370, 374 ("For an act or omission to be a nuisance in Oklahoma, it must be unlawful."); <i>Moore v. Texaco</i> , 244 F.3d 1229, 1231 (10th Cir. 2001) (applying Oklahoma law and holding that plaintiff landowner could not prevail on its claim for public nuisance against Texaco because the plaintiff "failed to show that Texaco caused pollution or damage to the property").
24	The State has not identified a duty that the Teva and Actavis Generic Defendants owed the State,	<i>See Wofford v. E. State Hosp.</i> , 1990 OK 77, 795 P.2d 516, 519

	much less demonstrated a breach of that duty.	("Oklahoma courts have recognized that the existence of a duty depends on the <i>relationship between the parties</i> and the general risks involved in the <i>common undertaking</i> ." (emphasis added).
25	The State has not identified any "right" which the Teva and Actavis Generic Defendants have infringed.	Okla. Stat. tit. 50, § 7 (a public nuisance claim must implicate a public right)
26	The State has not identified any Oklahoma law that the Teva or Actavis Generic Defendants supposedly violated.	Okla. Stat. tit. 50, § 1 (requiring an unlawful act) <i>See, e.g., Nuncio v. Rock Knoll Townhome Vill., Inc.</i> , 2016 OK CIV APP 83, ¶ 8, 389 P.3d 370, 374 ("For an act or omission to be a nuisance in Oklahoma, it must be unlawful."); <i>Moore v. Texaco</i> , 244 F.3d 1229, 1231 (10th Cir. 2001) (applying Oklahoma law and holding that plaintiff landowner could not prevail on its claim for public nuisance against Texaco because the plaintiff "failed to show that Texaco caused pollution or damage to the property").
27	The Actavis Generic Defendants sold FDA-approved generic medicines and did not market or promote the safety or efficacy of any of those opioid medicines, much less to any doctors in Oklahoma	Okla. Stat. tit. 50, §§ 1–2 (requiring an unlawful act) <i>See, e.g., New York ex rel. Schneiderman v. Actavis, PLC</i> , No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), <i>aff'd</i> , 787 F.3d 638 (2d Cir. 2015) (generic manufacturers "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon

		which they compete”)
28	Prior to 2011, Teva USA sold FDA-approved generic medicines and did not market or promote the safety or efficacy of any of those opioid medicines, much less to any doctors in Oklahoma	Okla. Stat. tit. 50, §§ 1–2 (requiring an unlawful act) <i>See, e.g., New York ex rel. Schneiderman v. Actavis, PLC</i> , No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), <i>aff’d</i> , 787 F.3d 638 (2d Cir. 2015) (generic manufacturers “compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete”)
29	The State cannot identify any false or misleading statement by Cephalon or Teva USA to any Oklahoma prescriber, much less one that influenced any prescriber to write a harmful opioid prescription.	Okla. Stat. tit. 50, §§ 1–2 (requiring an unlawful act)
30	Off-label marketing is not inherently false or misleading.	<i>United States v. Caronia</i> , 703 F.3d 149, 165 (2d Cir. 2012); <i>In re Actimmune Mktg. Litig.</i> , 614 F. Supp. 2d 1037, 1051 n.6 (N.D. Cal. 2009) (“off-label marketing of an approved drug is itself not inherently fraudulent”).
31	“Off-label” prescribing is an entirely proper practice of medical professionals’ prescribing a medicine—including Actiq or Fentora—for a purpose different from that specifically approved by the FDA. Therefore, the State cannot impose liability.	<i>See, e.g., Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341, 351 n.5 (2001) (off-label prescribing and use “often is essential to giving patients optimal medical care”); <i>Ind./Ky./Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.</i> , No. 13-7167, 2014 WL 2115498, at *7 (E.D. Pa. May 21, 2014).
32	The Teva and Actavis Generic Defendants cannot be held liable for interfering with a right, which	Okla. Stat. tit. 50, §§ 1–2 (requiring an unlawful act)

	does not satisfy Oklahoma's public nuisance statute, which requires an unlawful act or omission.	
33	The State Cannot Show That A Teva or Actavis Generic Defendant Had An Impact On Or Otherwise Harmed The Community As A Whole, Much Less All At The Same Time.	Okla. Stat. tit. 50, § 2
34	The alleged public nuisance did not affect "an entire community or neighborhood or considerable number of persons." Indeed, the State cannot show that any allegedly false or misleading marketing by the Teva or Actavis Defendants caused any harm to a single Oklahoma resident, to the State, or to anyone else in Oklahoma—much less harmed an "entire community."	Okla. Stat. tit. 50, § 2
35	The alleged public nuisance did not affect an entire community or neighborhood or considerable number of persons "at the same time." Indeed, the State cannot show that any allegedly false or misleading marketing by the Teva or Actavis Defendants caused any harm to a single Oklahoma resident, to the State, or to anyone else in Oklahoma—much less harmed an entire community "at the same time."	Okla. Stat. tit. 50, § 2
36	The Teva and Actavis Generic Defendants Are All Separate And Distinct Entities As A Matter of Law.	<i>See, e.g., N.L.R.B. v. Greater Kansas City Roofing</i> , 2 F.3d 1047 (10th Cir. 1993); <i>Buckner v. Dillard</i> , 1939 OK 144, 184 Okla. 586, 89 P.2d 326, 329.
37	Defendants Teva USA, Cephalon, Watson Labs, Actavis LLC, and Actavis Pharma are all separate legal entities and cannot be held responsible for the acts of others.	<i>See, e.g., N.L.R.B. v. Greater Kansas City Roofing</i> , 2 F.3d 1047 (10th Cir. 1993); <i>Buckner v. Dillard</i> , 1939 OK 144, 184 Okla. 586, 89 P.2d 326, 329.
38	The State has not alleged—and certainly cannot satisfy the requirements for—any veil piercing theory.	<i>See, e.g., N.L.R.B. v. Greater Kansas City Roofing</i> , 2 F.3d 1047 (10th Cir. 1993); <i>Buckner v. Dillard</i> , 1939 OK 144, 184 Okla. 586, 89 P.2d 326, 329.
39	The State cannot prove the elements of its claim against Teva USA.	Okla. Stat. tit. 50, §§ 1–2 <i>McCall v Chesapeake Energy</i> ,

		2000 OK CIV APP 59.
40	The State cannot prove the elements of its claim against Cephalon.	Okla. Stat. tit. 50, §§ 1-2 <i>McCall v Chesapeake Energy</i> , 2000 OK CIV APP 59.
41	The State cannot prove the elements of its claim against Watson Labs.	Okla. Stat. tit. 50, §§ 1-2 <i>McCall v Chesapeake Energy</i> , 2000 OK CIV APP 59.
42	The State cannot prove the elements of its claim against Actavis LLC.	Okla. Stat. tit. 50, §§ 1-2 <i>McCall v Chesapeake Energy</i> , 2000 OK CIV APP 59.
43	The State cannot prove the elements of its claim against Actavis Pharma.	Okla. Stat. tit. 50, §§ 1-2 <i>McCall v Chesapeake Energy</i> , 2000 OK CIV APP 59.
44	The State Cannot Establish Concerted Activity Between The Defendants.	<i>See Dunham v. Marine Midland Tr. Co. of N.Y.</i> , 1935 OK 560, 175 Okla. 461, 53 P.2d 254, 256; <i>Gaylord Entm't Co. v. Thompson</i> , 1998 OK 30, ¶ 40, 958 P.2d 128, 148
45	There is no evidence of the elements of conspiracy under Oklahoma law, including no agreement, no agreement to engage in unlawful activity, and no overt act.	<i>See Dunham v. Marine Midland Tr. Co. of N.Y.</i> , 1935 OK 560, 175 Okla. 461, 53 P.2d 254, 256 (In order for a conspiracy to exist there must be another and wholly independent agreement, express or implied, from which may be erected a conspiracy to defeat the laws of Oklahoma.); <i>Gaylord Entm't Co. v. Thompson</i> , 1998 OK 30, ¶ 40, 958 P.2d 128, 148 (“A civil conspiracy consists of a combination of two or more persons to do an unlawful act, or to do a lawful act by unlawful means. Unlike its criminal counterpart, civil conspiracy itself does not create liability. In order to be liable the

		conspirators must pursue an independently unlawful purpose or use an independently unlawful means. <i>There can be no civil conspiracy where the act complained of and the means employed are lawful.</i>) (emphasis added).
46	The State Cannot Establish Any Agency Relationship To Hold The Teva or Actavis Generic Defendants Responsible For The Conduct Of Any Third Party	<i>Estate of King v. Wagoner County Bd. of County Com'rs</i> , 2006 OK CIV APP 118
47	The Teva and Actavis Generic Defendants cannot be held liable for statements made by third parties because the State has not shown an agency relationship—because there was no such relationship—between the Teva and Actavis Generic Defendants and third-party organizations and key opinion leaders.	Okla. Stat. tit. 50, § 1 <i>Estate of King v. Wagoner County Bd. of County Com'rs</i> , 2006 OK CIV APP 118, ¶ 27 (“An agency relationship will not be presumed, and the burden of proving the existence, nature and extent of the relationship ordinarily rests on the party asserting it.”).
48	The State cannot show that the Teva and Actavis Generic Defendants exercised any control over the content of the statements of third-party organizations and key opinion leaders absent an agency relationship, which the State has not shown.	<i>Murray County v. Homesales, Inc.</i> , 2014 OK 52, ¶ 15 (“The essential factor in any agency relationship is the principal’s right to control the conduct of the agent.”)
49	The State Contributed To The Harms It Alleges Were Caused By The Teva and Actavis Generic Defendants’ Conduct And Did Not Mitigate Any Alleged Harm.	<i>Story v. Hefner</i> , 540 P.2d 562 (Okla. 1975)
50	The State knew of harms associated with opioid misuse and failed to take steps to prevent the opioid abuse crisis in Oklahoma. Because the State’s acts and omissions contributed to the State’s alleged harms, the State is not entitled to the relief it seeks.	<i>Story v. Hefner</i> , 540 P.2d 562 (Okla. 1975) (“He who seeks equity must do equity and come into court with clean hands.”); <i>Krumme v. Moody</i> , 1995 OK 140, 910 P.2d 993, 996 (1995) (“Oklahoma law declares that ‘to receive equity, [a person] must do equity.’”); <i>McDonald v. Humphries</i> , 1990

