IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	STATE OF OKLAHOMA } S.S. CLEVELAND COUNTY } FILED In The Office of the Court Clerk OCT 30 2017 In the office of the Court Clerk MARILYN WILLIAMS
vs.	§	
(1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	Case No. CJ-2017-816 JURY TRIAL DEMANDED
Defendants.	§	

THE STATE'S OMNIBUS RESPONSE TO (i) DEFENDANTS' JOINT MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM; (ii) MOTION OF DEFENDANTS CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA INC. TO DISMISS PLAINTIFF'S PETITION FOR FAILURE TO STATE A CLAIM, OR, ALTERNATIVELY, FOR A MORE DEFINITE STATEMENT REQUIRING THE STATE TO PLEAD THE DETAILS OF ANY ALLEGED FRAUD; (iii) DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM; AND (iv) DEFENDANTS PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY INC.'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

While Defendants filed multiple joint and individual dismissal motions, they primarily rely on the same recycled arguments in each motion. As such, the State files this Omnibus Response to the following motions and respectfully requests each motion be denied in its entirety:

(i) Defendants' Joint Motion to Dismiss for Failure to State a Claim;

(ii) Motion of Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc. to Dismiss Plaintiff's Petition for Failure to State a Claim, or, Alternatively, for a More Definite Statement Requiring the State to Plead the Details of Any Alleged Fraud;

(iii) Defendants Janssen Pharmaceuticals, Inc. and Johnson and Johnson's Motion to Dismiss for Failure to State a Claim; and

(iv) Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc.'s Motion to Dismiss for Failure to State a Claim.[1]

[1] The State addresses Defendants' (1) Defendants' Joint Motion To Dismiss Based On Preemption, (2) Purdue's Motion To Dismiss Based On Preemption, And (3) Defendants' Joint Motion To Stay This Case Under The Primary Jurisdiction Doctrine And The Court's Inherent Authority To Stay Proceedings, by separate response, filed concurrently herewith.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes and Rules

Codes

Additional Authority:

I. INTRODUCTION

Defendants created the worst public health crisis in modern history. Families destroyed. Children killed. Babies addicted. Morgues overflowing. Prisons full. And, because addiction is a life long disease, we have only seen the tip of the iceberg.

The opioid epidemic is worse than any past U.S. drug crisis. It has caused more damage than any crime spike ever before. It has killed more people than vehicular accidents in every state, and in Oklahoma since 2009.[2] More Americans died from opioid overdose in 2016 alone than in the entire Vietnam War.[3] The opioid epidemic is worse than the HIV/AIDS epidemic of the 1980s and 1990s, whether measured by deaths or tax dollars spent.[4] In the words of Attorney General Jeff Sessions: "We are in the midst of the deadliest drug epidemic this country has ever seen.... Our country has seen nothing like it."

Some chief medical examiners across the country are so overwhelmed by the increase in drug overdose deaths, they have to store corpses in cold storage trailers in parking lots or at other locations and perform more autopsies than the industry allows, risking their accreditation.[5] One

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[2] *See* Arthur R. Williams, M.D., M.B.E., Adam Bisaga, M.D., *From AIDS to Opioids — How to Combat an Epidemic*, N. ENGL. J. MED 2016, 375(9), 813-815 (Sept. 1, 2016), http://www.nejm.org/doi/full/10.1056/NEJMp1604223#t=article ("[R]ates of drug-overdose deaths in this country have outpaced mortality from motor vehicle accidents since 2013. The rising death toll has been rivaled in modern history only by that at the peak of the AIDS epidemic in the early 1990s.").

[3] *See* German Lopez, *How to Stop the Deadliest Drug Overdose Crisis In American History*, VOX (Oct. 26, 2017), https://www.vox.com/science-and-health/2017/8/1/15746780/opioid-epidemic-end ("In 2016 alone, drug overdoses likely killed more Americans in one year than the entire Vietnam War. In 2015, drug overdoses topped annual deaths from car crashes, gun violence, and even HIV/AIDS during that epidemic's peak in 1995. In total, more than 140 people are estimated to die from drug overdoses every day in the US. About two-thirds of these drug overdose deaths are linked to opioids.").

[4] The State asks the Court to take judicial notice of the existence of all facts, data, and information referened herein with citations to publicly available, online sources. A fact is subject to judicial notice if it is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." 12 O.S. § 2202(B)(2). Courts regularly take judicial notice of factual information found online. *See Prescott v. Okla. Capitol Pres. Comm'n*, 2015 OK 54, ¶13 n.34, 373 P.3d 1032 (Gurich, J., concurring). The "court *shall* take judicial notice if requested by a party and supplied with the necessary information." *Id.* § 2202(D) (emphasis added).

[5] Katharine Q. Seeyle, *As Overdose Deaths Pile Up, a Medical Examiner Quits the Morgue*, THE NEW YORK TIMES (Oct. 7, 2017), https://www.nytimes.com/2017/10/07/us/drug-overdose-medical-examiner.html.

medical examiner, so affected by the epidemic, retired to pursue a divinity degree and to minister to youths to stay away from drugs.[6] The crisis has permeated every demographic in American society taking the lives of men, women and children without discrimination.

In this country, a baby is born addicted to opioids every 19 minutes on average.[7] From 2000 to 2012, the national rate of babies born with neaonatal abstinence syndrome increased fivefold. The opioid crisis is so severe, the President officially declared it a national public health emergency and created a bipartisan commission to address it. And, a recent government study estimated the national economic burden of the opioid crisis to be $78.5 billion per year.

Defendants created this crisis. ¶¶3-5, 51-71. Defendants peddle some of the most addictive drugs on Earth—prescription heroin. Defendants falsely and aggressivley marketed prescription heroin in violation of the law for years. ¶¶3-4. Each Defendant—individually and collectively—repeatedly told the Oklahoma medical community, physicians nationwide, and the public at large that their opioids are *not* addictive and are the most effective pain treatment available. *See id.*

Why? Because for over a century, physicians prescribed opioids with extreme caution and only for end-of-life palliative care, cancer-related pain, and limited post-operative recovery because opioids are highly addictive and harmful when taken for long periods of time. ¶1. Defendants knew that to generate profits, they had to create a market for their drugs where no market previously existed. ¶¶1-3. Defendants embarked on an aggressive, widespread marketing mission beginning in the 1990s to recraft the way physicians, hospitals, pharmacists and the public viewed opioids. ¶¶2-4, 51-66. Defendants deployed sales representatives to Oklahoma to convince the medical community (physicians, hospitals and pharmacists) that their "new" opioids were not

[6] *Id.*

[7] Duff Wilson & John Shiffman, *The most vulnerable victims of America's opioid epidemic: Helpless and Hooked, A Reuters Investigation*, REUTERS (Dec. 7, 2015), http://www.reuters.com/investigates/special-report/baby-opioids/.

addictive. Defendants claimed they had cracked the pain-treatment/addiction dilemma. Defendants claimed opioids could (and should) be prescribed for virtually any painful malady at high and lengthy doses. ¶¶52-57.

But Defendants' opioids were as addictive and harmful as ever. "[W]e are essentially talking about heroin pills."[8] The FDA-approved labels for Defendants' opioids warned of the risk of addiction. Defendants spent millions in branded and unbranded marketing, however, to assure doctors and pharmacists of just the opposite. ¶¶54, 70.[9] Defendants claimed patients could take their opioids with little or no risk of addiction.

Defendants armed their sales force messaging through clandestine funding and support of key marketing channels. ¶¶58-66. Defendants hired and paid physicians, such as Dr. Russell Portenoy and Dr. Lynn Webster, to act as "key opinion leaders" ("KOLs"). KOLs spoke at medical education seminars, spoke in the media, and published articles pushing more opioids and downplaying (if not altogether denying) the risk of addiction. ¶¶59-62. Defendants created and/or funded third-party pain advocacy front groups—such as the American Pain Foundation and the American Pain Society—to disseminate their message that opioids are not addictive and should be prescribed liberally. ¶¶63-71.

