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STATE OF OKLAHOMA S.S. STATE OF OKLAHOMA S.S. IN THEEDISTRICT COUNTY STATE OF OKLAHOMA APR 15		
STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, In the MARILY Plaintiff,		
Plaintiff,) Case No. CJ-2017-816	
v.) Honorable Thad Balkman	
PURDUE PHARMA L.P., et al.,	 Special Discovery Master: William C. Hetherington, Jr. 	
Defendants.)	

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COMANCHE COUNTY'S MOTION TO INTERVENE

Comanche County respectfully moves the Court for an Order, pursuant to 12 Okla. Stat. § 2024(A)(2), granting Comanche County leave to intervene as a Plaintiff in this action brought by the State of Oklahoma. Comanche County satisfies § 2024(A)(2)'s requirements for intervention as of right because its motion is timely, it has an interest in the subject matter underlying the litigation that may be impaired by the litigation, and because its interests are not adequately represented by the parties currently in the litigation. In the alternative, Comanche County respectfully moves the Court for an Order, pursuant to 12 Okla. Stat. § 2024(B)(2), granting Comanche County leave to intervene as a Plaintiff in this action because applicant's claims and the action have questions of law and fact in common. Pursuant to 12 Okla. Stat. § 2024(C), attached please find the Petition as Exhibit "A". In support of this Motion, Comanche County states as follows:

I. BACKGROUND AND FACTS WARRANTING INTERVENTION

1. Purdue Defendants ("Purdue") served Comanche County with a Subpoena Duces Tecum on November 19, 2018, seeking documents Purdue alleged were necessary and relevant to the matter involving the State of Oklahoma currently pending before this Court. 2. Comanche County filed its Motion to Quash on December 14, 2018.

3. Subsequently, at the hearing on the motion to quash on March 1, 2019, Comanche County became aware that it had a significant interest related to the very subject matter of the action before this Court. On record and under oath, Purdue counsel admitted the following:

The second category is services that are provided by these movants. Part of the State's damage model in this case separate and apart from this unlawful prescription, which is a several billion dollar claim, the State's damage model in this case is an abatement policy, which they claim should last for 20 or 30 years in which they claim will cost between 12 and 17 plus billion dollars. And they have identified dozens, if not hundreds, of items that they think fit within that abatement policy. It is our belief and we intend to prove that many, if not a majority, of those items are, in fact, not provided by the State, have never been provided by the State, are not paid for by the State, and in fact, are paid for and provided, to the extent they exist, by the movants; things like ambulatory services, things like end care service, things like education. So the second category of information we're seeking is the types of opioid-related services being provided by the movants.

Transcript of Proceedings on Motion to Quash, Case No. CJ-2017-816, p. 17:7-23 (Mar. 1, 2019), attached hereto as Exhibit "B".

4. Purdue counsel's statement provided evidence that the damage model being evaluated to determine the State of Oklahoma's damages and recovery included a majority of services provided for and held by cities and counties such as Comanche County. Purdue also made it clear that the Defendants in this case will attempt to use standing to assert the damages of cities and counties as a defense to the State of Oklahoma's claims.

5. The Special Master entered an order regarding the Motion to Quash on March 5, 2019, and in light of this development and the newly discovered facts, Comanche County was in the process of evaluating its position and forthcoming Motion to Intervene.

6. However, and in the interim, counsel for the State of Oklahoma reached out to counsel that represents Comanche County regarding a potential settlement which appears to give

Comanche County and other cities and counties the right to choose to 'opt in' and participate in the settlement.

7. Counsel for Comanche County attempted on various occasions to discuss with the State the damages model being used as it related to Comanche County and other cities and counties. All requests for information related to the damages model has been denied by the State.

8. Thereafter, counsel for the State of Oklahoma settled with Purdue, allocating money to cities and counties in an extremely small amount without any authority from cities and/or counties, including Comanche County. The amount is so low that counties and cities would potentially receive (from an unknown settlement matrix) a mere fraction of what counsel for the State is to receive in attorney fees. The Consent Judgment does not state how the \$12.5 million will be allocated, individually, to cities and counties.

9. Comanche County had no involvement in the settlement negotiations with Purdue and no prior knowledge of the settlement. In fact, the Consent Judgment does not contain any authority as to how the Attorney General can act on behalf of Comanche County in this lawsuit. The State cannot compromise Comanche County's damages. Comanche County is a separate legal entity with the right to sue on its own behalf and recover damages. *See* 19 Okla. Stat. § 1. Moreover, under Oklahoma law, the Oklahoma Legislature must appropriate or allocate funds received on behalf of the State of Oklahoma. *See* 74 Okla. Stat. § 18b(11) (the Attorney General as the chief law office of the state shall pay into the State Treasury, immediately upon its receipt, all monies belonging to the state).

10. The Consent Judgment entered on March 26, 2019, defines Releasors as "the State and the Attorney General and/or political subdivision of the State on whose behalf the Attorney General possesses, or obtains, the authority to bind." Consent Judgment as to Purdue, Case No. CJ-2017-816, Section I.1.1(t), March 26, 2019. Moreover, the Consent Judgment provides:

On the Effective Date of the Release, Releasors shall further be deemed to have released all claims, including all claims of any political subdivisions on whose behalf the Attorney General possesses the authority, or obtains the authority, to bind, against the Releasees regardless of whether any such Releasor ever seeks or obtains, any distribution under the Agreement. Any political subdivision that receives any payment from the State with funds obtained under the Agreement shall execute an Additional Release in the form set out in Exhibit B to the Agreement as a condition to receiving any such payment.

Id. at Section 5.2.

11. Counsel for the State of Oklahoma made representations to this Court at the Consent Judgment hearing that a city or county would not be a releasing party and not bound by the settlement, unless it chose to participate. However, language in the Consent Judgment can be wrongfully interpreted to suggest that the Attorney General asserts unfounded authority to bind certain political subdivisions without their consent or release, even if the city or county receive no compensation. Transcript of Proceedings, Case No. CJ-2017-816, Page 7, line 24 to Page 8, Line 9, March 26, 2019, attached hereto as Exhibit "C". Such language could be misconstrued to imply that the State has authority to litigate Comanche County's claims against the remaining Defendants as well as recover Comanche County's damages and allocate those damages for another purpose.