		OK 51, 810 P.2d 1262, 1269 (1990) (“Equity provides no relief when its aid becomes necessary through the party’s own fault.”).
51	The State, through the Oklahoma Health Care Authority, is only authorized by statute to reimburse medically necessary prescriptions.	Okla. Stat. tit. 317, § 30(3)(1)
52	The State, through the Oklahoma Health Care Authority, reimbursed and continues to reimburse for opioid medicines manufactured and sold by the Teva and Actavis Generic Defendants, and the State admits it reimburses for only medically necessary prescriptions.	Okla. Stat. tit. 317, § 30(3)(1)
53	The State’s position regarding medically necessary and “medically unnecessary” prescriptions is inconsistent with Oklahoma law and also inconsistent with the State’s prior actions.	Okla. Stat. tit. 317, § 30(3)(1)
54	The State’s claim is barred because it cannot show that the Teva or Actavis Generic Defendants caused a prescription to be made in Oklahoma that was not medically necessary under Oklahoma law.	Okla. Stat. tit. 317, § 30(3)(1)
55	The State’s Claim Is Barred By The First Amendment	United States Constitution, First Amendment and Oklahoma Constitution, Article II, § 22
56	The Teva and Actavis Generic Defendants’ speech regarding the promotion of its opioid medicines is protected by the First Amendment.	United States Constitution, First Amendment and Oklahoma Constitution, Article II, § 22 <i>See, e.g., Caronia</i> , 703 F.3d at 169; <i>see also Sorrell v. IMS Health Inc.</i> , 564 U.S. 552, 557 (2011) (“[s]peech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment”).
57	The State’s claim is barred by the applicable provisions of the United States Constitution and the Oklahoma Constitution because the alleged predicate acts underlying the State’s public nuisance claim concern lawful activity and are	United States Constitution, First Amendment; Oklahoma Constitution, Article II, § 22

	neither false nor misleading.	
58	The State’s Claim Against The Teva And Actavis Generic Defendants Is Preempted.	<i>PLIVA, Inc. v. Mensing</i> , 564 U.S. 604 (2011)
59	The State’s public nuisance claim against Cephalon and Teva USA (after 2011) is preempted by federal law because it is based upon nothing more than alleged off-label promotion.	<i>Buckman v. Pls.’ Legal Comm.</i> , 531 U.S. 341 (2001); <i>In re Celexa & Lexapro Mktg. & Sales Practices Litig.</i> , 779 F.3d34 (1st Cir. 2015); <i>Yates v. OrthoMcNeil-Janssen Pharms., Inc.</i> , 808 F.3d 281 (6th Cir. 2015).
60	The State’s claim against Teva USA and the Actavis Generic Entities with respect to their FDA-approved generic medicines is preempted by the federal duty of sameness that applies to generic manufacturers and well-settled Supreme Court law. In addition, the State cannot base its claims on the theory that Teva USA and the Actavis Generic Entities are liable merely for selling their generic medicines.	<i>PLIVA, Inc. v. Mensing</i> , 564 U.S. 604 (2011); <i>Mutual Pharmaceutical Co., v. Bartlett</i> , 570 U.S. 472 (2013); <i>McDaniel v. Upsher-Smith Laboratories, Inc.</i> , 893 F.3d 941 (6th Cir. 2018); <i>Morris v. PLIVA, Inc.</i> , 713 F.3d 774 (5th Cir. 2013) (per curiam).
61	The State’s “Abatement” Remedy Is An Improper Attempt At Recovering Damages	50 Okla. Stat. § 11; <i>State v. Twin C Convenience Store</i> , 218 P.3d 529, 532 (Okla. Civ. App. Ct. 2009)
62	Abatement is an equitable remedy, however the State seeks purely economic damages that are not aimed at abating the nuisance alleged here—false marketing of opioid medicines.	50 Okla. Stat. § 11 (“A public nuisance may be abated by any public body or officer authorized thereto by law”). <i>See, e.g., State v. Twin C Convenience Store</i> , 218 P.3d 529, 532 (Okla. Civ. App. Ct. 2009) (abatement is an equitable remedy).
63	The State’s “Abatement” Plan Is Speculative And Not Connected To The Alleged Nuisance.	<i>Magnolia Petroleum Co. v. Wright</i> , 124 Okla. 55, 254 P. 41, 45 (1926)
64	The State’s “abatement” plan does not address the alleged public nuisance—that is, Defendants’ alleged false marketing. Indeed, the Teva and Actavis Generic Defendants do not promote their opioid medicines. As a result, there is nothing to abate.	50 Okla. Stat. § 11 (“A public nuisance may be abated by any public body or officer authorized thereto by law”). <i>Magnolia Petroleum Co. v.</i>

		<i>Wright</i> , 124 Okla. 55, 254 P. 41, 45 (1926) (internal quotations and citations omitted) (courts can provide “relief against either public or private nuisances by compelling the abatement, or restraining the continuance of the existing nuisance . . .”).
65	The State’s “abatement” plan seeks costs associated with addressing issues other than allegedly false marketing.	50 Okla. Stat. § 11 (“A public nuisance may be abated by any public body or officer authorized thereto by law”); <i>Magnolia Petroleum Co. v. Wright</i> , 124 Okla. 55, 254 P. 41, 45 (1926) (abatement relief is limited to compelling the abatement . . . of the existing nuisance”).
66	The State’s “abatement” plan is legally insufficient because it seeks abatement as to issues over which the Teva and Actavis Generic Defendants have no control.	50 Okla. Stat. § 11 <i>Sipe v. Dale</i> , 1938 OK 377, 183 Okla. 127, 80 P.2d 569, 570
67	The State’s “abatement” plan is based upon speculation and conjecture and lacks an evidentiary foundation.	Okla. Stat. tit. 50 § 17
68	The State’s “Abatement” Plan Violates The Municipal Recovery Rule	32 A.L.R.6th 261; <i>Baker v. Smith & Wesson Corp.</i> , No. CIV.A. 99C-09-283-FS, 2002 WL 31741522, at *5; <i>Walker Cty. v. Tri-State Crematory</i> , 284 Ga. App. 34, 40, 643 S.E.2d 324, 329 (2007)
69	The State’s “abatement” plan seeks to recover money for numerous expenses that the State otherwise provides for public services in its role as a sovereign, which violates the “free public services” doctrine.	32 A.L.R.6th 261 (Originally published in 2008) (“[A]bsent specific statutory authorization or damage to government-owned property, a county cannot recover the costs of carrying out public services from a tortfeasor whose conduct caused the need for the

		<p>services.”</p> <p><i>See also Baker v. Smith & Wesson Corp.</i>, No. CIV.A. 99C-09-283-FS, 2002 WL 31741522, at *5 (Del. Super. Ct. Nov. 27, 2002) (“[S]tate legislatures establish local governments to provide core services for the public and pay for these services by spreading the costs to all citizens through taxation.”); <i>Walker Cty. v. Tri-State Crematory</i>, 284 Ga. App. 34, 40, 643 S.E.2d 324, 329 (2007) (County that established a crisis center, morgue, and other facilities to recover, move, store, and identify human remains discovered on a crematorium’s property was barred by the free public services doctrine).</p>
70	The State’s “Abatement” Remedy Is An Improper Attempt At Recovering Damages, Which The State Dismissed	State’s Notice of Voluntary Dismissal, Apr. 4, 2019 (dismissing all claims for damages and limiting case to statutory claim for public nuisance and remedy of abatement).
71	The State does not seek to “abate” the public nuisance (which involves alleged false marketing), but, instead, seeks past and future damages. This is improper because the State dismissed all requests for damages and has abandoned such relief.	State’s Notice of Voluntary Dismissal, Apr. 4, 2019 (dismissing all claims for damages and limiting case to statutory claim for public nuisance and remedy of abatement).
72	The State has not provided any evidence to show that the broad-range of addiction-related harms which serve as the basis for its public nuisance claim are temporary.	<i>Max Oil Co. Inc. v. Range Prod. Co. LLC</i> , 681 F. App’x 710, 717 (10th Cir. 2017).
73	The State’s Claim Is Barred By The Statute Of Limitations	<i>Cole v. Asarco Inc.</i> , No. 03-CV-327-GKF-PJC, 2010 WL

		711195, at *5 (N.D. Okla. Feb. 24, 2010); <i>Resolution Trust Corp. v. Grant</i> , 901 P.2d 807, 813 (Okla. 1995)
74	Under Oklahoma law, a two-year statute of limitations applies to nuisance claims unless an “actual obstruction of a public right” is alleged. The State has not identified any public right that has been interfered with; instead, the State alleges interference with a series of private rights.	<i>Cole v. Asarco Inc.</i> , No. 03-CV-327-GKF-PJC, 2010 WL 711195, at *5 (N.D. Okla. Feb. 24, 2010); <i>see also</i> 50 Okla. Stat. § 7 (“[n]o lapse of time can legalize a public nuisance, amounting to an actual obstruction of <i>public right.</i> ”) (emphasis added).
75	The statute of limitations started to run as soon as the State knew or should have known of the injury. By its own admission, the State was aware of the opioid crisis long ago, yet did not file its public nuisance claim under June 2017, after the statute of limitations had ended.	<i>Resolution Trust Corp. v. Grant</i> , 901 P.2d 807, 813 (Okla. 1995) (statute of limitations started to run as soon as the State “kn[e]w[] or, in the exercise of reasonable diligence, should have known of the injury”)
76	There Is No Joint And Several Liability	<i>Union Tex. Petroleum Corp. v. Jackson</i> , 909 P.2d 131, 149 (Okla. Ct. App. 1995)
77	There is no “single injury” such that the Teva and Actavis Generic Defendants are jointly and severally liable.	<i>Union Tex. Petroleum Corp. v. Jackson</i> , 909 P.2d 131, 149 (Okla. Ct. App. 1995) (Under Oklahoma’s common law, in order to be jointly and severally liable, the distinct acts of each defendant must “combine to produce directly a single injury.”).
78	The State cannot show joint and several liability because it cannot show that the Teva and Actavis Generic Defendants acted in concert with any other Defendant(s).	<i>Union Tex. Petroleum Corp. v. Jackson</i> , 909 P.2d 131, 149 (Okla. Ct. App. 1995) (Under Oklahoma’s common law, in order to be jointly and severally liable, the distinct acts of each defendant must “combine to produce directly a single injury.”).
79	The Teva and Actavis Generic Defendants are not	<i>See Walters v. Prairie Pil &</i>

	jointly and severally liable because the State's own actions and inactions contributed to the alleged public nuisance.	<i>Gas Co.</i> , 204 P. 906, 908 (Okla. 1922).
80	If Held Liable, The Teva And Actavis Generic Defendants Have A Right Of Contribution Against The State And Others.	Okla. Stat. tit. 12, § 832
81	If the Court holds the Teva and Actavis Generic Defendants liable for causing the public nuisance alleged, the Teva and Actavis Generic Defendants have a right to contribution against the State and other actors.	Okla. Stat. tit. 12, § 832
82	The State's alleged loss, damage, injury, harm, expense, diminution, or deprivation, was caused in whole or in part by the State's ratification of the Teva and Actavis Generic Defendants' allegedly deceptive or misleading conduct. For example, the State continues to reimburse opioid prescriptions that the State contends were fraudulently induced and supposedly harm Oklahoma residents.	Okla. Stat. tit. 12, § 832
83	If found liable, the Teva and Actavis Generic Defendants may not be compelled to make contribution beyond their pro rata share of the entire liability.	Okla. Stat. tit. 12, § 832
84	If Held Liable, The Teva And Actavis Generic Defendants Are Entitled To A Set-Off As A Result Of The Purdue Settlement.	Okla. Stat. tit. 12, § 832
85	If held liable, the amount of any judgment must be set-off in the amount of the Purdue settlement.	Okla. Stat. tit. 12, § 832 <i>See also In re Jones</i> , 804 F.2d 1133, 1143 (10th Cir. 1986) (“[I]t is the court's duty under Oklahoma law to credit the judgment by any settlements[.]”).
86	The Teva and Actavis Generic Defendants' Federal And State Constitutional Due Process Rights Have Been Violated, Are Continuing To Be Violated, And Will Be Violated Further If a Judgment Is Entered Against Them.	U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution
87	Any judgment entered against the Teva and Actavis Generic Defendants will violate their due process rights.	U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution

88	The rights of Cephalon are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding. Any contingency fee arrangement between the State and any third party in connection with this litigation gives that third party a financial interest in the outcome of this proceeding and violates the due process rights of Cephalon.	U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution <i>See, e.g., Marshall v. Jerrico, Inc.</i> , 446 U.S. 238 (1980).
89	The State's claim violates the Teva and Actavis Generic Defendants' right to due process because it is vague and fails to provide fair notice of the conduct prohibited by Oklahoma's nuisance statute. The statute, as applied here, is unduly vague and fails to give fair warning that it would apply in this context.	<i>Sessions v. Dimaya</i> , 138 S.Ct. 1204 (2018) ("The void-for-vagueness doctrine, as we have called it, guarantees that ordinary people have 'fair notice' of the conduct a statute proscribes."); <i>State ex rel. Okla. Bar Ass'n v. Minter</i> , 37 P.3d 763 (Okla. 2001) (Due process requires a "fair warning ... that intelligibly communicates the parameters of conduct to be proscribed" prior "to imposition of penalty, civil or criminal.")
90	The State cannot rely upon any alleged false marketing or other conduct done outside Oklahoma to sustain its claim of public nuisance within Oklahoma without violating the Due Process and Commerce Clauses of the United States Constitution.	May 9, 2019 Ruling (Balkman, J.) <i>See, e.g., Healy v. Beer Inst., Inc.</i> , 491 U.S. 324, 336 (1989) (Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State"); <i>BMW of N. Am., Inc. v. Gore</i> , 517 U.S. 559, 572-73 (1996) ("Alabama does not have the power, however, to punish BMW for conduct that was lawful where it occurred and that had no impact on Alabama

		or its residents.”); <i>Ass’n for Accessible Medicines v. Frosh</i> , 887 F.3d 664, 672 (4th Cir. 2018) (holding unconstitutional the State of Maryland’s attempt to “compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.”).
91	The Teva and Actavis Generic Defendants have been deprived of meaningful due process by the State’s failure to produce non-privileged material relevant to the State’s claims and the Teva and Actavis Generic Defendants’ defenses, such as, but not limited to, claims data information, the names of the Oklahoma doctors who supposedly were misled, information about Oklahomans who were allegedly harmed by Defendants’ medicines, and criminal investigative files.	U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution <i>See, e.g., Lindsey v. Normet</i> , 405 U.S. 56, 66 (1972).
92	The State’s claims are barred because it cannot meet its burden to prove liability based on acts occurring in Oklahoma.	<i>Healy v. Beer Inst., Inc.</i> , 491 U.S. 324, 336 (1989); <i>BMW of N. Am., Inc. v. Gore</i> , 517 U.S. 559, 572–73 (1996); <i>Ass’n for Accessible Medicines v. Frosh</i> , 887 F.3d 664, 672 (4th Cir. 2018)
93	The Teva and Actavis Generic Defendants will be deprived of meaningful due process if the Court admits hearsay evidence and the testimony of unqualified experts at trial.	U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution
94	Additional Defenses And Contentions	Okla. Stat. tit. 12, § 2008(A)(1); <i>Taylor v. Pate</i> , 1993 OK CIV APP 79, 859 P.2d 1124, 1127; <i>Rutherford v. United States</i> , 806 F.2d 1455, 1461 (10th Cir. 1986); 12 Okla. Stat. § 2019; 12 Okla. Stat. § 2012(B)(7); <i>Case v. Fireboard Corp.</i> , 743 P.2d 1062 (Okla. 1987); <i>Merritt v. Merritt</i> , 2003 OK 68, ¶ 15, 73 P.3d 878, 883; <i>Tortorelli v. Mercy Health Ctr., Inc.</i> , 2010

		OK CIV APP 105, ¶ 26, 242 P.3d 549, 560; <i>Barringer v Baptist Healthcare</i> , 2001 OK 29, 22 P3d 695; 12 Okla. Stat. § 2020; 12 Okla. Stat. § 2021; Okla. Stat. tit. 50, § 1; <i>N.H. v. Presbyterian Church (U.S.A.)</i> , 1999 OK 88, ¶ 0, 998 P.2d 592, 594; <i>State v. Twin C Convenience Store</i> , 218 P.3d 529, 532 (Okla. Civ. App. Ct. 2009); <i>Ward Petroleum Corp. v. Stewart</i> , 2003 OK 11, ¶ 5, 64 P.3d 1113, 1118; Okla. Stat. tit. 12, § 941; State's Notice of Voluntary Dismissal, Apr. 4, 2019; <i>Haenchen v. Sand Prod. Co.</i> , 1981 OK CIV APP 6, 626 P.2d 332, 335
95	The State's claim is barred because the State fails to state a claim upon which relief can be granted.	Okla. Stat. tit. 12, § 2008(A)(1)
96	The State's claim is barred because the State has failed to provide any evidence in support of their claim.	<i>Taylor v. Pate</i> , 1993 OK CIV APP 79, 859 P.2d 1124, 1127 (citing <i>Buckner v. General Motors Corp.</i> , 760 P.2d 803 (Okla. 1988) ("Summary judgment is proper when the record before the Court presents no genuine issue of material fact and one party is entitled to judgment as a matter of law.")).
97	The State's claim is barred by the doctrine of primary jurisdiction.	<i>See, e.g., Rutherford v. United States</i> , 806 F.2d 1455, 1461 (10th Cir. 1986) (The FDA has "primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise."); <i>Fent v. Oklahoma Nat. Gas Co., a Div. of Oneok Inc.</i> , 1994 OK 108, 898 P.2d 126, 134 ("A district court's judicial process will be suspended pending

		disposition of the issues referred to the administrative body.”).
98	The State failed to join one or more necessary and indispensable parties, including without limitation: health care providers, prescribers, patients, and other third parties whom the State alleges engaged in the unauthorized or illicit prescribing, dispensing, diversion, or use of prescription opioid medicines in Oklahoma.	12 Okla. Stat. § 2019; 12 Okla. Stat. § 2012(B)(7).
99	Liability cannot be apportioned by market share, including with respect to generic medicines for which the State offers no proof of any false or misleading marketing that led to the prescribing of generic medicines which in turn caused any Oklahoman harm.	<i>Case v. Fireboard Corp.</i> , 743 P.2d 1062 (Okla. 1987) (rejecting the “market share theory of liability” because “the public policy favoring recovery on the part of an innocent plaintiff does not justify the abrogation of the rights of a potential defendant to have a causative link proven between that defendant’s specific tortious acts and the plaintiff’s injuries where there is a lack of circumstances which would insure that there was a significant probability that those acts were related to the injury.”).
100	The State’s claim is barred by the doctrines of laches, waiver, and/or equitable estoppel.	<i>See, e.g., Merritt v. Merritt</i> , 2003 OK 68, ¶ 15, 73 P.3d 878, 883 (“Equitable estoppel is employed to prevent one party from taking a legal position inconsistent with an earlier action. . .”); <i>Smith v. Baptist Found. of Oklahoma</i> , 2002 OK 57, ¶ 9, 50 P.3d 1132, 1138 (Laches is an equitable defense to stale claims).
101	The State’s claim is barred by the learned intermediary doctrine.	<i>Tortorelli v. Mercy Health Ctr., Inc.</i> , 2010 OK CIV APP 105, ¶ 26, 242 P.3d 549, 560 (“[a] major underlying assumption of

		the learned intermediary doctrine is that a product has properties rendering it dangerous so as to require a doctor's prescription or order for its use"); <i>Butler</i> , 1994 OK CIV APP 22, 871 P.2d at 446 (proximate cause exists only if conduct causes injury "in a natural and continuous sequence, unbroken by any independent cause").
102	The State's claims are barred by the doctrine of judicial estoppel.	<i>Barringer v Baptist Healthcare</i> , 2001 OK 29, 22 P3d 695; <i>Messler v Simmons Gun Specialties</i> , 1984 OK 35, 687 P2d 121.
103	Because the State's claims against the Teva and Actavis Generic Defendants do not arise out of the same transaction, occurrence, or series of transactions or occurrences as those against the other Defendants, the claims against these Defendants are improperly joined and should be severed.	12 Okla. Stat. § 2020; 12 Okla. Stat. § 2021 <i>A-Plus Janitorial & Carpet Cleaning v. Emp'rs' Workers' Comp. Ass'n</i> , 936 P.2d 916, 926 (Okla. 1997) (There are "two requisites for joinder of parties: (1) a right to relief must be asserted by or against each plaintiff or defendant relating to or arising out of the <u>same transaction or occurrence</u> ; and (2) some question of law or fact common to all the parties will arise in the action.").
104	The State's claim is barred to the extent that it relies on or implicates the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of the State or third parties that are not subject to the Teva and Actavis Generic Defendants' control or authority and for which the Teva and Actavis Generic Defendants are not responsible and cannot be held liable.	Okla. Stat. tit. 50, § 1 (causation requirement) <i>See, e.g., State of North Dakota v. Purdue Pharma</i> , Case No. 08-2018-cv-01300 (Order 5/10/19) (dismissing nearly identical claims, including public nuisance claim, because