Defendants even helped initiate a movement to recast pain as the "5th Vital Sign." The four conventional vital signs of blood pressure, heart rate, respiratory rate and temperature are purely objective—they can be accurately measured and verified. Pain as the 5th Vital Sign, however, was purely subjective. This "vital sign" could be manipulated and was not subject to verification. The American Pain Society, a group previously led by Dr. Russell Portenoy, one of the most prominent

[8] John R. Roby, *Crack down on 'heroin pills,' opioid expert says*, PRESSCONNECTS.COM (June 7, 2016), http://www.pressconnects.com/story/news/local/2016/06/07/crack-down-heroin-pills-opioid-expert-says/85570900/.
[9] "Pet." and all citations to "¶__" or "¶¶__" refer to the Original Petition in this action, unless otherwise noted. All emphasis is added, and all internal quotes and citations are omitted, unless otherwise noted.

KOLs paid by Defendants to promote the liberal prescription of opioids for chronic non-cancer pain, even trademarked the phrase "Pain: the 5th Vital Sign.":

Think of that for a moment. Would anyone trademark blood pressure, heart rate, temperature or respiratory rate? No.

These front groups and their agents have financial relationships with all of the Defendants.[10] Defendants, their KOLs, and their front groups conspired to change the historical perception of opioids as highly addictive and harmful last-resort medications. ¶¶58-66. Their unlawful marketing efforts worked. Opioid prescriptions skyrocketed. ¶¶21-30. In 2012 alone, 128 opioid prescriptions were written for every 100 people in Oklahoma. ¶5. That is nearly 10 prescriptions written every minute of every day for 365 straight days.

Oklahoma has been hit particularly hard by Defendants' unlawful marketing. Based on 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed with approximately 877 milligrams of opioids distributed per adult resident. ¶26. As prescription opioid sales in Oklahoma increased, prescription drug overdose deaths also soared. *See* ¶22. From 1997 to 2006, Oklahoma prescription opioid sales increased fourfold with a parallel increase in prescription overdose deaths:

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[10] *See e.g., APS 2017 Presenter Financial Disclosure Information*, AMERICANPAINSOCIETY.ORG, http://americanpainsociety.org/uploads/2017am/Financial_Relationships.pdf (last visited, October 26, 2017); *Pain: Current Understanding of Assessment, Management, and Treatments*, AMERICANPAINSOCIETY.ORG, http://americanpainsociety.org/uploads/education/frontmatter.pdf (last visited, October 26, 2017).

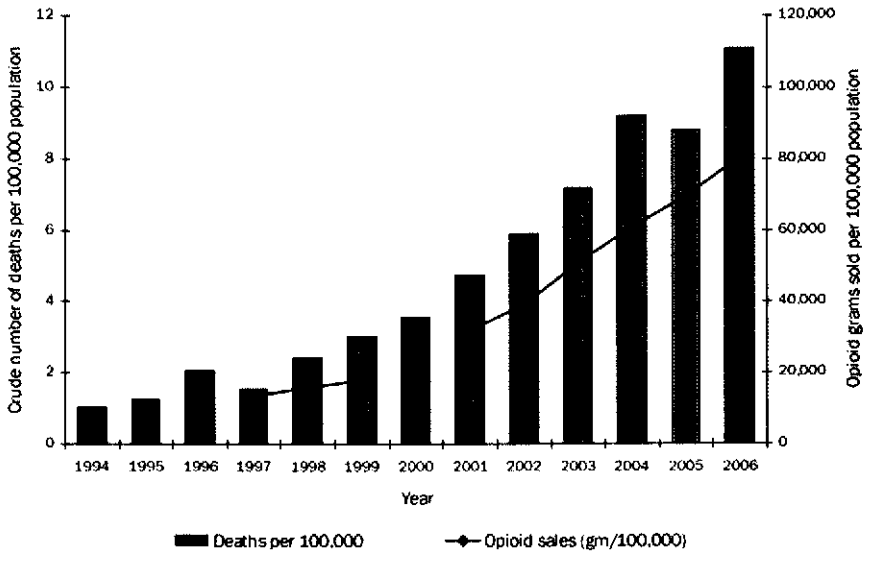
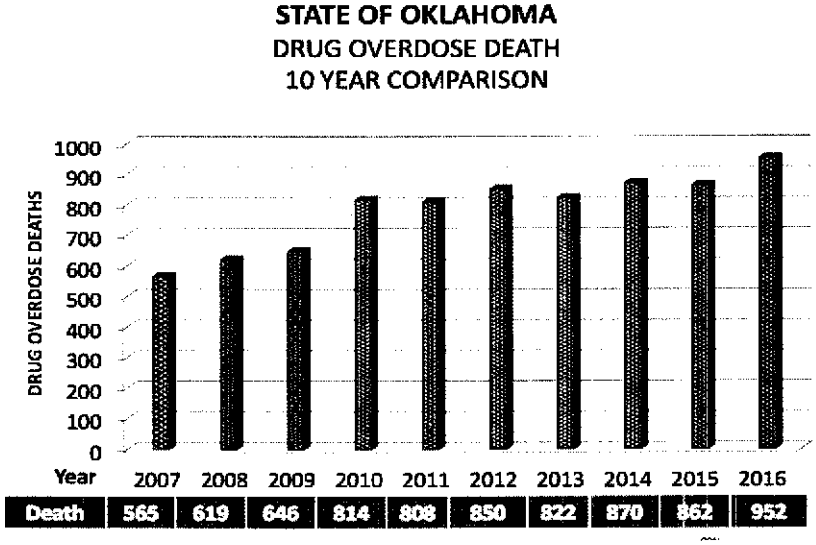


Figure 1. Unintentional medication-related overdose death rates and total sales of prescription opioids by year, Oklahoma, 1994–2006

The Centers for Disease Control ("CDC") found that opioid related deaths in Oklahoma "significantly" exceeded the national average as early as 2006.[11] Oklahoma drug overdose deaths continued to increase year over year, with 80% of these overdoses involving prescription opioids.[12]



[11] *See* Margaret Warner, Ph.D, Li Hui Chen, M.S., Ph.D, Diane M. Makuc, Dr.P.H., *NCHS Data Brief No. 22 – Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006* (Sept. 2009) at Figure 5, *available at* https://www.cdc.gov/nchs/products/databriefs/db22.htm.

[12] OKLAHOMA STATE DEPARTMENT OF HEALTH, *Protective Health, Injury Prevention Service, Drug Overdose*, https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_Overdose/index.html (last visited Oct. 26, 2017).

From 1999 to 2012, drug overdose deaths in Oklahoma increased eightfold, surpassing deaths from motor vehicles. ¶5. In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths. ¶23. In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate. ¶24. There are more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined. ¶25. And, Oklahoma leads the nation in non-medical use of opioid painkillers. ¶27.

As opioid prescription sales increased, Oklahoma's Medicaid reimbursements also skyrocketed. The rapid increase in opioid sales and Oklahoma State Medicaid reimbursements for prescription opioids is the direct and intended result of Defendants' deceptive marketing campaign to influence doctors' opioid-prescribing habits.

The accessibility and availability of prescription opioids also is fueling illicit opioid addiction. ¶28. According to the CDC, past misuse of prescription opioids is the strongest risk factor for a person to start and continue using heroin. *Id.* Between 2000 and 2014, overdose deaths from heroin nationwide quintupled. *Id.* "According to the American Society of Addiction Medicine, four out of five people who try heroin today started with prescription painkillers."[13] As the State passes stricter legislation to combat opioid over-prescription, Oklahomans addicted to prescription opioids are turning to illicit opioids such as heroin as a cheaper and more accessible alternative. ¶29. From 2007 to 2012, heroin deaths in Oklahoma increased ***tenfold***. *Id.* Nationally, opioid overdose deaths and heroin use have increased in lockstep with opioid sales volumes:[14]

[13] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, THE NEW YORKER (forthcoming Oct. 30, 2017 issue) https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

[14] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, ANNU. REV. PUBLIC HEALTH 2015, 36:559–74, *available at* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957, at Figure 1.