12. On April 4, the State of Oklahoma dismissed without prejudice *all* claims except for its claim of public nuisance. This directly impacts the interests and rights of Comanche County relating to the subject matter of this action; thus, Comanche County is so situated that the disposition of the action in its absence may impair or impede its ability to protect those interests.

II. ARGUMENT AND AUTHORITIES

This action arises out of the opioid crisis in the State of Oklahoma and cannot be fully evaluated and described without reference to and inclusion of Oklahoma cities and counties.

a. Comanche County May Intervene In This Action As A Matter Of Right

Comanche County moves to intervene in this action as of right under 12 Okla. Stat. § 2024(A)(2). A Section 2024(A)(2) motion should be granted if: (1) the application is "timely"; (2) "the intervenor must claim a significant interest relating to the property or transaction which is the subject of the action"; (3) the intervenor's interest "may, as a practical matter" be "impair[ed] or impede[d]"; and (4) the intervenor's interest is [not] adequately represented by existing parties. *Id.; Brown v. Patel,* 2007 OK 16, ¶¶ 16-18, 157 P.3d 117, 123-124. (citations omitted). Courts follow "a somewhat liberal line in allowing intervention." *Id.* (Oklahoma's "Pleading Code adopts a procedure for intervention based upon a federal counterpart."); *see Utah Ass 'n of Counties v. Clinton,* 255 F.3d 1246, 1249 (10th Cir. 2001) (holding the circuit follows a liberal line in allowing intervention); *Dowell v. Board of Ed. of Okla. City,* 430 F.2d 865, 868 (10th Cir. 1970) (holding a liberal line is allowed when deciding intervention).

Comanche County satisfies Section 2024(A)(2)'s requirements for intervention as of right because its motion is timely, it has an interest in the subject matter underlying the litigation that may be impaired by the litigation, and because its interests are not adequately represented by the parties currently in the litigation.

i. Timeliness

The Consent Judgment filed twelve days ago and the dismissal of all claims except for public nuisance were the culminating events that underscored the importance of Comanche County's involvement in this pending matter. The timeliness of a motion to intervene is evaluated "in light of all of the circumstances, including the length of time since the applicant knew of his interest in the case, prejudice to the existing parties, prejudice to the applicant, and the existence of any unusual circumstances." *Utah Ass 'n of Counties*, 255 F.3d at 1250 (quoting *Sanguine, Ltd. v. U.S. Dep't of the Interior*, 736 F.2d 1416, 1418 (10th Cir. 1984)). "The requirement of timeliness

is not a tool of retribution to punish tardy would be intervenors, but rather a guard against prejudicing the original parties by failure to appear sooner." *Utah Ass'n of Counties*, 255 F.3d at 1250. Courts should allow intervention where "greater justice could be attained." *Id.* (citations omitted).

Comanche County's actions are timely as it has been only a couple of weeks since it learned of the Consent Judgment, the Settlement Agreement was released, and less than one month since Purdue argued to the Special Master that cities' and counties' claims and damages were included in its evaluation and defense of the pending State case. Moreover, Comanche County's rights are being impacted without its involvement; thus limiting and affecting Comanche County's ability to seek damages and recourse for the egregious acts of *all* Defendants. The prejudice that Comanche County would suffer if not allowed to intervene far outweighs any hardship or nuisance that Defendants could allege. Therefore, Comanche County's Motion to Intervene is timely.

ii. Intervenor Comanche County's Interest

Pursuant to Section 2024(A)(2), the intervenor must "claim[] an interest relating to the property or transaction which is the subject of the action." The issues that are the subject of this lawsuit regard a public nuisance claim and a substantial settlement that takes into account Comanche County's damages and claims, an allocation to Comanche County that is minuscule, and without adequate consideration. As a result of the cities and counties being detrimentally affected by the Consent Judgment and whose damages and claims are being considered in the State of Oklahoma's public nuisance claim, Comanche County has a clear interest in the subject and outcome of the litigation. Courts have found that while the contours of the interest requirement had not been clearly defined, in this circuit, the interest must be "direct, substantial, and legally protectable." *Brown*, 157 P.3d at 125 (citing *Coalition of Arizona/New Mexico Counties for Stable Economic Growth v. Dept. of Interior*, 100 F.3d 837, 840 (10th Cir. 1996)). It is clear that

Comanche County has a very direct and substantial interest in the outcome of the proceeding. As such, it is proper that Comanche County be allowed to intervene and protect its interests in the subject matter of this litigation.

iii. Impairment of Interest

Pursuant to Section 2024(A)(2), Comanche County must also show that the disposition of this action may, as a practical matter, impair or impede its ability to protect its interest. Looking to the interpretation of the federal counterpart for guidance as directed by the Supreme Court of Oklahoma, the Tenth Circuit has held that "the question of impairment is not separate from the question of existence of an interest." *Natural Res. Def. Council v. U. S. Nuclear Regulatory Comm'n*, 578 F.2d 1341, 1345 (10th Cir. 1978); *see also Brown*, 157 P.3d at 124 (when looking at Section 2024(A)(2), the court "may look to the federal court interpretation when we apply similar language from our pleading code."). Moreover, Section 2024(A)(2) refers to impairment 'as a practical matter." "Thus, the court is not limited to consequences of a strictly legal nature." *Natural Res. Def. Council*, 578 F.2d at 1345. "To satisfy this element of the intervention test, a would-be intervenor must show only that impairment of [its] substantial legal interest is possible if intervention is denied. This burden is minimal."" *Utah Ass'n of Counties*, 255 F.3d at 1253 (citing *Grutter v. Bollinger*, 188 F.3d 394, 399 (6th Cir. 1999) (quoting *Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1247 (6th Cir. 1997)).