		manufacturer of opioids has no control over the product once it enters the market); <i>Prince v. B.F. Ascher Co.</i> , 2004 OK CIV APP 39, ¶ 20, 90 P.3d 1020, 1028 (there is no duty to “anticipate and prevent the intentional or criminal acts of a third party”).
105	To the extent any agents, employees, or contractors of Teva or Actavis caused any of the harm alleged by the State, such agents, employees, or contractors were acting outside the scope of the agency employment or contract with the Teva and Actavis Generic Defendants.	<i>See, e.g., N.H. v. Presbyterian Church (U.S.A.)</i> , 1999 OK 88, ¶ 0, 998 P.2d 592, 594 (liability may not be imposed where acts of employees were outside the scope of employment).
106	Any harm to the State must be set off against the benefits to the State as a result of the Teva and Actavis Generic Defendants’ lawful activity, including the benefits of their opioid medicines.	<i>See, e.g., State v. Twin C Convenience Store</i> , 218 P.3d 529, 532 (Okla. Civ. App. Ct. 2009) (abatement is an equitable remedy).
107	The State’s claims seek duplicate or double recovery on the same injury or damage, contrary to Oklahoma law.	<i>See, e.g., Ward Petroleum Corp. v. Stewart</i> , 2003 OK 11, ¶ 5, 64 P.3d 1113, 1118 (no double recovery is allowed for the same injury).
108	The State is not entitled to attorneys’ fees, costs, pre-judgment interest, or post-judgment interest.	Okla. Stat. tit. 50 § 1 et seq.
109	If the Teva and Actavis Generic Defendants are not found liable for the State’s claim of public nuisance, the Teva and Actavis Generic Defendants are entitled to court costs, witness fees, and attorney fees.	Okla. Stat. tit. 12, § 941
110	The State has waived any claim for damages by dismissing all other claims and only asserting one cause of action against the Teva and Actavis Generic Defendants for a temporary public nuisance.	State’s Notice of Voluntary Dismissal, Apr. 4, 2019
111	The State has waived and dismissed all claims for damages including past, future, and punitive damages.	State’s Notice of Voluntary Dismissal, Apr. 4, 2019
112	The State cannot avoid its waiver and dismissal by relabeling a damages claim as “abatement.”	State’s Notice of Voluntary Dismissal, Apr. 4, 2019
113	The Teva and Actavis Generic Defendants do not	<i>See, e.g., Haenchen v. Sand</i>

	waive their right to a jury trial as to any claim other than the State's public nuisance claim for abatement relief.	<i>Prod. Co.</i> , 1981 OK CIV APP 6, 626 P.2d 332, 335
114	The State's claim is barred, in whole or in part, by the State's failure to comply with the requirement that it identify each patient in whose claim(s) the State has a subrogation interest.	Okla. Stat. tit. 50, §§ 1-2 (requiring causation)
115	The State's claims is barred, in whole or in part, by principles of equity.	<i>Story v. Hefner</i> , 540 P.2d 562 (Okla. 1975) ("He who seeks equity must do equity and come into court with clean hands."); <i>Krumme v. Moody</i> , 1995 OK 140, 910 P.2d 993, 996 (1995) ("Oklahoma law declares that 'to receive equity, [a person] must do equity.'"); <i>McDonald v. Humphries</i> , 1990 OK 51, 810 P.2d 1262, 1269 (1990) ("Equity provides no relief when its aid becomes necessary through the party's own fault.").
116	The Teva and Actavis Generic Defendants adopt and incorporate all contentions of the Janssen Defendants not explicitly addressed herein.	Okla. Stat. tit. 50, §§ 1-2 (requiring causation)

B. J&J and Janssen⁹

⁹ The cited authorities are not intended to be exhaustive but provide the Court with bases for Janssen's anticipated defenses.

<p>1. Failure to prove the elements of a public nuisance abatement claim.</p>	<p>12 Okla. Stat. § 2012; 50 O.S. § 1 <i>et seq.</i>; ; <i>Briscoe v. Harper Oil Co.</i>, 1985 OK 43, ¶ 9, 702 P.2d 33, 36 (nuisance “is a class of wrongs which arises from an unreasonable, unwarranted, or unlawful use by a person or entity of <i>property</i> lawfully possessed” (emphasis added)); <i>Kirkland v. GMC</i>, 1974 OK 52, ¶ 29, 521 P.2d 1353, 1363 (“[T]he mere possibility that a defendant’s conduct “might have caused [a plaintiff’s] injury is not enough.”); <i>Atchison, Topeka & Santa Fe Ry. Co. v. Kelly</i>, 1928 OK 256, ¶ 10, 266 P. 775, 776 (“The defendant might abate its nuisance, but could not, by so doing, restore plaintiff’s premises.”); <i>Magnolia Petroleum Co. v. Wright</i>, 1926 OK 196, ¶ 2, 254 P.2d 41, 42 (government power to “abate and remove” “a nuisance” is the “power [t] prevent any act or omission of any duty . . . which act or omission . . . annoys, injures, or endangers the comfort lives, health, or safety of others ” (emphasis added)).</p>
<p>2. The State claims are barred, reduced, and/ or limited pursuant to applicable statutes of limitations and/or statute of repose.</p>	<p>12 Okla. Stat. § 95; 12A Okla. Stat. § 2-725; 76 Okla. Stat. § 90.11.</p>
<p>3. The claims asserted in the State’s Second Amended Petition are barred, in whole or in part, because the Food & Drug Administration (“FDA”) and DEA has exclusive or primary jurisdiction over the matters asserted in the Petition.</p>	<p>21 U.S.C. §§ 360, <i>et seq.</i></p>

<p>4. The State claims and alleged injuries are preempted by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, processing, and supply of Janssen's products and because Janssen's conduct was authorized by the FDA.</p>	<p><i>Merck Sharp & Dohme Corp. v. Albrecht</i>, No. 17-290 (U.S. May 20, 2019); <i>McKee v. Moore</i>, 1982 OK 71, 648 P.2d 21, 24 (“In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects.”); <i>Strayhorn v. Wyeth Pharm., Inc.</i>, 737 F.3d 378, 394 (6th Cir. 2013) (“Because . . . advertising and promotional materials are considered labeling, and because labeling is limited by federal law to the information contained in the [FDA-approved] labeling,” claims based on advertising are preempted.); 21 U.S.C. § 360, <i>et seq.</i> (and applicable regulations).</p>
<p>5. To the extent the State asserts claims that depend solely on violations of federal law, including any claims of a “fraud on the FDA” with respect to J&J or Janssen’s disclosure of information related to the safety of the products, such claims are barred and should be dismissed.</p>	<p><i>Buckman Co. v. Plaintiffs’ Legal Comm.</i>, 531 U.S. 341, 348 (2001) (“[W]e hold that the plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law.”).</p>
<p>6. To the extent the State’s public nuisance claim depends on actions maintained under the authority of a statute or regulatory body, the claim is barred.</p>	<p>50 Okla. Stat. § 4.</p>
<p>7. The State claims are barred, in whole or in part, by the doctrine of laches.</p>	<p><i>Unit Petroleum Co. v. Frost</i>, 2014 WL 585361, at *5 (N.D. Okla. Feb. 13, 2014) (“In order to prove the affirmative defense of laches, the defendant must demonstrate that there has been an unreasonable delay in asserting the claim and that the defendant was materially prejudiced by that delay.” (quoting <i>Jacobsen v. Deseret Book Co.</i>, 287 F.3d 936, 949 (10th Cir. 2002)); <i>Smith v. Baptist Found. of Okla.</i>, 2002 OK 57, ¶ 9, 50 P.3d 1132, 1138 (“Laches is an equitable defense to stale claims.”).</p>

<p>8. The State claims are barred, in whole or in part, by waiver.</p>	<p>12 Okla. Stat. § 2008(C); <i>State Farm Mut. Auto. Ins. Co. v. Petsch</i>, 261 F.2d 331, 334 (10th Cir. 1958) (“The constituent elements of waiver are an existing right, knowledge of that right, and an intention to relinquish or surrender it.”).</p>
<p>9. The State claims are barred, in whole or in part, by principles of equity.</p>	<p><i>Krumme v. Moody</i>, 1995 OK 140, 910 P.2d 993, 996 (“[T]o receive equity, [one] must do equity.”); <i>Armstrong v. Maple Leaf Apartments, Ltd.</i>, 436 F. Supp. 1125, 1150 (N.D. Okla. 1977) (“It is a firmly established rule of equity jurisprudence that he who seeks equity must do equity, that only conscience, good faith and diligence can put equity into operation, and that he who comes into equity must come with clean hands.”).</p>
<p>10. The State is not entitled to equitable relief, in whole or in part, because an adequate remedy at law exists.</p>	<p><i>Quarles v. Little River Energy Co.</i>, 2008 WL 185715, at *2 (N.D. Okla. Jan. 18, 2008) (“This Court hereby declines to exercise its equitable jurisdiction, as plaintiffs have an adequate remedy at law.”); <i>Harvell v. Goodyear Tire and Rubber Co.</i>, 2006 OK 24, ¶ 18, 164 P.3d 1028, 1035 (“Where the plaintiff has an adequate remedy at law, the court will not ordinarily exercise its equitable jurisdiction to grant relief . . .”).</p>
<p>11. The State may not recover on its claims because of the doctrine of unclean hands or estoppel.</p>	<p><i>Story v. Hefner</i>, 1975 OK 115, 540 P.2d 562, 567 (“He who seeks equity must do equity and come into court with clean hands.”).</p>
<p>12. The State claims are barred, in whole or in part, by the learned intermediary doctrine.</p>	<p><i>McKee v. Moore</i>, 1982 OK 71, 648 P.2d 21, 24 (“In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects.”).</p>

<p>13. Some or all of the State's claims are barred by the sophisticated user doctrine.</p>	<p><i>Duane v. Okla. Gas & Elec. Co.</i>, 1992 OK 97, 833 P.2d 284, 286 (“But there is no duty on a manufacturer or seller . . . to warn a knowledgeable user of the product of dangers associated therewith.”); <i>Wicker ex rel. Estate of Wicker v. Ford Motor Co.</i>, 393 F. Supp. 2d 1229, 1234 (W.D. Okla. 2005) (“To recover on her claim of manufacturers’ products liability under Oklahoma law, plaintiff must prove that . . . the defect rendered the tractor unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to the community as to its characteristics” where “an ‘ordinary consumer’ is one who would be ‘foreseeably expected to purchase the product.’”).</p>
<p>14. The State claims are barred, in whole or in part, by patients’ provision of informed consent.</p>	<p><i>Tortorelli v. Mercy Health Ctr., Inc.</i>, 2010 OK CIV APP 105, ¶ 26, 242 P.3d 549, 560 (“The learned intermediary doctrine is an exception to the manufacturer’s duty to warn an ultimate consumer and shield a manufacturer from liability if it has adequately warned a prescribing physician of a danger which is the cause of the consumer’s injury.”); <i>Martin v. Stratton</i>, 1973 OK 124, 515 P.2d 1366, 1369 (“Informed consent identifies a principle that every person has a right to determine what shall be done with his own body and therefore, in situations where medical treatment involves grave risks of collateral injury even if performed on a non-negligent manner, the law imposes a duty upon physicians to inform the patient of options available and risks attendant upon each so the patient can make an informed exercise of choice.”).</p>