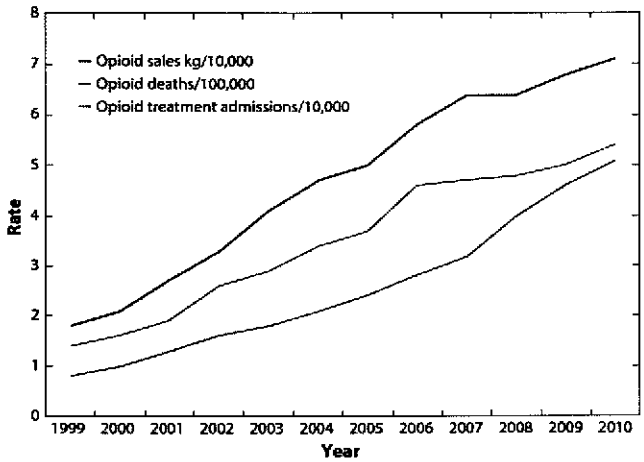


Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

Defendants' conduct is affecting even Oklahoma's youngest and most vulnerable citizens. Oklahoma hospitals report increasing numbers of newborns testing positive for drugs or alcohol. ¶30. In 2014, the number of newborns testing positive for prescription medications doubled from 2013. *Id.* Babies born with neonatal abstinence syndrome ("NAS") require lengthy hospital stays and intense medical treatment, dramatically increasing health care costs for the State. *Id.*

Each week Oklahomans are overdosing, incarcerated, going into the foster care system, being born addicted to opioids. Nearly 10 Oklahomans die every week of a prescription drug overdose.[15] And, each week, the State of Oklahoma is forced to bear the resulting massive health care, criminal justice, foster care and lost productivity costs, among others.

Confronted with this epidemic, Defendants have forced Oklahoma State agencies to allocate significant State resources to addressing the crisis wrought by their unlawful conduct. In 2012, Oklahoma Governor Mary Fallin, confronting "one of the most serious public health and safety threats to [the] state," commissioned a workgroup to develop a state plan with the goal to reduce opioid abuse. The initial plan was released in 2013, with the goal of reducing unintentional

[15] *International Overdose Awareness Day is August 31*, OKLAHOMA HEALTH CENTER FOUNDATION (Sept. 1, 2017), http://www.oklahomahealthcenter.com/news/m.blog/21/international-overdose-awareness-day-is-august-31.

opioid overdose deaths in the State by 15% in five years. The plan requires coordination between health care providers, law enforcement, public health, regulatory boards, state legislature and community based organizations.

A sample of some of the extensive State effort expended to implement the plan includes, among other things:

- employing a statewide media campaign that included PSAs reaching over 1.3 million Oklahomans, establishing a website, TakeasPrescribed.com, digital advertising, social-media outreach and press engagements;
- developing statewide delivery of overdose prevention and community training presentations and continuing medical education programs regarding pain and opioid management;
- updating the opioid prescribing guidelines and distributing and promoting the guidelines to regulatory boards, hospitals and prescribers;
- developing a practice facilitation toolkit to provide onsite training and consultation services in Medicaid contracted practices;
- creating 175 drop-boxes across the state for safe disposal and destruction of unused prescription opioids;
- educating pharmacies, prescribers and nursing staff regarding proper medication storage and disposal;
- establishing prescription drug "take-back" programs;
- enhancing the State's prescription monitoring program ("PMP"); and
- expanding the availability of Naloxone—an expensive opioid-overdose antidote—for first responders and implementing Statewide over-the-counter access to Naloxone.

The Oklahoma Legislature also passed legislation to form the Oklahoma Commission on Opioid Abuse to study and evaluate the epidemic and recommend changes to State policy to address it. The Commission's mission is "to develop and promote a list of best practices and legislative priorities to reduce prescription drug misuse and diversion and to prevent overdose death" and to "evaluate data from various agencies in order to develop a comprehensive approach for prevention, intervention, education and treatment for victims and families of the opioid crises." The Opioid Commission has already conducted three large-scale meetings and heard from numerous medical professionals, addiction experts, law enforcement agencies, and Oklahomans whose lives and families have been negatively affected by Defendants' opioids.

The State's efforts are significant. But these efforts alone will not undo the decades of harm Defendants have inflicted on the State of Oklahoma and its citizens—harm that will continue for years to come. More must be done.

The State filed the Petition as just one of many steps it must take to deal with the problems Defendants caused. This is not the first time governmental entities have sued to attempt to hold some of the Defendants accountable for their egregious conduct. For example, in:

- **2004**: Defendant Purdue paid $10 million to the State of West Virginia related to claims of deceptive marketing of its opioid OxyContin.[16]
- **2007**: Defendant Purdue plead guilty to federal felony charges for misbranding OxyContin, admitting it fraudulently marketed by falsely claiming OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications, despite no medical research to support these claims, paying over $634 million.[17]
- **2007**: Defendant Purdue paid $19.5 million for claims related to the unlawful marketing of OxyContin brought by a coalition of 27 Attorneys General, including Oklahoma's.[18]
- **2008**: Defendant Cephalon plead guilty to federal criminal charges for off-label marketing of several drugs, including its opioid Actiq, and agrees to a civil settlement under the federal False Claims Act, paying $425 million to the U.S. and multiple state governments, including Oklahoma.[19]
- **2015**: Defendant Purdue paid approximately $24 million to Kentucky for misleading marketing regarding the risks of addiction associated with OxyContin.[20]

But these civil and criminal actions did not stop Defendants. Regarding the 2007 Purdue settlement, David Hart, Assistant Attorney-in-Charge, Oregon Department of Justice, testified to

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[16] Landon Thomas Jr., *Maker of OxyContin Reaches Settlement With West Virginia*, THE NEW YORK TIMES (Nov. 6, 2004) http://www.nytimes.com/2004/11/06/business/maker-of-oxycontin-reaches-settlement-with-west-virginia.html?_r=0.

[17] Opinion and Order, *United States of America v. The Purdue Frederick Company, Inc., et al.*, No. 1:07CR00029 (W.D. Va. July 23, 2007), http://www.vawd.uscourts.gov/OPINIONS/JONES/107CR00029.PDF.

[18] Department of Justice, Testimony of David Hart to the United States Senate Committee on Finance, at 31, *available at* https://www.finance.senate.gov/imo/media/doc/23feb2016Hart.pdf. Oklahoma participated in this settlemet and received a share of the settlement funds.

[19] *Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing*, USDOJ.GOV (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html. Oklahoma participated in this settlement and received a share of the settlement funds.

[20] *Kentucky settles lawsuit with OxyContin maker for $24 million*, CBSNEWS.COM (Dec. 23, 2015) https://www.cbsnews.com/news/kentucky-settles-lawsuit-with-oxycontin-maker-for-24-million/.

the US. Senate Finance Committee in 2016 that had he "fully appreciate[d] the severity of the opioid epidemic and the long lasting effects of Purdue's OxyContin promotion" he "would have advocated for a settlement which would have required more extensive remedial action...to correct the inappropriate prescribing patterns for opioids that Purdue's marketing helped create."[21]

The conduct continued. More people have become addicted. More children have died. More babies are born addicted. More morgues are over capacity.

So, now, Oklahoma is fighting back. Oklahoma is not alone in this fight. ***The entire Nation is fighing back***.

Eight other states—New Mexico, Mississippi, New Hampshire, Ohio, Washington, South Carolina, Louisiana and Missouri—have filed lawsuits against some or all of the Defendants concerning their unlawful marketing of their opioids. A 41-state coalition of Attorneys General has issued subpoenas to opioid manufacturers, including entities affiliated with each Defendant named herein, as part of an ongoing opioid-marketing investigation. Dozens of lawsuits asserting similar claims have been filed by counties and cities in state and federal courts across the country. And, just last week, the President of the United States officially declared the opioid crisis a national public health emergency.[22]

In light of this national effort to hold Defendants accountable for creating the most severe public health nuisance in history, the cavalier tone of their Motions to Dismiss is alarming. Even more alarming is the fact that Defendants had the audacity to file a motion to stay discovery—that is to delay discovery of the truth—claiming that there was little to no way the State could even

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[21] Department of Justice, Testimony of David Hart to the United States Senate Committee on Finance, at 2, *available at* https://www.finance.senate.gov/imo/media/doc/23feb2016Hart.pdf.

[22] *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis.

state a claim against Defendants under Oklahoma's liberal notice pleading standards. But, that is what Defendants do best—market lies.

Defendants will do anything to make money. And they will do anything to avoid accountability. They misrepresent facts. They mispresent the law. They blame the State. They blame the entire Oklahoma medical community. They blame patients. They blame victims. And they assert baseless arguments to delay this lawsuit. The delay caused by Defendants' legal tactics is as deadly as it is baseless. Indeed, based on 2016 data, **in the time since the State filed this action on June 30, 2017, over 150 Oklahomans will have died from opioid-related drug overdoses.**

Defendants must be held accountable. The only way to do that is to bring them to trial in front of twelve jurors. If Defendants truly did nothing wrong, the jury will say so. But if Defendants did do something wrong, the jury will so find. And, if Defendants did nothing wrong, they should have no reason whatsoever to want to delay this case, stonewall discovery or obfuscate the facts. Quite the contrary, the only way the truth will be known, the only way either side will get justice, is to let this case proceed to discovery and trial by jury. There, and only there, will the facts be fairly judged. Defendants' motions to dismiss must be denied.