Comanche County has a requisite interest in this matter. Upon information and belief, Comanche County's damages were taken into account in evaluating the claims and damages at issue in this litigation, and the settlement with Purdue. While the State of Oklahoma has refused to produce documents or information provided in the damage model, Purdue counsel stated on the record that a substantial, if not a majority of damages sought were for cities and counties, not the State of Oklahoma. The allocation of \$12.5 million to 597 municipalities and 77 counties means Comanche County could potentially receive an allocation of \$18,545.99. Again, Comanche County has no access to even the criteria for allocation. The amount Comanche County would recover under the State's settlement with Purdue will provide minimal assistance in abating the public nuisance of the opioid epidemic in Comanche County; yet, Comanche County had no ability to intercede in the settlement negotiations or allocation. Comanche County has substantial damages. Comanche County has damages from the opioid epidemic related to its county run hospital, law enforcement and court costs, and detention center. The impairment Comanche County would suffer if not allowed to intervene and assert its rights is substantial.

iv. The Existing Parties Do Not Adequately Represent Comanche County's Interest

The burden to show inadequacy of representation is minimal and requires only a showing that representation "may" be inadequate. *Sanguine*, 736 F.2d at 1419 (*citing Trbovich v. United Mine Workers*, 404 U.S. 528, (1972)). It is apparent by the size of the recent settlement that allocates a mere 5% to all of Oklahoma's counties and cities that the representation is not adequate on behalf of cities and counties nor in their best interests. Certainly, the current parties to this action will not adequately represent Comanche County's interests.

Comanche County employs thousands of people and is responsible for funding medical insurance plans for its employees. This includes close to 2,000 county employees who are employed by Comanche County Hospital Authority ("CCHA"). Through CCHA, Comanche County provides a wide range of healthcare services to its residents. The CCHA Board of Trustees sets policy and exercises authority over the Comanche County Memorial Hospital. Comanche County, *not* the State of Oklahoma, is solely responsible for the above. Thus, the interests of protecting the health, welfare and safety of Comanche County's citizens and addressing the opioid

epidemic and expenditures to combat said epidemic are distinct and different from the State of Oklahoma's.

At this point, despite representations by Purdue that the State is using city and county damages in its Damage Model, Comanche County has no way to determine or verify the veracity of these representations nor does it know whether city and county damages were used in its settlement negotiations with Purdue. The only way the interests and rights of Comanche County (as well as the other interests and rights of the other cities and counties) can be protected is by its involvement in this action.

Therefore, the interests of the State of Oklahoma and Comanche County do not align, and Comanche County's interests are not adequately represented.

b. Comanche County Is Entitled To Intervene Permissively

If the Court determines in its discretion that Comanche County cannot intervene as a matter of right, Comanche County seeks permissive intervention pursuant to Section 2024(B)(2). The Supreme Court of Oklahoma has stated that permissive intervention is within the sound legal discretion of the trial court based upon the nature of the lawsuit and the facts and circumstances of the case. *See Skrapka v. Bonner*, 187 P.3d 202, 208-209 (Okla. 2008). Section 2024(B)(2) does not require the intervenor to have a direct person or pecuniary interest in the subject of the litigation. *Sec. & Exch. Comm'n v. U.S. Realty & Improvement Co.*, 310 U.S. 434, 459 (1940). Instead, it requires simply that the intervenor have a "claim or defense that shares with the main action a common question of law or fact." Here, Comanche County does have a direct personal interest in the subject matter of this litigation.

The nature of this litigation includes almost identical factual allegations and only one claim, public nuisance, against the Manufacturer Defendants, including Purdue. Indeed, as discussed above, the remaining claim and the Consent Judgment stem from the exact litigation that

Comanche County and many other cities and counties in Oklahoma are pursuing against Purdue and the Manufacturer Defendants. As a result, the Court should allow Comanche County to permissively intervene into the litigation in order for its interests to be adequately represented and protected.

CONCLUSION

Comanche County respectfully requests that this Court grant its Motion to Intervene as a matter of right under 12 Okla. Stat. § 2024(A)(2) or permissively intervene under 12 Okla. Stat. § 2024(B)(2). Alternatively, Comanche County seeks to intervene for the limited purpose of having the Protective Order(s) modified to include Comanche County and the Court enter an Order that requires Comanche County to be involved in all on-going settlement negotiations with Defendants.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that on the ____ day of April, 2019, a true and correct copy of the above and foregoing document was mailed, postage prepaid to:

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EXHIBIT A

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IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA and BOARD OF COUNTY COMMISSIONERS OF COMANCHE COUNTY,)))))
Plaintiffs,)
v.))
(1) PURDUE PHARMA L.P.;(2) PURDUE PHARMA, INC.;) Case No. CJ-2017-816
(3) THE PURDUE FREDERICK	
COMPANY;) Honorable Thad Balkman
	 Honorable Thad Balkman Special Discovery Master: William C. Hetherington, Jr.
(11) WATSON LABORATORIES, INC.;	
(12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	

Defendants.

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MOVANT COMANCHE COUNTY'S INTERVENOR PETITION

INTRODUCTION

1. In 2017, the United States saw a record number of drug overdose deaths,

totaling 72,000 people and an approximate ten percent increase from 2016. The 2017

drug overdose death toll is higher than the peak annual death totals for HIV, car wrecks. or gun deaths. Analysts pointed to the opioid epidemic ravaging communities across the country (growing number of opioid users) and prescription opioids becoming deadlier. The opioid epidemic has been particularly devastating in Oklahoma and Comanche County as a result of corporate greed.

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2. Comanche County employees dozens of people and is responsible for funding medical insurance plans for its employees. This includes close to 2,000 county employees who are employed by Comanche County Memorial Hospital. Comanche County provides a wide range of healthcare services to its residents through Comanche County Memorial Hospital, an Oklahoma non-profit Public Trust. The Comanche County Hospital Authority Board of Trustees sets policy and exercises authority over the hospital.

3. Comanche County brings this action in its own legal capacity to protect the health, safety, and welfare of all its residents.

4. Opioids are highly addictive and, historically, medical professionals have prescribed them in limited circumstances to patients with cancer, terminal illnesses, or acute short-term pain. Defendants manufacture opioids and, therefore, the limited uses for which medical professionals prescribed opioid prescriptions undermined Defendants' ability to maximize profits. Thus, Defendants sought to maximize their profits by selling more opioids. Defendants sought, and indeed accomplished this goal, by expanding the market beyond the limited circumstances of medically necessary opioid use and

successfully convinced medical professionals to prescribe opioids to a broader range of patients for longer periods of time.