<p>15. The State claims are barred, in whole or in part, by the State's failure to join indispensable parties.</p>	<p>12 Okla. Stat. § 2012(B); 12 Okla. Stat. § 2019; <i>Amoskeag Sav. Bank v. Eppler</i>, 1938 OK 210, 77 P.2d 1158, 1161 (“There is a class whose interests in the subject matter of the suit, and the relief sought, are so bound up with that of the other parties that their legal presence as parties to the proceeding is an absolute necessity, without which the court cannot proceed. In this class, such persons are necessary and indispensable parties.”).</p>
<p>16. The State claims are barred because J&J and Janssen have been improperly joined as Defendants in this action.</p>	<p>12 Okla. Stat. § 2012(B); 12 Okla. Stat. § 2021; <i>A-Plus Janitorial & Carpet Cleaning v. Emp'rs' Workers' Comp. Ass'n</i>, 1997 OK 37, 936 P.2d 916, 926 (Joinder is permissible only if “right to relief . . . relat[es] to or aris[es] out of the same transaction or occurrence.”); <i>Watson v. Batton</i>, 1998 OK CIV APP 50, 958 P.2d 812, 814 (“The fact that the injuries may be difficult to separate does not, in itself, permit joinder of these completely separate causes of action.”).</p>
<p>17. The State claims are barred, in whole or in part, because the State's alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, was caused in whole or in part by the doctrine of ratification.</p>	<p><i>Shephard v. CompSource Okla.</i>, 2009 OK 25, ¶ 14, 209 P.3d 288, 293 (“Ratification is defined as the giving of sanction and validity to something done by another. In cases involving allegedly tortious acts or decisions by employees of governmental entities, ratification occurs in the course of the claim review process provided by the Governmental Tort Claims Act.” (citations omitted)).</p>

<p>18. The State's injuries and damages, if any, are barred, in whole or in part, by the actions, omissions, and/ or conduct of third parties over whom Johnson & Johnson has no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault. Alternatively, Johnson & Johnson is entitled to contribution from such other third parties.</p>	<p>12 Okla. Stat. § 832; <i>Prince v. B.F. Ascher Co., Inc.</i>, 2004 OK CIV APP 39, 90 P.3d 1020, 1028 (quoting <i>Henry v. Merck and Co., Inc.</i>, 877 F.2d 1489, 1492 (10th Cir. 1989) ("The general rule is that, absent special circumstances, no duty is imposed on a party to anticipate and prevent the intentional or criminal acts of a third party. Oklahoma follows that rule."); Restatement (Second) of Torts § 886A ("[W]hen two or more persons become liable in tort to the same person for the same harm, there is a right of contribution among them, even though judgment has not been recovered against all or any of them.").</p>
<p>19. The State claims, to the extent that they relate to J&J and Janssen's advertising, public statements, lobbying, associations, or other activities protected by the First Amendment of the U.S. Constitution, Article II, section 22 of the Constitution of the State of Oklahoma, or any other similar state law or constitutional provisions which protect J&J and Janssen's rights to freedom of speech and association, are barred.</p>	<p>U.S. Const. amend. I; Okla. Const. art. II, § 22; <i>Citizens United v. Fed. Election Comm'n</i>, 558 U.S. 310, 342 (2010) ("The Court has recognized that First Amendment protection extends to corporations."); <i>N.A.A.C.P. v. Claiborne Hardware Co.</i>, 458 U.S. 886, 913 (1982) ("While States have broad power to regulate economic activity, we do not find a comparable right to prohibit peaceful political activity such as that found in the boycott in this case. This Court has recognized that expression on public issues has always rested on the highest rung of the hierarchy of First Amendment values.") (internal quotations omitted); <i>E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.</i>, 365 U.S. 127, 137-38 (1961) ("To hold that the government retains the power to act in this representative capacity and yet hold, at the same time, that the people cannot freely inform the government of their wishes would impute to the Sherman Act a purpose to regulate, not business activity, but political activity.").</p>

<p>20. The State claims or, at a minimum, the State's requests for relief are barred because J&J and Janssen's conduct complained of by the State was not the proximate or legal cause of the injuries or damages incurred by the State or any other party.</p>	<p><i>Kirkland v. GMC</i>, 1974 OK 52, ¶ 29, 521 P.2d 1353, 1363 (“[T]he mere possibility that” a defendant’s conduct “might have caused [a plaintiff’s] injury is not enough.”); <i>Atchison, Topeka & Santa Fe Ry. Co.</i>, 1928 OK 256, ¶ 6, 266 P. 775, 776 (The State may recover from Janssen only “for such injury . . . as was the direct and proximate result of its wrongful act, if any.”); <i>Twyman v. GHK Corp.</i>, 2004 OK CIV APP 53, ¶¶ 51-52, 93 P.3d 51, 61 (“[T]hey also failed in their burden to prove proximate causation, an essential element of the . . . nuisance claim . . .”).</p>
<p>21. The State claims, to the extent they seek civil monetary penalties, joint and several liability, or punitive damages, violate J&J and Janssen's right to procedural due process under the Fifth and Fourteenth Amendments of the U.S. Constitution and the Constitution of the State of Oklahoma and therefore fail to state a cause of action upon which monetary penalties or punitive damages can be awarded.</p>	<p>U.S. Const. amends. V, XIV; Okla. Const. art. II, § 7; <i>BMW v. Gore</i>, 517 U.S. 559, 574-75 (1996) (“Three guideposts, each of which indicates that BMW did not receive adequate notice of the magnitude of the sanction that Alabama might impose for adhering to the nondisclosure policy adopted in 1983, lead us to the conclusion that the \$2 million award against BMW is grossly excessive: the degree of reprehensibility of the nondisclosure; the disparity between the harm or potential harm suffered by Dr. Gore and his punitive damages award; and the difference between this remedy and the civil penalties authorized or imposed in comparable cases.”).</p>

<p>22. The State claims, to the extent they seek civil monetary penalties or joint and several liability, violate J&J and Janssen’s right to protection from “excessive fines” as provided in the Eighth Amendment of the U.S. Constitution and the Constitution of the State of Oklahoma and violates J&J and Janssen’s rights to substantive due process provided in the Fifth and Fourteenth Amendments of the U.S. Constitution and the Constitution of the State of Oklahoma and therefore fail to state a cause of action supporting the claim for civil and monetary penalties.</p>	<p>U.S. Const. amend. VIII; Okla. Const., art. II, § 9; <i>Timbs v. Indiana</i>, 139 S. Ct. 682, 687 (2019) (incorporating the Eighth Amendment’s Excessive Fines Clause against the States in a civil <i>in rem</i> proceeding); <i>Paroline v. United States</i>, 572 U.S. 434, 446 (2014) (“[H]olding each possessor of [child pornography] liable for the conduct of thousands of other independently acting possessors and distributors, with no legal or practical avenue for seeking contribution.... might raise questions under the Excessive Fines Clause of the Eighth Amendment.”).</p>
<p>23. The State claims, to the extent they rely on vague terms of the Oklahoma public nuisance statute, violate J&J and Janssen’s due process rights under the Fifth and Fourteenth Amendments of the U.S. Constitution and the Constitution of the State of Oklahoma and therefore fail to state a cause of action.</p>	<p>U.S. Const. amends V, XIV; Okla. Const. art. II, § 7; <i>Sessions v. Dimaya</i>, 138 S. Ct. 1204, 1213 (2018) (“The void-for-vagueness doctrine, as we have called it, guarantees that ordinary people have “fair notice” of the conduct a statute proscribes.”); <i>State ex rel. Okla. Bar Ass’n v. Minter</i>, 2001 OK 69, n.55, 37 P.3d 763, 744 (Due process requires a “fair warning . . . that intelligibly communicates the parameters of conduct to be proscribed” prior “to imposition of penalty, civil or criminal.”); <i>Samson Res. Co. v. Cloud</i>, 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.”).</p>
<p>24. The State claims against J&J and Janssen are barred or limited by the economic loss rule.</p>	<p><i>Okla. Gas & Elec. Co. v. McGraw-Edison Co.</i>, 1992 OK 108, 834 P.2d 980, 982 (“[C]onsequential damages sound[] in contract, not in manufacturers’ product liability.”); <i>Waggoner v. Town & Country Mobile Homes, Inc.</i>, 1990 OK 139, 808 P.2d 649, 653 (adopting the U.S. Supreme Court’s reasoning and concluding, “purely economic losses are not recoverable in products liability”).</p>

<p>25. No retroactivity.</p>	<p><i>Eastern Enters. v. Apfel</i>, 524 U.S. 498, 532-33 (1998) (“Retroactivity is generally disfavored in the law, in accordance with ‘fundamental notions of justice’ that have been recognized throughout history.” (citations omitted)); <i>MFA Ins. Co. v. Hankins</i>, 1980 OK 66, 610 P.2d 785, 787 (“Statutes are to be construed as having a prospective operation unless the purposes and intention of the Legislature to give them a retroactive effect is expressly declared, or is necessarily implied from the language used. In every case of doubt the doubt must be resolved against the retrospective effect.” (quoting <i>State v. Engineered Coatings, Okla.</i>, 1975 OK 149, 542 P.2d 508, 509)).</p>
<p>26. J&J and Janssen’s rights under the Due Process Clause of the U.S. Constitution and the Constitution of the State of Oklahoma are violated by any financial or other arrangement and by any personal connection to the subject matter of the lawsuit that might distort a government attorney’s duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding.</p>	<p><i>Marshall v. Jerrico, Inc.</i>, 446 U.S. 238 (1980) (“A scheme injecting a personal interest, financial or otherwise, into the enforcement process may bring irrelevant or impermissible factors into the prosecutorial decision and . . . raise serious constitutional questions.”); <i>People ex rel. Clancy v. Superior Court</i>, 39 Cal.3d 740, 750 (1985) (“Thus, we hold that the contingent fee arrangement between the City and Clancy is antithetical to the standard of neutrality that an attorney representing the government must meet when prosecuting a public nuisance abatement action.”).</p>