The fate of Oklahoma's public health depends on it.

II. SUMMARY OF THE ARGUMENT

The State asserts causes of action for public nuisance and unjust enrichment, claims under the Oklahoma Medicaid False Claims Act ("OMFCA"), the Oklahoma Medicaid Program Integrity Act ("OMPIA") and the Oklahoma Consumer Protection Act ("OCPA"), and claims for common-law fraud (actual and constructive). In response, Defendants seek dismissal of the *entire* Petition, contending *all* of the State's claims sound in fraud and, thus, are subject to a heightened

particularity pleading standard. Jt. MTD at 6. Defendants also grossly misrepresent key facts and holdings of several cases they rely upon.

First, the State's public nuisance, unjust enrichment, and OCPA claims do not sound in fraud. These claims are not subject to the heightened pleading standard. Quite the contrary, these claims are governed by Oklahoma's liberal notice pleading standard under Oklahoma Code of Civil Procedure Section 2008. 12 O.S. §2008(A)(1) (requiring a "short and plain statement of the claim showing that the pleader is entitled to relief"); *Gens v. Casady Sch.*, 2008 OK 5, ¶9, 177 P.3d 565 (Oklahoma is a "notice pleading state"). Under this standard, a "pleading *must not* be dismissed for failure to state a legally cognizable claim *unless* the allegations indicate *beyond any doubt* that the litigant can prove *no* set of facts which would entitle him to relief." *Frazier v. Bryan Memorial Hosp. Auth.*, 1989 OK 73, ¶13, 775 P.2d 281 (emphasis in original).

The Petition adequately pleads these claims under this simple pleading standard. And Defendants know it. That is why they ignore the State's public nuisance and unjust enrichment claims, devoting just **one page** to each claim in over 100 pages of briefing. Jt. MTD at 33-34, 36.

The harm Defendants have caused the State of Oklahoma is a classic public nuisance. A "public nuisance" is defined in relevant part as "unlawfully doing an act, or omitting to perform a duty, which act or omission either … injures or endangers the comfort, repose, health, or safety" of "an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." 50 O.S. §§1-2. Defendants' unlawful marketing of opioids has injured and endangered the health and safety of Oklahoma citizens at large in myriad ways, as the Petition details.

Moreover, Defendants can be held jointly and severally liable for the public nuisance they have caused. *See* 23 O.S. §15(B) (preserving joint and several liability in "actions brought by or on behalf of the state.").

Defendants cannot seriously claim they are not on notice of the State's public nuisance claim or that there is "no set of facts" that would entitle the State to relief on this claim. They are acutely aware of the problems they have caused Oklahoma and the nation. The publicly available facts alone are insurmountable:

- President Trump created a bipartisan national commission to address the crisis and officially declared the opioid epidemic a national pubic health emergency;
- 7 states have filed substantially similar actions against Defendants;
- Over 60 cities and counties have filed suit against these same Defendants for causing substantial economic, health, and social harm to their communities;
- 41 states have created a multi-state working group to further investigate Defendants' marketing of opioids;
- The national news media has repeatedly dedicated prime-time coverage to the opioid epidemic, including a 60 Minutes report viewed by 15 million people and week-long special on NBC;
- There is a plethora of publicly available data and scientific studies showing Oklahomans are dying every day from the drugs that Defendants manufacture and market;
- The State is collecting and incinerating unnecessary and unused opioids by the truckload to keep them off the street; and
- The State has been forced to create a prescription drug abuse task force and an Opioid Commission, pass remedial legislation, reform opioid prescribing guidelines, and implement educational programs, among other things, to combat this epidemic.

Defendants' opioids created a nuisance that has crushed Oklahoma. Defendants are on notice of the nuisance—they created it.

The same is true for the State's unjust enrichment claim. Defendants raked in billions creating this public nuisance. That is textbook unjust enrichment. Similarly, the OCPA makes deceptive or misleading advertisement and marketing unlawful. This is the exact conduct alleged in the Petition. Defendants cannot credibly argue there is "*no* set of facts" that entitle the State to relief on these claims.

Second, Defendants rely upon federal law in hopes that they can confuse the Court into applying more strict federal standards instead of Oklahoma's more liberal pleading standards. The heightened "plausibility" federal pleading standard set forth in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007), does not apply in this State Court action. *See Edelen v. Bd. of Comm'r*, 2011 OK CIV APP 116, ¶3, 266 P.3d 660 ("Oklahoma has not adopted this pleading standard...We decline to adopt a different pleading standard here."). Moreover, even for the State's fraud-based claims governed by Section 2009(B), "it is unnecessary to plead *each element* of fraud in detail if the *circumstances* constituting fraud are stated with particularity." *Gay v. Akin*, 1988 OK 150, ¶8, 766 P.2d 985 (emphasis in original). This Section must be read in conjunction with Section 2008, which requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." *Id.* at ¶17; 12 O.S. §2008(A)(1).

In this context, Section 2009(B):

> **...requires only the degree of specificity necessary to enable the opposing party to prepare his responsive pleadings and defenses.** The clear weight of authority holds that Rule 9 requires specification of the time, place and content of an alleged false representation, but not the circumstances or evidence from which fraudulent intent could be inferred. If the circumstances are set out, there is no requirement that the word "fraud" even be used. **"Particularity" does not mean the plaintiff has to plead detailed evidentiary matters.** This interpretation of § 2009(B) harmonizes with the pleading code[.]

Gay, 1988 OK 150, ¶¶17-18. When applied to the State's OMFCA, OMPIA, and common law fraud claims, it is clear the Petition identifies circumstances constituting fraud such that Defendants were able to prepare their responsive pleadings.

Third, Defendants' motions (i) are procedurally defective, (ii) should be stricken to the extent they seek dismissal of the fraud claims, or (iii) should be re-filed as or converted into motions to supply the necessary particulars so the Court can make the necessary rulings. Indeed, even assuming for the sake of argument that the State did not plead fraud with particularity, which

it did, the Petition is not subject to dismissal because "[f]ailure to plead fraud with specificity is not a ground for dismissal." *Muller v. Muller*, 2013 OK CIV APP 90, ¶10, 311 P.3d 1247; *Estrada v. Kriz*, 2015 OK CIV APP 19, ¶23, 345 P.3d 403. As the Oklahoma Supreme Court has repeatedly held:

> The method for securing the missing information is not by pressing for dismissal but rather by a *motion to supply the necessary particulars* that would support the allegations of fraud. Because the record is devoid of any *denied request for particulars,* the defendants are not entitled to have the petition tested by the *Gay v. Akin* rule. Applying the *Conley v. Gibson* standards, we find that the petition, even if wanting in some particularity, is not subject to dismissal. The defendants are entitled to a post-remand opportunity to press for specific information.

A-Plus Janitorial & Carpet Cleaning v. Emp'rs' Workers' Compensation Ass'n, 1997 OK 37, ¶36, 936 P.2d 916; *State of Oklahoma, ex rel. Okla. Tax Comm'n v. Texaco, Inc.*, 2005 OK 52, ¶15, 131 P.3d 705. Here, Defendants did not file a motion to supply the necessary particulars. Instead, Defendants filed four motions to dismiss seeking (i) dismissal of the entire Petition, or (ii) in the alternative, that "the State should be compelled to provide the requisite factual details of each of its claims, which all sound in fraud." *See* Jt. MTD at 8, n.9 (citing *A-Plus Janitorial & Carpet Cleaning*, 1997 OK 37, ¶36); *see also* Teva MTD at 20. Defendants' alternative argument—which is relegated to a single footnote—cannot be construed as a motion to supply the necessary particulars, nor does it remedy the fact that Defendants' primary argument is for dismissal of the entire Petition. Thus, Defendants failed to file the proper motion for the relief they seek.