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5. Defendants chose to falsely downplay the risk of opioid addiction and overstate the efficacy of opioids for more wide-ranging conditions, including chronic non-cancer pain, in a willful effort to maximize their profits at the expense of human life. Over several years, Defendants implemented unprecedented and large-scale deceptive marketing campaigns that misrepresented the risks of addiction from their opioids and pushed unsubstantiated benefits. Defendants were extremely successful in increasing the sales of opioids. For example, sales of OxyContin rose from roughly \$48 million in 1996 to roughly \$3 billion by 2009.

6. This epidemic has been building for years and the effects of this crisis have only been exacerbated by Defendants' efforts to conceal and minimize the risks of opioid addiction.

7. Upon information and belief, Comanche County has been overwhelmed by the devastation from opioid addiction and its costs to provide a wide range of social services, from child welfare to law enforcement, have substantially increased. The result has been that virtually every family in Comanche County has personally experienced or knows someone who has been adversely impacted by the opioid epidemic.

8. These costs and adverse effects of the opioid epidemic could have been, and should have been, prevented by Defendants. The prescription drug industry is required to implement and follow processes that stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients.

9. Instead of acting with reasonable care, Defendants intentionally and/or recklessly saturated communities with opioids and pocketed billions of dollars in the process.

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10. Defendants also flooded the market with false declarations designed to convince doctors, patients, and government entities that prescription opioids posed a low risk of addiction. Those claims were false¹ and Defendants knew it.

11. As a direct result of Defendants' actions, criminal acts have been committed, not only by residents of Comanche County seeking to obtain opioids, but also by physicians themselves. Defendants created an environment where physicians sought to profit at the expense of their patients who would become addicted to opioids at the expense of Comanche County.

12. Defendants' actions directly and foreseeably caused damages to Comanche County, including but not limited to, actual costs, lost opportunity costs, healthcare and emergency care costs, costs for social services for those suffering from opioid addiction, overdose, or death; counseling, treatment and rehabilitation services; treatment of infants born with opioid-related medical conditions; welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation; and law enforcement and public safety relating to the opioid epidemic within the County. Comanche County has also suffered substantial damages due to the lost productivity of its residents, increased

¹ See Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at <u>http://turnthetiderx.org/</u>.

administrative costs, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by Comanche County.

13. Comanche County also seeks the abatement of the continuing epidemic created by Defendants' wrongful and/or unlawful conduct.

II. <u>THE PARTIES</u>

A. Plaintiff

14. Comanche County, by and through Board of County Commissioners of Comanche County, is an organized county within the State of Oklahoma, a body corporate and politic, with the statutory authority and power to sue and be sued. Comanche County provides a wide range of services on behalf of its residents, including but not limited to social services for families and children, public health, public assistance, law enforcement and emergency care. Plaintiff is referred to as "Comanche County" or "County".

B. Manufacturer Defendants

15. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

16. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. Its partners are Purdue Pharma Inc., a citizen of New York and Connecticut, and Purdue Holdings L.P. Purdue Holdings L.P.'s partners are Purdue Pharma Inc., a citizen of New York and Connecticut; PLP Associates Holdings Inc., a citizen of New York and Connecticut; and PLP Associates Holdings L.P. PLP Associates Holdings L.P.'s partners are PLP Associates Holdings Inc., a citizen of New York and Connecticut; and BR Holdings Associates L.P. BR Holdings Associates L.P.'s partners are BR Holdings Associates Inc., a citizen of New York and Connecticut; Beacon Company; and Rosebay Medical Company L.P. Beacon Company's partners are Stanhope Gate Corp., a citizen of the British Virgin Islands and Jersey, Channel Islands; and Heatheridge Trust Company Limited, a citizen of Jersey, Channel Islands. Rosebay Medical Company L.P.'s partners are Rosebay Medical Company, Inc., a citizen of Delaware and Oklahoma; R. Sackler, a citizen of Texas; and J. Sackler, a citizen of Connecticut. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

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17. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S., including Oklahoma. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99

billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Purdue has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

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18. CEPHALON, INC. is a Delaware corporation with its principal place in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

19. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including in Oklahoma. The Federal Drug Administration ("FDA") approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

20. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon- branded

products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly owned subsidiary of Teva Ltd. on prescription savings cards, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva's USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Oklahoma and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon"). Cephalon has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

21. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-**JANSSEN** PHARMACEUTICALS, INC. known JANSSEN now as PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen"). Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

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22. Janssen manufactures, promotes, sells, and distributes drugs in the United States., including in Oklahoma, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Janssen has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

23. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of

January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as "Actavis").

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24. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, including in Oklahoma. Actavis has , registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

25. Collectively, Purdue, Cephalon, Janssen, and Actavis are the "Manufacturer Defendants".

III. JURISDICTION AND VENUE

26. This Court has jurisdiction over this action because Defendants conduct business in Comanche County and throughout Oklahoma and have deliberately engaged

in significant acts and omissions within Comanche County that have injured its residents. Defendants purposefully directed their activities at Comanche County, including, but not limited to, marketing, distributing, or selling prescription opioids within Comanche County.

27. Venue is proper in Comanche County, State of Oklahoma.

28. This action is non-removable because there is incomplete diversity of residents, no substantial federal question presented, and a claim for the abatement of a public nuisance in Comanche County based on state law.

IV. ADDITIONAL FACTUAL BACKGROUND

A. Overview of National Opioid Epidemic

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29. Historically, opioids were considered too addictive and debilitating to be part of a long-term pain management regimen for chronic pain. Prior to the 1990s, the medical profession adhered to the standard that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer and end-of-life care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time as well as the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, medical professionals generally did not prescribe opioids for chronic pain.

30. Moreover, opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before,

thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse for those addicted to opioids.

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31. As described herein, Defendants engaged in conduct that directly caused medical professionals to unwittingly prescribe long-term and increased amounts of opioids to "aggressively" treat pain. Defendants did so to take advantage of a much larger and lucrative market for chronic pain patients.

32. As a result of Defendants' wrongful conduct, prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.² From 1999 to 2013, the amount of prescription painkillers prescribed and sold in the United States nearly quadrupled. Yet, there had not been an overall change in the amount of pain reported by patients.

33. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention ("CDC") declared prescription painkiller overdoses to be at epidemic levels. The press release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin) and oxymorphone (Opana).

² Katherine M. Keyes et al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

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- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically, according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.³

34. Many Americans, including residents of Comanche County, are now addicted to prescription opioids and the number of deaths due to prescription opioid overdose has reached epidemic levels. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.⁴ The President of the United States has declared the opioid epidemic a public health emergency.

³ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html. ⁴ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-deathestimates.pdf.

35. The National Institute on Drug Abuse identifies addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."⁵ The economic burden of prescription opioid misuse alone is hundreds of billions of dollars a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.⁶

36. Deaths from prescription opioids have quadrupled in the past 20 years and treatment admission and emergency room visits related to the abuse of opioids for non-medical use have also dramatically increased.

37. According to the CDC,⁷ opioid deaths and treatment admissions are tied to opioid sales.

38. Defendants have continued their wrongful and unlawful conduct, despite their knowledge that such conduct is causing and continuing to cause the opioid epidemic.

⁵ Opioid Crisis, NIH. National Institute Drug Abuse (available on at https://www.drugabuse.gov/drugs- abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, MMWR MORB MORTAL WKLY REP. 2016:65, doi:10.15585/mmwr.mm655051e1). ⁶ Id. (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, MED CARE 2016;54(10):901-906, doi:10.1097/MLR.00000000000625). ⁷ U.S. Dep't of Health & Human Servs., Addressing Prescription Drug Abuse in the United States, available at https://www.cdc.gov/drugoverdose/pdf/hhs prescription drug abuse report 09. 2013.pdf.

B. Overview of Opioid Epidemic in Oklahoma and Comanche County

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39. Communities have been devastated by the opioid epidemic as a result of Defendants' deceptive marketing and diversion of opioids. Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths.

40. In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate. Oklahoma had the 10th highest drug overdose death rate in the nation in 2014. Opioids are the most common class of drug involved in unintentional overdose deaths in Oklahoma.

41. In 2015, 823 fatal drug overdoses occurred in Oklahoma, an almost 140% increase over 2001, with opioids contributing to the largest number of these deaths. As of 2015, there were more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined.

42. In Oklahoma, more overdose deaths involved hydrocodone or oxycodone than methamphetamines, heroin, and cocaine combined.

43. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident with approximately 877 milligrams of opioids distributed per adult resident.

44. A National Survey on Drug Use and Health revealed Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers.

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45. From 2007-2013, there were seventy-nine (79) unintentional poisoning deaths in Comanche County. Nearly six out of ten unintentional poisoning deaths involved at least one prescription painkiller. One of the most common substances in the overdose deaths was Fentanyl. Roughly nine out of ten unintentional poisoning deaths were to Lawton residents. In 2016 alone, drug overdoses killed eighteen (18) people per 100,000 residents in Comanche County.

46. The Comanche County Sheriff's Department now carries Naloxone and/or Narcan, antidotes to opioid overdose, and uses them virtually on a daily basis to save the lives of Comanche County residents.

47. The Defendants' saturation of communities with prescription opioids has created accessibility and availability of prescription opioids, which is fueling illicit opioid addiction. According to the CDC, past misuse of prescription opioids is the strongest risk factor for a person starting and using heroin. Between 2000 and 2014, the number of overdose deaths from heroin nationwide quintupled.

48. Defendants' conduct is affecting even Comanche County's youngest and most vulnerable citizens. At the Henley-Hillis Center for Women & Children at Comanche County Memorial Hospital, about 2.9% of all deliveries involve infants who test positive for opioids, which is roughly forty (40) infants per year. Of the opioid positive infants, roughly fifty percent (50%) have an extended stay in the hospital for

withdrawal treatment. The national rate of babies born with neonatal abstinence syndrome ("NAS"), a group of conditions newborns experience when withdrawing from exposure to drugs like opioids, increased fivefold from 2000 to 2012. In 2014, the number of newborns testing positive for prescription medications doubled the number reported in 2013.

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C. Manufacturer Defendants False, Deceptive And Unfair Marketing Of Opioids

49. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used for treatment of chronic pain, resulting in opioid treatment for a much larger segment of the population, and for a longer time, of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

50. The deceptive marketing schemes included, among others, (1) false or misleading direct, branded advertisements; (2) false or misleading direct-to-physician marketing, also known as "detailing;" (3) false or misleading materials speaker programs, webinars, and brochures; and (4) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Manufacturer Defendants also retained the services

of certain physicians, known as "key opinion leaders" ("KOLs") to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

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51. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the seriousness of addiction; (2) created and promoted the concept of "pseudo addiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

52. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

53. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

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54. Upon information and belief, Defendants knew or should have known that such dissemination of misinformation would include prescribers and impact their prescribing practices of opioids.

55. Manufacturer Defendants' efforts have been extremely successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁸ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

⁸ See Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at <u>http://turnthetiderx.org/</u>.

56. Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

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1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids

57. Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around Comanche County. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout Comanche County.

58. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around Comanche County, as they did nationwide. Across the opioid pharmaceutical industry, corporate headquarters funded and oversaw "core message" development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants' messages are consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

59. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training

materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on their performance and compliance.

i. Direct Marketing

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60. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of opioids. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

61. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Purdue ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

62. Each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. The Manufacturer Defendants spent in

excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

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63. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate, and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by an individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

64. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."⁹

ii. Indirect Marketing

65. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and KOLs, and industry-funded organizations

⁹ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

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The Manufacturer Defendants deceptively marketed opioids in Comanche 66. County through unbranded advertising - e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their and speaker programs, the Manufacturer Defendants similarly own detailers controlled the distribution of these messages in scientific publications, treatment Continuing Medical Education ("CME") programs, guidelines, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third parties.

67. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and

conceal their scheme to deceive doctors and patients about the risks and benefits of longterm opioid use for chronic pain.

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68. Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. Upon information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

69. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have

long known – that opioids are addictive drugs, unsafe in most circumstances for longterm use – was untrue, and that the "compassionate" treatment of pain required opioids.