<p>27. To the extent that the State’s claims are based on the alleged conduct of other Defendants, and the State seeks to impose liability on J&J and/or Janssen only by virtue of J&J’s and/or Janssen’s ownership of another Defendant’s shares, membership within another Defendant’s unincorporated entity, or similar affiliation, the State cannot prove facts necessary to support a claim to pierce the corporate veil, or to otherwise hold J&J and/or Janssen liable merely by virtue of its corporate affiliation with other Defendants.</p>	<p><i>United States v. Best Foods</i>, 524 U.S. 51, 61 (1998) (“It is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation (so-called because of control through ownership of another corporation’s stock) is not liable for the acts of its subsidiaries.”); <i>Gilbert v. Sec. Fin. Corp. of Okla.</i>, 2006 OK 58, 152 P.3d 165, 175 (“Corporations are distinct legal entities, and generally one corporation will not be held responsible for the acts of another.”), <i>abrogated on other grounds by</i> <i>Montgomery v. Airbus Helicopters, Inc.</i>, 2018 OK 17, 414 P.3d 824.</p>
<p>28. The State claims are barred to the extent providers prescribed and/or their patients used J&J and/or Janssen’s products after becoming aware of their alleged risks and to the extent the State reimbursed Medicaid claims, or incurred any other form of alleged damages, after becoming aware of the alleged risks associated with J&J and/or Janssen’s products.</p>	<p><i>McKee v. Moore</i>, 1982 OK 71, 648 P.2d 21, 24 (“In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects.”); <i>Tortorelli v. Mercy Health Ctr., Inc.</i>, 2010 OK CIV APP 105, ¶ 26, 242 P.3d 549, 560 (“The learned intermediary doctrine is an exception to the manufacturer’s duty to warn an ultimate consumer and shield a manufacturer from liability if it has adequately warned a prescribing physician of a danger which is the cause of the consumer’s injury.”).</p>

29. Comparative negligence, contributory negligence, comparative fault, and causation.

23 Okla. Stat. §§ 12, 13, 14; *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, 204 P. 906, 908 (“[W]here a riparian landowner sues a group of separate leaseholders for damages for polluting a stream, and the evidence shows that part of the damage inflicted was occasioned by the defendants and part by a tenant of the plaintiff, not a party to the action, either with the plaintiffs’ consent or as the result of the ordinary use of the premises by the tenant, the plaintiff will not be entitled to recover from the defendants sued, unless he is able to produce evidence which will enable the court to separate the amount of damage inflicted by the group of defendants sued from the amount of damages resulting from the acts of the tenant, and to enter judgments against the defendants for the damages thus shown.”); *Am. Agency Sys., Inc. v. Marceleno*, 2002 OK CIV APP 79, 53 P.3d 929, 935 (citing *Nat’l Union Fire Ins. Co. v. A.A.R. W. Skyways, Inc.*, 1989 OK 157, 784 P.2d 52, 56) (“Defendants are severally liable if the plaintiff is assigned any degree of comparative responsibility, and a negligent plaintiff may only recover from each tortfeasor that tortfeasor’s proportionate share of responsibility based on degree of fault.”); *City of Tulsa v. Tyson Foods*, 258 F. Supp. 2d 1263, 1301 (N.D. Okla. 2003) (vacated pursuant to settlement) (“When a nuisance results from negligent conduct of the defendant, the contributory negligence of the plaintiff is a defense to the same extent as in other actions founded on negligence.”).

<p>30. Failure to mitigate injuries and damages.</p>	<p><i>Houck v. Hold Oil Corp.</i>, 1993 OK 167, 867 P.2d 451, 460 (“This is so because if the cost of repairing the injury is greater than the diminution in market value of the land, the latter is the true measure of damages; the rule of avoidable consequences requiring that in such case the plaintiff shall diminish the loss as much as possible.”); <i>Burlington N. and Santa Fe Ry. Co. v. Grant</i>, 505 F.3d 1013, 1027 (10th Cir. 2007) (Under Oklahoma nuisance law, “plaintiffs [are required] to mitigate their damages.”).</p>
<p>31. To the extent any agents, employees, or contractors of J&J and/or Janssen caused any of the damages alleged by the State, such agents, employees, or contractors were acting outside the scope of the agency employment, or contract with J&J and/or Janssen, and any recovery against J&J and/or Janssen must be reduced by the proportionate fault of such agents, employees, or contractors.</p>	<p><i>Meyer v. Holley</i>, 537 U.S. 280, 285 (2003) (“It is well established that traditional vicarious liability rules ordinarily make principals or employers variously liable for the acts of their agents and employees in the scope of their authority or employment.”); Restatement (Second) of Agency § 219.</p>
<p>32. Should J&J and/or Janssen be held liable to the State, which liability is specifically denied, J&J and/or Janssen would be entitled to a credit or setoff for the benefits to the State as a result of J&J and/or Janssen’s lawful activity, and to a credit or setoff for all sums of money received or percentage of fault available from or on behalf of any other parties liable for the same alleged injury.</p>	<p>12 Okla. Stat. § 832; <i>Morris v. Sanchez</i>, 1987 OK 110, 746 P.2d 184, 185-87 (applying the rule in Restatement (Second) of Torts § 920 to conclude that plaintiff could not recover costs of raising unwanted child born after failed sterilization because the benefits of the healthy child offset the damage); Restatement (Second) of Torts § 920 (“When the defendant’s tortious conduct has caused harm to the plaintiff or to his property and in so doing has conferred a special benefit to the interest of the plaintiff that was harmed, the value of the benefit conferred is considered in mitigation of damages, to the extent that this is equitable.”).</p>

<p>33. The State claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from any failure of providers or their patients to read and heed warnings provided with J&J and/or Janssen's products.</p>	<p><i>State v. Wyeth</i>, 411 F. Supp. 2d 1318, 1322 (W.D. Okla. 2006) ("Moreover, the learned intermediary doctrine assumes that the treating physician will heed any warnings given, that is, that the doctor will incorporate those warnings into the risk/benefit analysis in deciding whether the prescribe a given drug.").</p>
<p>34. The State claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with J&J and/or Janssen's products, which are unavoidable even within the scope of prescribed and intended use, but which are reasonable in comparison to the benefits conferred.</p>	<p><i>Tansy v. Dacomed Corp.</i>, 1994 OK 146, 890 P.2d 881, 885 ("While products liability law seeks to protect the public from unreasonably dangerous products, Comment k seeks to protect another facet of the public's interest—that of having available new products whose benefits are great enough as to justify associated risks. It protects certain manufacturers who develop new products which at the time of manufacture are incapable of being made totally safe, and shields certain products by classifying them as 'unavoidably unsafe' rather than as 'defective.'"); <i>McKee v. Moore</i>, 1982 OK 71, 648 P.2d 21, 24 ("Comment k of the Restatement (Second) of Torts s 402A (1965) postulates that a drug manufacturer is not to be held strictly liable for injuries caused by an unavoidably dangerous drug if the warning is adequate."); Restatement (Second) of Torts § 402A, cmt. k (1965).</p>
<p>35. The injuries and damages alleged by the State, if any, were caused and brought about by a pre-existing condition, idiosyncratic reaction to the products at issue, or other conditions for which J&J and/or Janssen has no responsibility or control, and, therefore, J&J and Janssen are without fault.</p>	<p><i>Tayar v. Roux Labs., Inc.</i>, 460 F.2d 494, 496 (10th Cir. 1972) (finding a manufacturer had no liability for damages to a plaintiff who had an "idiosyncratic reaction which caused her to be unusually susceptible to agents which are normally safe for use by the public"); <i>Merrill v. Beaute Vues Corp.</i>, 235 F.2d 893, 896 (10th Cir. 1956) ("The law requires a person to reasonably guard against probabilities, not possibilities.").</p>

<p>36. The State claims are barred, in whole or in part, by any alteration, modification, or misuse of J&J and/or Janssen's products by prescribing providers, their patients, or any other third parties, for which J&J and Janssen cannot be held responsible.</p>	<p><i>Fields v. Volkswagen of Am., Inc.</i>, 1976 OK 106, 555 P.2d 48, 56 ("Generally when we speak of the defense of misuse or abnormal use of a product we are referring to cases where the method of using a product is not that which the maker intended or is a use that could not reasonably be anticipated by a manufacturer."); <i>Prince v. B.F. Ascher Co.</i>, 2004 OK CIV APP 39, ¶ 14, 90 P.3d 1020, 1027 (affirming summary judgment for manufacturer where the product, an inhaler, had been altered to extract the active ingredient to obtain a stimulant effect).</p>
<p>37. The State claims are barred to the extent they allege harms resulting from any illicit use or abuse of J&J and/or Janssen's products on the part of the medication users, for which J&J and Janssen cannot be held responsible.</p>	<p><i>Gaines v. Providence Apartments</i>, 1987 OK 129, 750 P.2d 125, 126-27 ("Where the negligence complained of only creates a condition which thereafter reacts with a subsequent, independent, unforeseeable, distinct agency and produces an injury, the original negligence is the remote rather than the proximate cause thereof."); <i>Prince v. B.F. Ascher Co., Inc.</i>, 2004 OK CIV APP 39, ¶ 24, 90 P.3d 1020, 1029 ("Ballard's injection into his veins of a solution made from the propylhexedrine he extracted from Bensedrex® was certainly independent of Appellees' manufacture and sale of the product as a nasal inhaler, and unquestionably sufficient in and of itself to bring about Ballard's death. In addition, as discussed above, Appellees were not required to anticipate Ballard's criminal acts in this regard. Accordingly, Prince cannot overcome Appellees' supervening cause defense and her negligence claim fails as a matter of law.").</p>