Fourth, Defendants improperly deride the State's Petition for so-called "group" pleading. Jt. MTD at 6-8. However, the Petition does not group plead. To the contrary, the Petition states claims against Defendants who conspired, acted in concert, and engaged in common conduct. Further, the group pleading doctrine is wholly inapplicable and ignores the fact that Defendants' common actions created a "single injury" to the State of Oklahoma, which gives rise to joint and

several liability. *See* 23 O.S. §15(B) (preserving joint and several liability in "actions brought by or on behalf of the state."). Further, Defendants fail to disclose that in *Gay*—the only Oklahoma state court case Defendants rely on—the Oklahoma Supreme Court expressly **upheld** the general averments made under the circumstances there:

> ...where knowledge of the alleged specific unlawful acts committed by the Institution and the individual Directors is imputed to each of the Directors as a matter of law, ***the allegations of fraud averred against the defendants as a group (without specific reference to each individual defendant) is sufficient to support a reasonable inference of fraud as to each of the individual Directors***.

Id. at ¶15.

Fifth, Defendants intentionaly mischaracterized the definition of "constructive fraud" to mislead the Court. The true definition of constructive fraud in Oklahoma is "any breach of a duty which, regardless of the actor's intent, gains an advantage for the actor by misleading another to his prejudice." *Patel v. OMH Med. Ctr., Inc.*, 1999 OK 33, ¶ 34, 987 P.2d 1185. Though Defendants actually quote the foregoing language from *Patel* in their Joint Motion to Dismiss, they ***omitted*** the underlined key language ("regardless of the actor's intent") and replaced it with an elipses, which fundamentally alters and misstates the definition. *See* Jt. MTD at 35. That is, Defendants engaged in constructive fraud in this Court by omitting this necessary language from the definition of "constructive fraud." Under the true definition, the Petition states a claim for constructive fraud.

Sixth, despite Defendants' incredible effort to blame the Oklahoma medical community for relying upon Defendants' deceptive marketing, the learned intermediary doctrine does not apply to these facts. Defendants blame everyone but themselves for the opioid epidemic, including every physician who prescribes opioids. These are the very physicians Defendants targeted for years. *Id.* at 19-20. Defendants claim physicians are "learned intermediaries" who are ultimately responsible

for any errors in prescribing. *Id.*at 19. This argument ignores the Petition's allegations that Defendants engaged in a marketing scheme to change the way physicians perceived, and thus prescribed, opioids. ¶¶1-4.

Seventh, and most shocking, Defendants wrongfully blame the State itself for the opioid epidemic. Defendants claim the "State's decision to reimburse an opioid prescription" is an "independent, intervening event[.]" Jt. MTD at 19. This argument is as wrong as it is offensive. To start, the State does not only seek to recover the State Medicaid dollars spent on unnecessary opioid prescriptions. The State also seeks to recover penalties, the cost to abate this public nuisance, and a broad spectrum of damages ranging from the costs of treatment, to lost tax dollars, to recovering and destroying the excess drugs sold by Defendants, to law enforcement costs. Moreover, the State does not have the resources to police each and every claim submitted to Oklahoma Medicaid prior to payment, and, even if it did, such a time-consuming claim-by-claim review would needlessly delay treatment to those Medicaid patients who need it most. For this reason, the appropriate functioning of the Oklahoma Medicaid system is dependant upon *lawful* marketing and self-police by drug manufacturers. And, Defendants spent millions in an effort to deceive state agencies, including the Oklahoma Drug Utilization Review Board, which approves the list of medications covered by Medicaid and is made up of physicians and pharmacists.

Eighth, Defendants incorrectly treat the FDA approval process as a "get out of jail free" card. *See* Jt. MTD at 2-4. Contrary to Defendants' arguments, the Petition does not allege the FDA wrongly approved Defendants' opioids or that Defendants defrauded the FDA. Rather, the Petition alleges Defendants grossly mischaracterized the indications for which the FDA approved their opioids and wholly disregarded the FDA's warnings of addiction risk. ¶70. FDA approval does not rescue Defendants from these failings. Rather, the FDA-approved labels indict Defendants'

marketing behavior. Defendants chose to market opioids like they were candy. In fact, one of these opioids, Defendant Cephalon's Actiq, is actually called a "lollipop"; it is a powerful, fentanyl lozenge on a stick.

Defendants created an opioid market where none existed. Then Defendants fed a limitless supply of deadly dangerous drugs into the State. Defendants injected so many pills into the State that the State had to create a drop-box program where citizens can dump unused pills to prevent abuse. The State has hauled these pills off by the truckload. Literally. But more heroin pills are coming. And, with more herion pills comes more addiction, more tragedy and more death.

III. FACTUAL BACKGROUND—DEFENDANTS CREATED THE WORST PUBLIC HEALTH EPIDEMIC IN AMERICAN HISTORY

The State stands on its Petition. As explained herein, the Petition complies with all Oklahoma pleading standards by adequately alleging facts upon which relief can be granted and providing Defendants sufficient notice. This is clear from the more than 100 pages of fact-intensive arguments Defendants raised in their motions that are more properly reserved for trial. The Petition, like the publicly available information and judicially noticeable information, make it clear Defendants have created the most severe public nuisance in Oklahoma history. Defendants cannot claim they do not understand the State's Petition and claims.

For the past century, medical professionals only prescribed opioids in limited circumstances to treat cancer pain, the terminally ill, and acute short-term pain, such as in post-operative recovery.[23] That all changed in the 1990s, when Defendant Purdue initiated its deceptive marketing campaign related to the sale of its opioid, OxyContin. Defendant Purdue's 1996, 1998 and 2001 Budget Plans show Purdue intended to "increase the number of prescriptions for strong opioids," "convince health care professionals to use OxyContin earlier in the patient's treatment

[23] Kolodny et al., *supra* note 14.

cycle," "enhance the acceptance of opioids for non-cancer pain," "[a]ttach an emotional aspect to non-cancer pain so physicians treat it more seriously and aggressively," "enhance the acceptance of opioids for non-cancer pain through educational efforts," and "[c]onvince health care professionals…to aggressively assess and treat both non-cancer pain and cancer pain." The other Defendants soon joined in.

Defendants engaged in a massive, expensive, complex and highly coordinated effort to encourage physicians to prescribe highly addictive opioids to treat chronic non-cancer pain despite the dearth of scientific evidence demonstrating opioids are safe and effective for this purpose. Defendants executed their marketing campaign with surgical precision to change the perception of opioids and thus prescribing patterns in two key ways: falsely minimizing the risk of opioid abuse and addiction and touting unsubstantiated benefits of opioids to treat chronic non-cancer pain. The intended and direct result of Defendants' multi-faceted, coordinated marketing campaign was a rapid increase in the prescribing and consumption of opioids in the State of Oklahoma, which has one of the highest prescription rates in the country.

Defendants spent millions of dollars on branded and unbranded deceptive marketing to promote and encourage aggressive opioid prescribing to treat chronic non-cancer pain throughout Oklahoma. ¶¶51-66. Much of Defendants' false and deceptive marketing was unbranded marketing through seemingly unbiased medical professionals (*i.e.*, KOLs) and third-party advocacy front groups, which Defendants funded and influenced. ¶¶58-66. Often working in concert with each other, KOLs and/or front groups, Defendants influenced the content of the vast majority of professional resources on the use of opioids to treat chronic non-cancer pain to minimize the risk of opioid abuse and addiction and overstate the benefits. *Id.*

Defendants paid KOLs to give speeches, make media appearances, present continuing medical education ("CME") courses, author books and articles, conduct studies and perform other work to convince physicians they could aggressively prescribe opioids to treat patients with chronic non-cancer pain without consequence. ¶¶58-62. While acting as paid consultants, advisors and speakers for Defendants, the KOLs held leadership positions in front groups funded and influenced by Defendants and served on committees that drafted treatment guidelines encouraging doctors to liberally prescribe opioids to treat chronic non-cancer pain. *Id.*

For example, Defendants utilized KOL Dr. Portenoy, the former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, to promote opioid use for the treatment of chronic non-cancer pain and minimize the risk of abuse and addiction. ¶61. Dr. Portenoy received honoraria, research support and/or consulting fees from Defendants Cephalon, Purdue and Janssen and other opioid manufacturers, and was a paid consultant to Defendants Cephalon and Purdue. ¶61.[24] Simultaneously, Dr. Portenoy served on the board of directors of the American Pain Foundation ("APF"), a front group that in 2010 received 90% of its funding from the drug and medical device industry, including Defendants Cephalon, Janssen and Purdue.[25] Dr. Portenoy also was a past president of the American Pain Society ("APS"), a known front group that received substantial funding from Defendant Purdue and that aggressively lobbied to make pain "the 5th vital sign," as discussed above.[26] Dr. Portenoy served on the committee that drafted clinical guidelines issued by APS and the American Association of

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[24] *The Need to Individualize Pain Therapy: You Are Not Me!*, EMERGING SOLUTIONS IN PAIN, http://www.emergingsolutionsinpain.com/index.php?option=com_continued&view=frontmatter&Itemid=303&course=98 (May 6, 2011).