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70. In 2007, multiple states sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack a reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

71. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long- term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. Manufacturer Defendants utilized many KOLs, including many of the same ones.

72. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Janssen and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

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73. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted.¹⁰

74. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that less

¹⁰ Good Morning America (ABC television broadcast Aug. 30, 2010).

than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."¹¹ Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."¹²

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75. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013. He is a Senior Editor of Pain Medicine and the author of numerous CMEs sponsored by Cephalon and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

76. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U DEA, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than twenty (20) of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

77. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a fivequestion, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.

¹¹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012,

https://www.wsj.com/articles/SB10001424127887324478304578173342657044604. ¹² *Id*.

The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

78. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Oklahoma and doctors treating residents of Comanche County.¹³

79. Dr. Webster also was a leading proponent of the concept of "pseudo addiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book Avoiding Opioid Abuse While Managing Pain—a book

¹³ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

that is still available online—when faced with signs of abnormal behavior, increasing the dose "in most cases . . . should be the clinician's first response."¹⁴ Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."¹⁵

80. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

81. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the

¹⁴ Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).

¹⁵ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012,

http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

82. Manufacturer Defendants Cephalon, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including APS, American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and the Pain & Policy Studies Group ("PPSG").¹⁶

83. The most prominent of the Manufacturer Defendants' Front Groups was APF, which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning veterans. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain

¹⁶ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to% 20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group .pdf.

treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach the residents of Comanche County.

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84. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of a total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Manufacturer Defendants Purdue, Cephalon, and others to avoid using its line of credit.

85. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

86. Plaintiff is informed, and believes, that on several occasions representatives of Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking

to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

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87. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."¹⁷

88. Another front group for the Manufacturer Defendants was AAPM. With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

89. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort

¹⁷ Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-

<u>companies-</u> ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendants Purdue and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

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90. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

91. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

92. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who coauthored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website

until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.¹⁸

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93. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.¹⁹ Doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Actavis and Purdue discussed treatment guidelines with doctors during individual sales visits.

94. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Manufacturer Defendants Janssen, Cephalon, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.²⁰ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan

¹⁸ The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).

 ¹⁹ Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).
 ²⁰ Id.

Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in Comanche County during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

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95. The Manufacturer Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Janssen and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that a FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

D. Manufacturer Defendants' Marketing Scheme Misrepresented The Risks And Benefits of Opioids

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1. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

96. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of longterm opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked. These misrepresentations, which are described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

97. Opioid manufacturers, including Manufacturer Defendant Purdue, have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Petition. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term

opioid use in Comanche County and each continues to fail to correct its past misrepresentations.

98. Some illustrative examples of the Manufacturer Defendants' false,

deceptive, and unfair claims about the purportedly low risk of addiction include:

- a. Actavis' predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- d. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- e. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."²¹

²¹ Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter APF,

f. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Janssen and Cephalon in Oklahoma and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

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g. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.²²

99. These claims are contrary to longstanding scientific evidence. A 2016

opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."²³ The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."²⁴

²³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
²⁴ Id. at 2, 25.

Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakersguide.pdf.

 $^{^{22}}$ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

100. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.²⁵

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101. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to both doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. "pseudoaddiction") – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

²⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016),

https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

102. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

103. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- b. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients and not opioids are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.
- c. On information and belief, detailers for the Manufacturer Defendants have touted and continue to tout to doctors in

Oklahoma the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

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104. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

105. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

106. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be

ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur."²⁶

107. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat) – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

108. Contrary to the Manufacturer Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." (Emphasis added). The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."

109. The Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment

²⁶ Available at, <u>http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf</u>.

when patients built up tolerance and lower dosages did not provide pain relief. Some

illustrative examples of these deceptive claims are described below:

- a. On information and belief, Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available online.²⁷
- c. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- d. On information and belief, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- e. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
- f. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit

²⁷ Available at, <u>https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf</u>.

and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

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- g. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.
- h. On information and belief, Purdue's detailers have told doctors in Oklahoma that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

110. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

111. The Manufacturer Defendants' deceptive marketing of the so-called abusedeterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

112. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids can be defeated – often quickly and easily – by

those determined to do so. The 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."²⁸

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113. Despite this lack of evidence, the Manufacturer Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

114. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, on information and belief, these detailers: (1) falsely claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) falsely claim that

²⁸ Matthew Perrone et al., Drugmakers push profitable, but unproven, opioid solution, Center for Public Integrity (Dec. 15, 2016), available at <u>https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution</u>. Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) falsely claim Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

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115. These statements and omissions by Purdue are false and misleading. Purdue knew and should have known that reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.²⁹ Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.³⁰

116. The development, marketing, and sale of AD opioids are a continuation of the Manufacturer Defendants' strategy to use misinformation to drive profit. The

³⁰ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider, Mar. 14, 2016, available at <u>http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3</u>.

²⁹ Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin," (2015) 72.5 *JAMA Psychiatry* 424-430.

Manufacturer Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

2. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

117. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. ³¹ The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

118. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on

³¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

your body and your mental health," and help patients enjoy their lives.

- b. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- c. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."
- d. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves the patients' function.
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- f. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."³²
- g. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a

³² Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*],

https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

patient to "continue to function."

h. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain." The Policymaker's Guide was originally published in 2011.

3. Purdue's, Cephalon's and Janssen's sales representatives have conveyed, and continue to convey, the message that opioids will improve patient function.

119. As the FDA and other agencies have made clear for years, these claims have no support in scientific literature.

120. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."³³ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

121. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs (nonsteroidal anti-

³³ Letter from Thomas Abrams to Doug Boothe, *supra* note 14.

inflammatory drugs), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain. The Manufacturer Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids.

122. For example, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and

deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

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123. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm.

124. Despite this, on information and belief, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe.³⁴ As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

³⁴ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million & Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <u>https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html</u>.

125. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

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- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non- oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" and not just cancer pain.

126. The Manufacturer Defendants, both individually and collectively, made,

promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations.

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127. On information and belief, the Manufacturer Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

128. Moreover, at all times relevant to this Petition, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

129. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or significance of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the

Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could Comanche County have detected it.

130. The Manufacturer Defendants' efforts to artificially increase the number of opioid prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."³⁵ Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid- related morbidity."³⁶ Accordingly, the Manufacturer Defendants' false and misleading statements directly caused the current opioid epidemic.