<p>38. To the extent the State asserts claims premised on actual or constructive fraud, false representation, deceit, concealment, or similar alleged misconduct, the State fails to prove its claims with particularity, including, but not limited to, the time, place, and content of the alleged misrepresentations or concealments, and the specific misrepresentations or concealments of each separate Defendant. To the extent the State seeks special items of damages, including, but not limited to, exemplary or punitive damages, the State fails to specifically state their nature or provide detail sufficient to inform J&J or Janssen of the nature of its claim.</p>	<p>12 Okla. Stat. §§ 2009(B)(G).</p>
<p>39. To the extent the State seeks to impose liability on J&J and/or Janssen for broad, general statements regarding the value or quality of J&J and/or Janssen's products which were made to and reasonably understood by providers as opinion, such statements cannot constitute false representations as a matter of law.</p>	<p><i>Hall v. Edge</i>, 1989 OK 143, 782 P.2d 122, 126 ("Generally, the false representation must be a statement of existing fact and not a mere expression of opinion."); <i>Greene v. Humphrey</i>, 1954 OK 247, 274 P.2d 535, 537.</p>
<p>40. J&J and/or Janssen's liability, if any, will not result from its conduct, but will result solely from obligations imposed by law. Thus, J&J and Janssen are entitled to complete indemnity, express or implied, by other parties.</p>	<p>12 Okla. Stat. § 832; <i>Caterpillar Inc. v. Trinity Indus., Inc.</i>, 2006 OK CIV APP 48, 134 P.3d 881, 886 ("The right [of indemnity] exists when one who is only constructively liable to the injured party and is in no manner responsible for the harm is compelled to pay damages for the tortious act of another.").</p>
<p>41. The State claims are barred to the extent they seek duplicate or double recovery on the same injury or damage, contrary to Oklahoma law.</p>	<p><i>Houck v. Hold Oil Corp.</i>, 1993 OK 166, 867 P.2d 451, 454 ("[N]o double recovery is allowed for the same injury."); <i>Tate v. Browning-Ferris, Inc.</i>, 1992 OK 72, 833 P.2d 1218, 1223 n.15 ("As in any case where there are multiple remedies, Oklahoma law will allow only one recovery to make the plaintiff whole.")</p>

<p>42. The State is not entitled to attorneys' fees, costs, pre-judgment interest, or post-judgment interest.</p>	<p><i>State ex rel. Tal v. City of Oklahoma City</i>, 2002 OK 97, ¶ 16, 61 P.3d 234, 243 (“Exceptions to the [American] Rule [that litigants pay for their own representation] are narrowly defined . . . and carved out with great caution . . . because it is understood liberality of attorney fee awards against the non-prevailing party has a chilling effect on our open access to courts guarantee.” (citations omitted)).</p>
<p>43. The State’s damages, if any, are limited to reasonable damages, and exclude unconscionable and grossly oppressive damages contrary to substantial justice. Further, the State cannot recover damages in excess of those allowed by applicable statutory law.</p>	<p>U.S. Const. amends. VIII, XIV; 23 Okla. Stat. § 97; <i>BMW v. Gore</i>, 517 U.S. 559, 574-75 (1996) (“Three guideposts, each of which indicates that BMW did not receive adequate notice of the magnitude of the sanction that Alabama might impose for adhering to the nondisclosure policy adopted in 1983, lead us to the conclusion that the \$2 million award against BMW is grossly excessive: the degree of reprehensibility of the nondisclosure; the disparity between the harm or potential harm suffered by Dr. Gore and his punitive damages award; and the difference between this remedy and the civil penalties authorized or imposed in comparable cases.”); <i>Paroline v. United States</i>, 572 U.S. 434, 446 (2014) (“[H]olding each possessor of [child pornography] liable for the conduct of thousands of other independently acting possessors and distributors, with no legal or practical avenue for seeking contribution. . . . might raise questions under the Excessive Fines Clause of the Eighth Amendment.”).</p>
<p>44. The State claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.</p>	<p><i>Heckler v. Chaney</i>, 470 U.S. 821, 831–33 (1985) (federal agency decisions receive discretion because of the “general unsuitability for judicial review of agency decisions”); <i>United States v. Rx Depot, Inc.</i>, 290 F. Supp. 2d 1238, 1248–49 (N.D. Okla. 2003).</p>

<p>45. The conduct of J&J and Janssen, as well as the products at issue, conformed with the FDCA and the requirements of the FDA. Moreover, the activities of J&J and Janssen alleged by the State conformed with all state and federal statutes, regulations, and industry standards based on the state of scientific and medical knowledge existing at the relevant times alleged by the State.</p>	<p>50 Okla. Stat. § 4; <i>Prohias v. Pfizer, Inc.</i>, 490 F. Supp. 2d 1228, 1235 (S.D. Fla. 2007) (“Thus, even if the advertisements did not comport precisely with [the drug’s] approved label . . . , the alleged advertisements generally comport with the approved label, and are therefore not misleading as a matter of law.”).</p>
<p>46. To the extent the State’s claims seek to impose liability on J&J and/or Janssen solely on the basis of its proportionate participation in Oklahoma’s market for opioid products, and without establishing a causative link between J&J and/or Janssen’s specific conduct and the State’s alleged injuries, such claims are barred under federal and Oklahoma law.</p>	<p>U.S. Const. amends. V, XIV; <i>Honda Motor Co. v. Oberg</i>, 512 U.S. 415, 421, 430-32 (1994) (Dispensing with judicial review of the size of punitive awards—“a safeguard against excessive verdicts for as long as punitive damages have been awarded”—violates due process.); <i>Pacific Ins. Corp. v. Haslip</i>, 499 U.S. 1, 22 (1991) (State tort law must impose a “sufficiently definite and meaningful constraint” on the amount of damages a defendant may be forced to pay.); <i>Case v. Fibreboard</i>, 1987 OK 79, 743 P.2d 1062, 1064-67 (“Although plaintiffs in asbestos related injury cases may not be able in all cases to identify potential defendants, the public policy favoring recovery on the part of an innocent plaintiff does not justify the abrogation of the rights of a potential defendant to have a causative link proven between that defendant’s specific tortious acts and the plaintiff’s injuries where there is a lack of circumstances which would insure that there was a significant probability that those acts were related to the injury. We therefore would not recognize the applicability of a market share theory of liability to asbestos injury litigation under Oklahoma law.”).</p>

<p>47. The State claims are barred, in whole or in part, by the doctrines of res judicata, collateral estoppel, and/or issue or claim preclusion.</p>	<p>12 Okla. Stat. § 2008; <i>Miller v. Miller</i>, 1998 OK 24, 956 P.2d 887, 896 (“The doctrine of claim preclusion is designed to prevent piecemeal litigation through the splitting of a single claim into separate lawsuits. When claim preclusion is asserted the court must analyze the claim involved in the prior action to ascertain whether it is in fact the same as that asserted in the subsequent action.”); <i>Wabaunsee v. Harris</i>, 1980 OK 52, 610 P.2d 782, 785 (“[I]n Oklahoma, res judicata bars a second action where the parties and the two causes of action are the same.”).</p>
<p>48. The State claims are barred, in whole or in part, by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of res judicata, collateral estoppel, issue or claim preclusion, failure to fulfill conditions precedent, failure to provide requisite notice, accord and satisfaction, and compromise and settlement.</p>	<p><i>Boatsman v. Boatsman</i>, 1984 OK 74, 697 P.2d 516, 519 (“A consent judgment is entitled res judicata treatment and precludes relitigation of the same claim.”).</p>
<p>49. The State claims are barred, in whole or in part, for lack of standing.</p>	<p><i>Eldredge v. Taylor</i>, 2014 OK 92, ¶ 9, 339 P.3d 888, 891 (“The threshold criteria of standing are (1) a legally protected interest which must have been injured in fact—i.e., suffered an injury which is actual, concrete and not conjectural in nature, (2) a causal nexus between the injury and the complained-of conduct, and (3) a likelihood, as opposed to mere speculation, that the injury is capable of being redressed by a favorable court decision.”) (internal citations omitted); <i>Matter of Estate of Doan</i>, 1986 OK 15, 727 P.2d 574, 576 (“[S]tanding to raise issues in a proceeding must be predicated on interest that is direct, immediate and substantial.”)(internal quotations omitted); <i>McFarland v. Atkins</i>, 1979 OK 3, 594 P.2d 758, 760–63.</p>

<p>50. The State claims are barred, in whole or in part, by the State's failure to comply with the requirement that it identify each patient in whose claim(s) the State has a subrogation interest.</p>	<p><i>Patton v. Jenkins</i>, 1993 OK CIV APP 18, 847 P.2d 831, 831 (insurance company could "seek enforcement of its subrogation interest in a lawsuit brought in the name of its insured"); <i>Muskogee Title Co. v. First Nat. Bank & Tr. Co. of Muskogee</i>, 1995 OK CIV APP 29, 894 P.2d 1148, 1150.</p>
<p>51. The State claims are barred, in whole or in part, by conflict preemption.</p>	<p><i>PLIVA, Inc. v. Mensing</i>, 131 S.Ct. 2567 (2011); <i>Mutual Pharm. Co. v. Bartlett</i>, 133 S.Ct. 2466 (2013).</p>
<p>52. The State claims are barred, in whole or in part, under the constitutional principles of separation of powers.</p>	<p>U.S. Const. art. I, § 1; <i>id.</i> art. II, § 2, cl. 2; <i>id.</i> art. III, § 1; Okla. Const. art. IV, § 1; <i>Okla. Educ. Ass'n v. State ex rel. The Okla. Legislature</i>, 2007 OK 30, 158 P.3d 1058, 1066 ("The plaintiffs are attempting to circumvent the legislative process by having this Court interfere with and control the Legislature's domain of making fiscal policy decisions and of setting educational policy by imposing mandates on the Legislature and by continuing to monitor and oversee the Legislature. To do as the plaintiffs ask would require this Court to invade the Legislature's power to determine policy. This we are constitutionally prohibited from doing."); <i>State ex rel. York v. Turpen</i>, 1984 OK 26, 681 P.2d 763, 766-77 ("The Court is not authorized to consider the desirability wisdom or practicability of fiscal legislation as a working proposition. To a certainty, our fundamental law establishes that these questions belong to the legislative branch of government. . . . The true import of the doctrine of separation of powers is that the whole power of one department shall not be exercised by the same hands which possess the whole power of either of the other departments; and that no one department ought to possess <i>directly</i> or <i>indirectly</i> an overruling influence over the others.").</p>