[25] AMERICAN PAIN FOUNDATION 2010 ANNUAL REPORT at 18 & 21, *available at* https://www.documentcloud.org/documents/277604-apf-2010-annual-report.html; *see also* Thomas Catan & Evan Perez, *A Pain-Drug Champion has Second Thoughts*, THE WALL STREET JOURNAL (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604?mg=prod/accounts-wsj.

[26] Catan & Perez, *supra* note 24.

Pain Medicine ("AAPM"), a front group that zealously advocated for using opioids to treat chronic non-cancer pain, touting opioids as "essential" for the treatment of chronic non-cancer pain.[27]

In media appearances, Dr. Portenoy often parroted Defendants' false claim that less than 1% of opioid users become addicted. ¶61. For example, in 2010, Dr. Portenoy said the following on *Good Morning America*:

> *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 that person is not going to become addicted.*

Id. Dr. Portenoy has since acknowledged certain of his statements about opioids were false and unsupported. *Id.* In an interview, Dr. Portenoy admitted that Defendants sought to skew the message regarding the addictiveness of opioids when they perceived it was profitable to do so:

> [w]hen the pharmaceutical industry began to perceive that there was huge profit by expanding the use of opioids for chronic non-cancer pain, and the educational messaging went out there as if chronic non-cancer pain and chronic cancer pain should be taught in the same way, without any reference to balance, without any reference to the risk of abuse and addiction. ***Then that skewing of the message undoubtedly promoted inappropriate prescribing and has led to negative outcomes***.

Defendants also utilized KOL Dr. Lynn Webster, the former Chief Medical Director of Lifetree Clinical Research, a pain clinic in Utah, to spread misrepresentations regarding opioid use through CMEs, speeches, books and other materials. ¶62. Dr. Webster was a consultant, member of the advisory board and/or received honoraria from Defendants Purdue, Janssen and Cephalon, among other drug manufacturers.[28] Dr. Webster also was a former president and board member of

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[27] Russell K. Portenoy et al. for the American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, THE JOURNAL OF PAIN, Vol 10, No 2 (Feb. 2009), *available at* http://www.jpain.org/article/S1526-5900(08)00831-6/pdf.

[28] *See, e.g.*, AMERICAN ACADEMY OF PAIN MEDICINE, *2012 Safe Opioid Prescribing Course*, http://test.painmed.org/cme/safeprescribing/ (last visited Oct. 26, 2017).

the AAPM.[29] Dr. Webster authored CMEs funded by Defendants Cephalon and Purdue and frequently served as an expert witness or consultant on cases on behalf of doctors charged with improper prescribing of opioids.[30] While acting as a KOL, Dr. Webster's pain clinic was raided by the United States Drug Enforcement Agency ("DEA") as part of its investigation of overprescribing opioids.[31] Although the DEA closed the investigation without charges, 20 of Dr. Webster's former patients died of opioid overdoses.[32]

In 2007, Dr. Webster co-authored *Avoiding Opioid Abuse While Managing Pain*, a guide for practitioners that promoted the use of opioids for the treatment of chronic non-cancer pain and repeatedly minimized the risk of opioid addiction. In his book, Dr. Webster states "research clearly indicates that most patients treated with prescribed opioids for acute or chronic pain will not become addicted to their medication" and "[t]rue opiate addiction that results from long-term opioid therapy is relatively rare."[33]

Dr. Webster also was a proponent of the concept of "pseudoaddiction," which Defendants used to convince prescribers that classic signs of addiction should actually be treated with even *more* opioids because they were signs the patient was experiencing undertreated pain. ¶62. In defining "pseudoaddiction," Dr. Webster claimed:

> [a] patient may suffer from pain that is not controlled by prescribed medication...The patient then escalates the dose or otherwise defies medical orders in an attempt to curb the pain. The resulting drug-seeking behavior may look like addiction, but it is not. If the patient had not experienced pain or required treatment

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[29] *See, e.g.*, AMERICAN ACADEMY OF PAIN MEDICINE, *AAPM Council of Past Presidents*, http://www.painmed.org/membercenter/council-of-past-presidents/ (last visited Oct. 26, 2017).

[30] *Managing Patient's Opioid Use: Balancing the Need and Risk*, EMERGING SOLUTIONS IN PAIN (Nov. 1, 2011), http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_continued&view=frontmatter&Itemid=303&course=209; MEDSCAPE.COM, https://www.medscape.org/viewarticle/516583_7 (last visited Oct. 26, 2017).

[31] John Fauber, *Deaths Trigger DEA Probe of Specialist*, MEDPAGETODAY (Feb. 20, 2013), https://www.medpagetoday.com/neurology/painmanagement/37441.

[32] *Id.*

[33] LYNN R. WEBSTER & BETH DOVE, AVOIDING OPIOID ABUSE WHILE MANAGING PAIN 19, 30 (2007).

> with opioids, a substance-abuse problem would not have developed. The patient may seek prescriptions from more than 1 provider or may repeatedly visit a hospital emergency department. He or she may even alter a prescription to obtain more medication.[34]

Dr. Webster recommends that if patients present this type of aberrant, abuse-indicative behavior, then "in most cases" *increasing the dose* "should be the clinician's first response."[35]

Like Dr. Portenoy, Dr. Webster, has since acknowledged certain of his statements were false and unsupported. For example, Dr. Webster acknowledged that the concept of "pseudoaddiction" that he repeatedly promoted **had no basis in fact**, admitting: "the concept of pseudoaddiction obviously became too much of an excuse to give patients more medication…It led us down a path that caused harm. It is already something we are debunking as a concept." ¶68.

Defendants also funded and collaborated with front groups to produce and disseminate treatment guidelines, patient education guides, books, CME courses, articles and other materials and establish pain treatment advocacy websites, that promoted chronic opioid treatment, minimized the risk of opioid abuse and addiction and overstated the benefits of opioids to treat chronic non-cancer pain. ¶¶63-66.

For example, although APF described itself as an independent nonprofit organization and "the largest advocacy organization for people with pain," it was funded nearly entirely by the drug and medical device industry including Defendants Cephalon, Janssen and Purdue. ¶64. Some of APF's board members were well-known KOLs with extensive financial ties to Defendants and other opioid manufacturers including, but not limited to, Dr. Portenoy and Dr. Perry Fine.[36] While a member of APF's board of directors, KOL Dr. Fine was the lead author of a study sponsored by

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[34] *Id.* at 58-59.
[35] *Id.* at 59.
[36] *See* notes 27-28 *supra*.

Defendant Cephalon that found its opioid Fentora was "generally safe and well-tolerated" in non-cancer patients even though it is only indicated for severe cancer pain.[37] Dr. Fine also acted as a consultant and speaker and received research support from Defendant Purdue, acted as a consultant and served on the advisory board of Defendant Cephalon, acted as a consultant and speaker and provided educational services to Defendant Janssen, and served on the advisory board and received honoraria for serving on the advisory board of Defendant Actavis.[38] Dr. Fine also was a former President of the front group AAPM.[39] AAPM's current President, Dr. Steven P. Stanos, is another KOL with financial ties to Defendants Purdue and Janssen. Dr. Stanos was the activity chairperson for an October 2011 CME that promoted the concept of "pseudoaddiction" to health care providers.[40] At the time, Dr. Stanos served on the speakers' bureaus of Purdue and Janssen, and other drug manufacturers and as a consultant or advisory board member for Purdue and Janssen and other drug manufacturers.[41]

APF issued pain treatment guides sponsored in part by Defendants Purdue and Cephalon and other drug manufacturers for patients, journalists and policymakers. ¶64.[42] Many of the expert

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[37] Perry G. Fine, MD, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, JOURNAL OF PAIN AND SYMPTOM MANAGEMENT Vol. 40 No. 5, p.747 (Nov. 2010), http://www.jpsmjournal.com/article/S0885-3924(10)00390-8/pdf.