V. <u>CAUSES OF ACTION</u>

A. Public Nuisance, (Against all Defendants)

131. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

132. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or . omissions which endanger or injury the property, health, safety and/or comfort of a considerable

³⁵ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm .

³⁶ Id.

number of persons in Comanche County by their production, promotion, and marketing of opioids for use by residents of Comanche County.

133. Defendants' misrepresentations and omissions regarding opioids, as set forth above, have created an opioid addiction epidemic in Comanche County that constitutes a public nuisance. Defendants have created a condition that affects entire communities, neighborhoods, and considerable numbers of persons at the same time.

134. Defendants' misrepresentations and omissions regarding opioids constitute unlawful acts and/or omissions of duties, which annoy, injure, or endanger the comfort, repose, health, and/or safety of others, and offend decency to a considerable number of persons in Comanche County. It has even caused deaths, serious injuries, and a severe disruption of public peace, order and safety.

135. Defendants have a duty to abate the nuisance caused by the prescription opioid epidemic.

136. Defendants have failed to abate the nuisance they created.

137. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

138. As a direct result of Defendants' conduct, Comanche County and its residents have suffered actual injury and economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, social services and other services, lost tax revenue, as well as injury and death of residents of Comanche County.

139. Defendants are liable to Comanche County for the costs of abating the nuisance created by Defendants.

JURY TRIAL DEMAND

140. Plaintiff hereby requests a trial by jury.

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RELIEF

WHEREFORE, Plaintiff respectfully prays for relief and judgment as follows:

1. Abatement of the public nuisance Defendants have created and all costs necessary to abate such nuisance;

2. Enter judgment against Defendants requiring Defendants to pay damages in excess of \$75,000;

3. Enter judgment against Defendants awarding Plaintiff its reasonable attorneys' fees, all costs and expenses, pre-judgment and post-judgment interest; and,

4. All other such and further relief to which Plaintiff is entitled.

Respectfully submitted,

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-and-

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-and-

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Attorneys for Plaintiff

EXHIBIT B

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1	IN THE DISTRICT COURT OF CLEVELAND COUNTY
2	STATE OF OKLAHOMA
3	STATE OF OKLAHOMA, ex rel.,)
4	MIKE HUNTER) ATTORNEY GENERAL OF OKLAHOMA,)
5	Plaintiff,)
6	vs.) Case No. CJ-2017-816
7	(1) PURDUE PHARMA L.P.;)
8	<pre>(2) PURDUE PHARMA, INC.;) (3) THE PURDUE FREDERICK) COMPANY:</pre>
9	COMPANY;) (4) TEVA PHARMACEUTICALS) USA, INC;)
10	(5) CEPHALON, INC.;)
11	<pre>(6) JOHNSON & JOHNSON;) (7) JANSSEN PHARMACEUTICALS,) INC.;)</pre>
12	(8) ORTHO-MCNEIL-JANSSEN) PHARMACEUTICALS, INC.,)
13	n/k/a JANSSEN PHARMACEUTICALS;) (9) JANSSEN PHARMACEUTICA, INC.)
14	n/k/a JANSSEN PHARMACEUTICALS,) INC.;)
15	(10) ALLERGAN, PLC, f/k/a) ACTAVIS PLC, f/k/a ACTAVIS,)
16	INC., f/k/a WATSON) PHARMACEUTICALS, INC.;)
17	(11) WATSON LABORATORIES, INC.;) (12) ACTAVIS LLC; AND)
18	(13) ACTAVIS PHARMA, INC.,) f/k/a WATSON PHARMA, INC.,)
19	Defendants.
20	PORTIONS OF TRANSCRIPT MAY BE COVERED UNDER PROTECTIVE ORDER
21	TRANSCRIPT OF PROCEEDINGS OF REQUESTED EXCERPT HAD ON MARCH 1, 2019
22	AT THE CLEVELAND COUNTY COURTHOUSE BEFORE THE HONORABLE WILLIAM C. HETHERINGTON, JR.,
23	RETIRED ACTIVE JUDGE AND SPECIAL DISCOVERY MASTER
24	
25	REPORTED BY: ANGELA THAGARD, CSR, RPR

* •

APPEARANCES: 1 ON BEHALF OF THE PLAINTIFF: 2 MR. ETHAN A. SHANER 3 ATTORNEY GENERAL'S OFFICE 313 N.E. 21ST STREET 4 OKLAHOMA CITY, OK 73105 5 MR. BRADLEY E. BECKWORTH (VIA TELEPHONE) 6 ATTORNEY AT LAW 3600 N. CAPITAL OF TEXAS HWY, SUITE 350 7 AUSTIN, TX 78746-3211 8 9 ON BEHALF OF THE CITY OF OKLAHOMA CITY, THE CITY OF BROKEN ARROW, AND COMANCHE COUNTY: 10 MR. CHRISTOPHER J. BERGIN MR. HARRISON LUJAN 11 ATTORNEYS AT LAW 1101 N. BROADWAY AVENUE, SUITE 205 OKLAHOMA CITY, OK 73103 12 13 14 ON BEHALF OF DELAWARE COUNTY, GARVIN COUNTY, MCCLAIN COUNTY, OSAGE COUNTY, OTTAWA COUNTY, PAWNEE COUNTY, 15 AND SEMINOLE COUNTY: MR. GEORGE GIBBS 16 ATTORNEY AT LAW 17 601 S. BOULDER, SUITE 500 TULSA, OK 74119 18 19 ON BEHALF OF ORTHO MCNEIL JANSSEN PHARMACEUTICALS, INC.; 20 JANSSEN PHARMACEUTICA, INC.; JANSSEN PHARMACEUTICALS, INC.; AND 21 JOHNSON & JOHNSON: MR. DAVID L. KINNEY 22 ATTORNEY AT LAW 23 HIPOINT OFFICE BUILDING 2500 MCGEE DRIVE, SUITE 140 NORMAN, OK 73072 24 25

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6	MR. ERIC WOLF PINKER ATTORNEY AT LAW
7	2100 ROSS AVENUE, SUITE 2700 DALLAS, TEXAS 75201
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9	ON BEHALF OF TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.;
10 11	ACTAVIS LLC; ACTAVIS PHARMA, INC.; AND WATSON LABORATORIES, INC.:
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13	ONE LEADERSHIP SQUARE, 15TH FLOOR 211 NORTH ROBINSON
14	OKLAHOMA CITY, OK 73102
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But nonetheless, the movants have relevant evidence regarding the standards and policies they use when administering, prescribing, and allowing the administration of opioid medications in their jurisdictions. Those standards will rebut the State's expert in that regard, we believe. That's the first category.