<p>53. To the extent the State seeks relief for J&J and Janssen's conduct that was not actionable at the time it occurred, the State's claims are barred because they violate J&J and Janssen's procedural and substantive due process rights under the Fourteenth Amendment to the U.S. Constitution and under Article II, section 7 of the Constitution of the State of Oklahoma and J&J and Janssen's right to be free from retroactive or ex post facto laws as guaranteed by Article I, section 10 of the United States Constitution and by Article II, section 15 of the Oklahoma Constitution.</p>	<p>U.S. Const. art. I, § 10; <i>id.</i> amend. XIV; Okla. Const. art. II, § 7; <i>id.</i> art. II, § 15; <i>Eastern Enters. v. Apfel</i>, 524 U.S. 498, 532-33 (1998) ("Retroactivity is generally disfavored in the law, in accordance with 'fundamental notions of justice' that have been recognized throughout history." (citations omitted)); <i>MFA Ins. Co. v. Hankins</i>, 1980 OK 66, 610 P.2d 785, 787 ("Statutes are to be construed as having a prospective operation unless the purposes and intention of the Legislature to give them a retroactive effect is expressly declared, or is necessarily implied from the language used. In every case of doubt the doubt must be resolved against the retrospective effect." (quoting <i>State v. Engineered Coatings, Okla.</i>, 1975 OK 149, 542 P.2d 508, 509)).</p>
<p>54. To the extent the State seeks relief for J&J and/or Janssen's conduct without a showing that J&J and/or Janssen's conduct was a cause in fact or legal cause of its alleged injuries, the State's claims are barred because they violate J&J and/or Janssen's procedural and substantive due process rights under the Fourteenth Amendment to the U.S. Constitution and under Article II, section 7 of the Constitution of the State of Oklahoma.</p>	<p>U.S. Const. amend. XIV; Okla. Const. art. II, § 7; <i>Arizona v. Clark</i>, 548 U.S. 735, 749 (2006) (A State's deviation from custom violates due process if it "offends a principle of justice so rooted in the traditions and conscience of our people as to be ranked as fundamental." (internal quotation marks, alterations, and citations omitted)); <i>Honda Motor Co. v. Oberg</i>, 512 U.S. 415, 430-32 (1994) ("A State's "abrogation of a well-established common law protection against arbitrary deprivation of property" violates the Due Process Clause where the State "has removed that safeguard without providing any substitute procedure and without any indication that the danger of arbitrary awards has in any way subsided over time.").</p>

55. The State is not entitled to joint and several liability for its public nuisance claim.

23 Okla. Stat. §§ 12, 13, 14; *Walters v. Prairie Oil & Gas Co.*, 1922 OK 52, 204 P. 906, 908 (“[W]here a riparian landowner sues a group of separate leaseholders for damages for polluting a stream, and the evidence shows that part of the damage inflicted was occasioned by the defendants and part by a tenant of the plaintiff, not a party to the action, either with the plaintiff’s consent or as the result of the ordinary use of the premises by the tenant, the plaintiff will not be entitled to recover from the defendants sued, unless he is able to produce evidence which will enable the court to separate the amount of damage inflicted by the group of defendants sued from the amount of damages resulting from the acts of the tenant, and to enter judgments against the defendants for the damages thus shown.”); *Northup v. Eakes*, 1918 OK 652, 178 P. 266, 268 (joint and several liability on theory of indivisibility requires proof that acts “combine[d] to produce directly a single injury.”); *Am. Agency Sys., Inc. v. Marceleno*, 2002 OK CIV APP 79, 53 P.3d 929, 935 (citing *Nat’l Union Fire Ins. Co. v. A.A.R. W. Skyways, Inc.*, 1989 OK 157, 784 P.2d 52, 56) (“Defendants are severally liable if the plaintiff is assigned any degree of comparative responsibility, and a negligent plaintiff may only recover from each tortfeasor that tortfeasor’s proportionate share of responsibility based on degree of fault.”); *City of Tulsa v. Tyson Foods*, 258 F. Supp. 2d 1263, 1301 (N.D. Okla. 2003) (vacated pursuant to settlement) (“When a nuisance results from negligent conduct of the defendant, the contributory negligence of the plaintiff is a defense to the same extent as in other actions founded on negligence.”).

56. The State claims based on Noramco's and Tasmanian Alkaloids' sales are preempted by applicable federal law relating to the manufacture and sale of Active Pharmaceutical Ingredient ("API") for controlled substances.	21 U.S.C. § 801 et seq.; <i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001).
57. The denial of a jury trial on the State's claim for monetary recovery to address the damages caused by an alleged nuisance violates Janssen's rights to a jury trial under the Oklahoma and United States constitutions.	U.S. Const. amend. VII; Okla. Const. art. II, § 19; 12 Okla. Stat. § 556 ("Issues of fact arising in actions for the recovery of money . . . shall be tried by a jury."); <i>Smicklas v. Spitz</i> , 1992 OK 145, 846 P.2d 362, 367 ("If . . . damages are sought, the existence of a nuisance and its resulting damages are questions of fact for the jury.").
58. Janssen incorporates Teva's contentions and defenses to the extent they apply to Janssen.	United States Constitution; Oklahoma Constitution; Oklahoma statutes; common law.

C. Defendants' Claims for Relief

All Defendants request that judgment be entered in their favor and against the State on all claims and that they be awarded their costs, attorneys' fees, and all other relief accorded by law. If judgment is entered against one or more Defendants, Defendants request set-off and contribution from joint tortfeasors in accordance with the law. Defendants request apportionment of liability with joint and/or ghost tortfeasors in accordance with the law.

5. MISCELLANEOUS:

a. Is a jury waived?

The Johnson and Johnson defendants have not waived jury trial. The Teva and Actavis Generic Defendants have not waived jury trial on any issues or claims except for abatement of a public nuisance.

b. Is Additional Discovery Requested?

i. State: No additional discovery requested at this time.

ii. Teva and Actavis Generic Defendants: The State has been ordered to produce additional documents from the Medical Examiner's Office and the Employee Group Insurance Department. Additionally, the State has been ordered to produce a prepared witness on the Teva and Actavis Generic Defendants Corporate Deposition Topic 17. The State's responses to Requests for Admission from the Teva and Actavis Generic Defendants were due May 15,

2019. To date, the Teva and Actavis Generic Defendants have not received the discovery to which they are entitled. Besides the discovery identified above, the Teva and Actavis Generic Defendants have no other outstanding discovery requests at this time.

- c. A trial brief is not required by the Court but may be filed by the parties by May 23, 2019.
- d. Other Matters:
 - i. Opening Statements: The State shall have 2 hours to present its opening statement and may divide that time among lawyers. Each of the Defendant families shall have 2 hours total to present their respective opening statements and may divide that time among lawyers, as appropriate. If any party lodges an objection during an opening statement, time spent arguing the objection shall not count against any party's time.
 - ii. Seating:
 - A. All fact witnesses other than party representatives will be excluded from the courtroom until they are called to testify.
 - B. The first three rows in the gallery on the State's side shall be reserved for use by the State. The first four rows in the gallery on the Defendants' side shall be reserved for use by the Defendants. Each Defendant shall have two rows.
 - iii. Exhibits:
 - A. The parties shall provide the Court with hard copies of all exhibits they intend to use with a witness prior to examining the witness on direct examination.
 - B. The parties shall provide the witness and opposing counsel (and the Court for cross-examinations) with exhibits (*i.e.*, a paper copy) as each exhibit is proffered. By the end of each court day during trial, the parties shall ensure that admitted exhibits are marked with exhibit stickers and submitted to the Court.
 - C. The parties shall exchange trial exhibits and quotations from depositions to be used in opening statements no later than 5:00 p.m. on Saturday, May 25. Objections, if any, to the use of such items must be lodged no later than 5:00 p.m. on Sunday, May 26 by e-mail to the Court.

iv. Pending motions that the Defendants have filed, joined, or intend to join:

None at this time.¹⁰

v. The State lacks a privilege log.

vi. The Teva and Actavis Generic Defendants shall present their case-in-chief after the State does so. The Janssen Defendants shall present their case-in-chief after the Teva and Actavis Generic Defendants do so.

vii. Witnesses:

A. The Parties have agreed to provide at least 48 hours' notice for each witness called during their respective case-in-chief.

B. The Parties have agreed to provide 72 hours' notice for each witnesses called during their respective case-in-chief residing outside of Cleveland County, Oklahoma.

C. Defendants reserve their right to object to the State calling any witness that it did not identify in its March 1, 2019 Amended Disclosure of Individuals Likely to Have Discoverable Information that May Be Used to Support the Claims or Defenses.

6. **THE STATE'S EXHIBITS:**

See Exhibit "D" attached hereto. No exhibit shall be admissible in the parties' case in chief, unless it's been identified in the parties' exhibit list. The parties reserve the right to offer an exhibit not listed for purposes of impeachment, rebuttal, or if otherwise ordered by the Court.

7. **DEFENDANTS' EXHIBITS:**

J&J Defendants: See Exhibit "E" attached hereto. No exhibit shall be admissible in the parties' case-in-chief, unless it's been identified in the parties' exhibit list. The parties reserve the right to offer an exhibit not listed for purposes of impeachment, rebuttal, or if otherwise ordered by the Court.

Teva and Actavis Generic Defendants: See Exhibit "F" attached hereto. No exhibit shall be admissible in the parties' case-in-chief, unless it's been identified in the parties' pretrial exhibit list. The parties reserve the right to offer an exhibit not listed for purposes of impeachment, rebuttal, or if otherwise ordered by the Court. The Teva and Actavis Generic Defendants reserve the right to add additional exhibits to its exhibit list that were

¹⁰ Defendants continue to object to the denial of their motion to sever.

produced by the State on May 17 and May 21, 2019.

8. **THE STATE'S WITNESSES:**

See Exhibit "A" attached hereto.

9. **DEFENDANTS' WITNESSES:**

See Exhibit "B" for the Teva and Actavis Generic Defendants' list of witnesses.

See Exhibit "C" for the Janssen Defendants' list of witnesses.

10. **ESTIMATED HEARING TIME:**

- a. State's Case: 20 days
- b. Janssen's Case: 20 days
- c. Teva and Actavis Generic Defendants' Case: 20 days

11. **PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW:**

The deadline for submitting proposed findings of fact and conclusions of law shall be determined by the Court at a later date.

12. **STIPULATIONS:**

The parties stipulate for purposes of this case only, and without waiving any other defenses that may be available to them, that the Court has personal jurisdiction over the Janssen, Teva and Actavis Generic Defendants. The parties further stipulate that venue is proper.

13. **SETTLEMENT:**

Has the possibility of settlement been explored? - Yes.

14. **TRIAL DATE SET:** May 28, 2019.¹¹

Dated this 23 day of May, 2019.

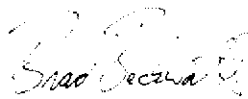


THE HONORABLE THAD BALKMAN

¹¹ Defendants renew their objection to the May 28, 2019 trial date.

DISTRICT COURT JUDGE

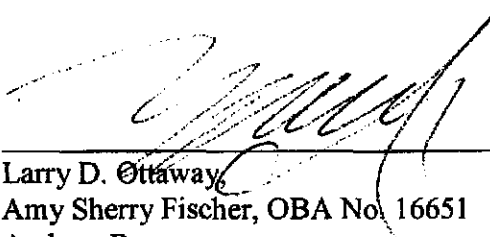
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