[38] Perry G. Fine, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, THE JAMA NETWORK (Oct. 5, 2011), https://jamanetwork.com/journals/jama/article-abstract/1709738; Portenoy et al., *supra* note 26; Perry Fine, MD, Lynn Webster, MD, Charles Argoff, MD, *AAPM Response to PROP Petition to the FDA that Seeks to Limit Pain Medications for Legitimate Noncancer Pain Sufferers*, PAIN MEDICINE Vol. 13, Issue 10, 1 Oct. 2012, pp.1259-1264, https://academic.oup.com/painmedicine/article/13/10/1259/1932704/American-Academy-of-Pain-Medicine-Response-to-PROP.

[39] *See* notes 27-28 *supra.*

[40] *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, (Session 1 of a Joint 3-Hour Breakfast Symposium Held During the American Osteopathic Association 117th Annual Osteopathic Medical Conference and Exposition on Oct. 11, 2012), *available at* http://docplayer.net/38268219-Chronic-pain-management-and-opioid-use-easing-fears-managing-risks-and-improving-outcomes.html.

[41] *Id.*

[42] *See, e.g., Treatment Options: A Guide for People Living with Pain*, AMERICAN PAIN FOUNDATION, *available at* https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Oct. 28, 2017).

advisors that developed, edited and reviewed the guidelines were KOLs with significant financial ties to Defendants, including Dr. Portenoy.[43] These guides were riddled with the same lies. For example, APF's pain treatment guide for reporters stated, "[m]any people living with pain and even some healthcare providers falsely believe opioids [] are universally addictive" yet "[s]tudies have shown that the risk of addiction is small when these medicines are properly prescribed and taken as directed."[44] APF's guide for patients claims, "[d]espite the great benefit of opioids, they are often under-used," because "providers may be afraid to give them, and the public may be afraid to take them," suggesting that a fear of prescribing opioids or consuming opioids is unjustified.[45] APF's guide for policymakers sponsored by Defendant Purdue similarly claimed, "[u]nless a person with pain has a past or current personal or family history of substance abuse, the likelihood of addiction is low when opioids are appropriately prescribed, taken as directed and monitored by a responsible and knowledgeable healthcare provider."[46] The guide also promotes the deceptive concept of "pseudoaddiction."[47]

APF also lobbied vigorously against federal and state proposals to limit opioid use. For example, in 2009, the APF lobbied against the FDA's recommendation for physician and pharmacist certifications to ensure they had been educated about the risks of long-acting opioids.[48] And, APF filed *amicus curiae* briefs in support of opioid manufacturers and overprescribing

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[43] *See, e.g., id.* at 76.
[44] *A Reporter's Guide: Covering Pain and Its Management*, AMERICAN PAIN FOUNDATION (Oct. 2008), at 1, *available at* https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (last visited Oct. 28, 2017).
[45] *Treatment Options: A Guide for People Living with Pain, supra* note 41, at 11.
[46] *A Policymaker's Guide to Understanding Pain & Its Management*, AMERICAN PAIN FOUNDATION (Oct. 2011), at 28, *available at* https://www.documentcloud.org/documents/277603-apf-policymakers-guide.html (last visited Oct. 28, 2017).
[47] *Id.* at 32.
[48] *See* Charles Ornstein & Tracy Weber, *Dollars for Doctors - The Champion of Painkillers*, PROPUBLICA.ORG (Dec. 23, 2011), https://www.propublica.org/article/the-champion-of-painkillers; *see also* AMERICAN PAIN FOUNDATION, *APF Calls for Balanced Perspective on FDA's Proposed Risk Evaluation Mitigation Strategy (REMS) for Opioid Therapy* (May 28, 2009), *available at* https://www.documentcloud.org/documents/279029-apf-calls-for-balanced-perspective-on-fdas.

doctors in state and federal courts. For example, APF filed an amicus brief in support of a Virginia doctor accused of prescribing one patient 1,600 Roxicodone pain pills in one day and more than 500,000 pills to that patient over a three-year period, claiming the conviction would "deter physicians from treating chronic pain by prescribing opioid medications."[49] In its brief, APF relied on a text authored by KOL Dr. Portenoy to claim, "[e]xperience shows that patients rarely become addicted to prescribed opioids" and "respiratory depression, even extremely high levels, does not occur in the context of appropriate clinical treatment."[50]

In 1997 and 2001, the APS and AAPM issued consensus statements that endorsed the use of opioids to treat chronic non-cancer pain and minimized the risk of addiction. The 1997 Consensus statement claimed "[s]tudies indicate that the *de novo* development of addiction when opioids are used for relief of pain is low."[51] The co-author of the consensus statement, Dr. J. David Haddox, was a member of Defendant Purdue's speaker bureau and later Purdue's Vice President of Health Policy.[52] The 2001 consensus statement similarly claimed, "[m]ost specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy...do not usually develop addictive disorders."[53] It also promoted the concept of "pseudoaddiction" claiming "[a]n individual's behaviors that may suggest addiction sometimes are simply a reflection

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[49] *See* Brief for Amici the APF, 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. William Eliot Hurwitz*, No. 05-4474 (4th Cir. 2005) (the "APF-*Hurwitz* Brief"); *see also* Ornstein & Weber, *supra* note 47.

[50] APF-*Hurwitz* Brief at 9 (citing Russell Portenoy et al., *Acute and Chronic Pain, in* COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE 863-903 (Lowinson et al. eds., 4th ed. 2005)).

[51] J. David Haddox, DDS MD, Russell K. Portenoy, MD, et al., *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*, AMERICAN ACADEMY OF PAIN MEDICINE & AMERICAN PAIN SOCIETY (1997), at 2.

[52] *See* AMERICAN CHRONIC PAIN ASSOCIATION, *Advisory Board*, https://theacpa.org/Advisory-Board (last visited Oct. 26, 2017); John Fauber, *Follow the Money: Pain, Policy & Profit*, MEDPAGETODAY (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.

[53] *Definitions Related to the Use of Opioids for the Treatment of Pain: Consensus Statement of the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine*, AMERICAN SOCIETY OF ADDICTION MEDICINE (2001), *available at* https://www.asam.org/docs/default-source/public-policy-statements/1opioid-definitions-consensus-2-011.pdf?sfvrsn=0, at 2.

of unrelieved pain or other problems unrelated to addiction."[54]

In 2009, the APS and AAPM issued opioid treatment clinical guidelines that recommended primary care and specialty care health care providers use opioids to treat chronic pain.[55] Six of the 21 panelists involved in drafting the guidelines received financial support from Defendant Purdue and another 8 received support from other opioid manufacturers including Defendants Janssen and Cephalon.[56] These included well-known KOLs with extensive financial ties to Defendants, including Dr. Portenoy and Dr. Fine.[57] The APS/AAPM guidelines recommended opioids as "safe and effective" for the treatment of chronic non-cancer pain based on "low quality evidence."[58] The guidelines also minimized the risk of opioid addiction, claiming the risk is manageable even for those with a prior history of substance abuse.[59]

While headed by Dr. Portenoy, the APS began aggressively promoting the concept of "Pain as the 5th Vital Sign," encouraging health care practitioners to assess, monitor and treat pain as they would pulse, blood pressure, temperature and respiratory rate.[60] Soon after, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") and the Federation of State Medical Boards ("FSMB"), bought into the concept. In 2001, JCAHO, a non-profit organization that accredits and certifies thousands of healthcare organizations nationwide, created new pain management standards that required pain to be assessed in all patients.[61] During 2001 and 2002, Defendant Purdue funded a series of nine programs throughout the country to educate hospital

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[54] *Id.*
[55] Portenoy et al., *supra* note 26.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] Catan & Perez, WSJ, *supra* note 24.
[61] Sonia Moghe, *Opioid history: From 'wonder drug' to abuse epidemic*, CNN.COM (Oct. 14, 2016), http://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html.