7 The second category is services that are provided by these 8 movants. Part of the State's damage model in this case 9 separate and apart from this unlawful prescription, which is a 10 several billion dollar claim, the State's damage model in this 11 case is an abatement policy, which they claim should last for 12 20 or 30 years in which they claim will cost between 12 and 17 13 plus billion dollars.

And they have identified dozens, if not hundreds, of items 14 15 that they think fit within that abatement policy. It is our 16 belief and we intend to prove that many, if not a majority, of 17 those items are, in fact, not provided by the State, have never 18 been provided by the State, are not paid for by the State, and 19 in fact, are paid for and provided, to the extent they exist, 20 by the movants; things like ambulatory services, things like 21 end care service, things like education. So the second category of information we're seeking is the types of 22 23 opioid-related services being provided by the movants.

The third category of information we're seeking is efforts to investigate and limit alleged opioid use and misuse in

EXHIBIT C

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1	IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA
2	STATE OF OKLAHOMA, ex rel.,) MIKE HUNTER)
3	ATTORNEY GENERAL OF OKLAHOMA,
4	Plaintiff,)
5	VS) Case No. CJ-2017-816
6	(1) PURDUE PHARMA L.P.;) (2) PURDUE PHARMA, INC.;/)
7	 (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA,)
8	(1) INC.;) (5) CEPHALON, INC.;)
9	 (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, (7) JANSSEN PHARMACEUTICALS,
10	(%) ORTHO-MCNEIL-JANSSEN)
11	PHARMACEUTICALS, INC.,) n/k/a JANSSEN PHARMACEUTICALS;)
12	(9) JANSSEN PHARMACEUTICA, INC.) n/k/a JANSSEN PHARMACEUTICALS,)
13	INC.;) (10) ALLERGAN, PLC, f/k/a ACTAVIS)
14	PLC, f/k/a ACTAVIS, INC., f/k/a) WATSON PHARMACEUTICALS, INC.;)
15	(11) WATSON LABORATORIES, INC.;) (12) ACTAVIS LLC; AND)
16	(12) ACTAVIS PHARMA, INC., f/k/a) WATSON PHARMA, INC.,)
17	Defendants.
18	
19	
20)
21	TRANSCRIPT OF PROCEEDINGS HAD ON THE 26TH DAY OF MARCH, 2019,
22	BEFORE THE HONORABLE THAD BALKMAN, DISTRICT JUDGE
23	AND WILLIAM C. HETHERINGTON, JR., RETIRED ACTIVE JUDGE AND SPECIAL DISCOVERY MASTER
24	METINE MOTIVE CODOL MUD DIECTAL DIDCOVENT MADIEN
25	REPORTED BY: Tanya Burcham, CSR, RPR
	DISTRICT COURT OF OKLAHOMA - OFFICIAL TRANSCRIPT

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1	APPEARANCES
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3	ON BEHALF OF THE PLAINTIFF:
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25	
	DISTRICT COURT OF OKLAHOMA - OFFICIAL TRANSCRIPT

1	It is a \$270 million settlement. The payments break down as
2	follows. There is \$102.5 million paid by Purdue to the
3	foundation which will fund the center, the National Center,
4	that I will talk about in a minute through Oklahoma State.
5	Which we'll go over its mission, but it's created to treat,
6	study, educate, and deal with the opioid crisis here in
7	Oklahoma, and hopefully become a national presence. And what
8	we've envisioned is that it will be nothing unlike an MD
9	Anderson for cancer, Mayo Clinic, or the like that
10	MS. BIRNBAUM: For Oklahoma.
11	MR. BECKWORTH: For Oklahoma. We will have a place
12	here that is the bright shining light for trying to turn this
13	crisis around through treatment and education.
14	So 102.5 million will go there. That money is paid by
15	Purdue. Then there's an additional \$75 million that will be
16	paid by the Sackler families. The Purdue money will be coming
17	here in just a few days, as I'll explain. The Sackler money
18	will be paid in five \$15 million payments, the first of which
19	is January 10th of 2020. So this next January. That money
20	will also go to the foundation.
21	THE COURT: Are those annual payments?
22	MR. BECKWORTH: Yes, sir.
23	THE COURT: Okay.
24	MR. BECKWORTH: Then there is a \$12.5 million
25	payment by Purdue. And what that is being set up to do is to
	DISTRICT COURT OF OKLAHOMA - OFFICIAL TRANSCRIPT

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1 fund claims of cities and counties that are political 2 subdivisions here if they choose to participate. That money will be put into a fund. We're working on an allocation method 3 4 for that. If a city or county comes in, who has a claim, and 5 they decide to -- or elect to participate and take that funding, they'll have to sign the release that is here before 6 you, and then their claims, whatever they have against the 7 Purdue released entities will be gone. But that will be their 8 9 election.

10 THE COURT: What are the restrictions on how they 11 use that money?

12 MR. BECKWORTH: I don't think there are. 13 THE COURT: Okay. Ms. Dillsaver has --14 MS. DILLSAVER: If I could supplement 15 Mr. Beckworth's comments. Your Honor, the agreement required 16 that the funds be distributed in, and I don't have it right in 17 front of me, but essentially in accordance with the terms of 18 the agreement. And if you read throughout the agreement, the 19 entire intent of it is to put funding where it needs to 20 directly address the opioid epidemic in our state.

And so, again, the restrictions are not final, but they certainly are intent to ensure the terms of distribution require that the money be deployed directly to abate and remediate the opioid epidemic in those particular localities, whether it be a city or county.

-DISTRICT COURT OF OKLAHOMA - OFFICIAL TRANSCRIPT-