physicians and staff on how to comply with the JCAHO pain standards and to discuss postoperative pain treatment.[62] Under an agreement with JCAHO, Defendant Purdue exclusively was allowed to distribute certain educational videos and a book about pain management that were also available for purchase from JCAHO's website.[63] A book printed by JCAHO and sponsored by Defendant Purdue cited studies claiming, "there is no evidence that addiction is a significant issue when persons are given opioids for pain control" and called doctors' concerns about the risks of opioid addiction "inaccurate" and "exaggerated." [64] A 2003 GAO report suggested "Purdue's participation in these activities with JCAHO may have facilitated its access to hospitals to promote OxyContin."[65] Dr. David W. Baker, JCAHO's executive vice president for health care quality has since stated: "There is no doubt that the widely held belief that short-term use of opioids had low risk of addiction was an important contributor to inappropriate prescribing patterns for opioids and the subsequent opioid epidemic."[66] He acknowledged that "[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."[67]

FSMB, a trade group representing 70 state medical and osteopathic regulatory boards, with financial support from opioid manufacturers and front groups, developed written model guidelines to encourage federal and state regulatory agencies to adopt policies promoting the use of opioids for the treatment of chronic non-cancer pain.[68] The contributors to the 1998 Model Guidelines

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[62] UNITED STATES GENERAL ACCOUNTING OFFICE, GAO-04-110, *OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf, at 23, n.32.
[63] *Id.* at 23.
[64] Moghe, *supra* note 60.
[65] GAO-04-110, *supra* note 61.
[66] Moghe, *supra* note 60.
[67] *Id.*
[68] *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, THE FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC. (adopted May 2, 1998), *available at*

were front groups APS, AAPM and the University of Wisconsin Pain & Policies Study Group, all of which had extensive financial relationships with pharmaceutical companies, including Defendants.[69] Between 1999 and 2010, Defendant Purdue paid the UW Pain & Policies Study Group approximately $2.5 million.[70] From 1997 through 2012, FSMB received $2 million from opioid manufacturers including Defendants Purdue and Cephalon.[71]

The Model Guidelines described opioids as "essential" to the treatment of chronic pain, including chronic non-cancer pain.[72] The Model Guidelines also downplayed the risk of addiction stating, "[p]hysicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction."[73] The Guidelines even recommended prescribing opioids to patients at high risk for substance abuse or with a history of substance abuse.[74] They also failed to mention the severe risks of opioids including respiratory depression and overdose.[75] Instead, the Guidelines downplayed addiction claiming "inadequate understandings of addiction" lead to "inadequate pain control" and promoted the misleading concept of "pseudoaddiction," defining it as a "[p]attern of drug-seeking behavior of pain patients who are receiving inadequate pain treatment that can be mistaken for addiction."[76] The Model Guidelines were "widely distributed to state medical boards, medical professional organizations, other health regulatory boards, patient advocacy groups, pharmaceutical companies,

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http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model_0.pdf (cited hereinafter as the "FSMB 1998 Model Guidelines").

[69] SCOTT M. FISHMAN, MD, RESPONSIBLE OPIOID PRESCRIBING: A PHYSICIAN'S GUIDE (2007), Appendix B, p. 125.

[70] Fauber, *supra* note 51.

[71] Letter from FSMB to Senators Max Baucus and Charles Grassley (June 8, 2012), *available at* https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

[72] FSMB 1998 Model Guidelines.

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] *Id.*

state and federal regulatory and practicing physicians and health care providers."[77]

In 2003, the FSMB revised its Model Guidelines and adopted them in 2004 as its Model Policy.[78] The Model Policy continued to encourage the liberal prescription of opioids for chronic non-cancer pain repeating the claim from the Model Guidelines that opioids are "essential" to the treatment of chronic non cancer pain.[79] The Model Policy continued promoting the concept of "pseudoaddiction," describing drug-seeking behaviors as a "misinterpretation of relief seeking behaviors" rather than signs of addiction.[80] The Model Policy even threatens that undertreatment of pain is "a departure from standards of practice," and suggests physicians would be sanctioned by state medical boards for not prescribing opioids to treat chronic non-cancer pain.[81] At least 38 state medical boards, ***including the Oklahoma State Board of Medical Licensure and Supervision***, adopted the Model Guidelines or Model Policy in full or in part.[82]

FSMB, along with drug manufactures, including Defendants Cephalon and well-known front groups, APF and AAPM, among others, sponsored a book, *Responsible Opioid Prescribing: A Physician's Guide*, to translate FSMB's Model Policy to practitioners nationwide, including Oklahoma physicians.[83] At the time, the author, Dr. Scott Fishman, had financial ties to Defendants Cephalon, Janssen, and Purdue, among other drug manufacturers.[84] Dr. Fishman disclosed being on the speaker's bureau and receiving grants/research support from Defendant Purdue, and a consultant to Defendants Janssen, Cephalon and Purdue.[85] Dr. Fishman also served as Vice

[77] FISHMAN, *supra* note 68 at Appendix B, p. 125-26.
[78] *Id.*, p. 127.
[79] *Id.*, p.129.
[80] *Id.*, p.134.
[81] *Id.*, p.129.
[82] *Id.*, at p.3; OKLA. ADMIN. CODE §435:10-7-11 (2016).
[83] FISHMAN, *supra* note 68.
[84] *Id.*, p.vi.
[85] *Id.*

Chairman of APF's board of directors, past president of AAPM's and on APS's board of directors.[86] Despite these close financial ties to drug manufactures, the text presents Dr. Fishman as unbiased "Past President of the American Academy of Pain Medicine" and calls him a "true thought leader in academic medicine, clinical practice, and public health policy."[87]

In *Responsible Opioid Prescribing*, Dr. Fishman repeated many of the same lies from the Model Guidelines and Model Policy including touting opioids as "essential" to treat non-chronic cancer pain.[88] Dr. Fishman made the unsubstantiated claim that opioid therapy to relieve pain and improve function is "widely accepted" as "a legitimate medical practice" for acute and chronic non-cancer pain to relieve pain and improve function."[89] Dr. Fishman claimed opioids are "often underutilized" and pain is "undertreated" because of the "confusion about the risks associated with the use of these drugs, particularly about addiction."[90] He even employed the scare tactics of the FSMB Model Policy suggesting that physicians who do not treat pain may risk being sued or sanctioned by their medical boards, claiming, "not treating pain is often not a 'safe' option."[91] Dr. Fishman also promotes the deceptive concept of "pseudoaddiction."[92] Dr. Fishman even concludes that signs such as "[r]equesting analgesics by name, [d]emanding or manipulative behavior, [c]lock watching, [t]aking opioids for an extended period, [o]btaining opioid drugs from more than one physician, and [h]oarding opioids" are not indicative of addiction but rather "pseudoaddiction" and actually require *more* opioids to be prescribed.[93] From its release in 2007 through January 2012, *Responsible Opioid Prescribing* was distributed to physicians in all 50 states and the District

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[86] *Id.*, p. 137.
[87] *Id.*, p. 4.
[88] *Id.*, p. i.
[89] *Id.*, p.8.
[90] *Id.*, p.i.
[91] *Id.*, pp.27-29.
[92] *Id.* pp.62-63.
[93] *Id.*

of Columbia. [94] ***Between 2008 and 2011, Responsible Opioid Prescribing generated approximately $36,437.00 in book sales revenue from Oklahoma and, approximately 6,000 copies were distributed in Oklahoma.***[95]

Through these KOLs, front groups and others, Defendants preyed on the most vulnerable including, children, veterans and the elderly. *See* ¶51. APF's guide for policymakers sponsored by Defendant Purdue falsely represented that "less than 1% of children treated with opioids become addicted," a particularly egregious claim given the target population—children—a population for which the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guidelines") states the risk of opioid medication use is of great concern.[96]

In 2009, APF specifically targeted veterans. ¶64. For example, its publication, *Exit Wounds* (aimed at pain treatment for veterans), describes opioids as "unsurpassed" for their "pain-relieving properties" and the "'gold standard' of pain medications" that "despite their great benefits, [] are often underused."[97] *Exit Wounds* makes numerous misrepresentations, claiming for example that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."[98]

Defendants, in collaboration with front groups, also aggressively promoted opioid prescribing to the elderly. *See* ¶51. In 2009, the American Geriatrics Society ("AGS") published guidelines that state, "the risks [of addiction] are exceedingly low in older patients with no current

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[94] Letter from FSMB to Senators Max Baucus and Charles Grassley (June 8, 2012), *available at* https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf, at 5.
[95] *Id.*, p.16, 19.
[96] *A Policymaker's Guide to Understanding Pain & Its Management*, AMERICAN PAIN FOUNDATION (Oct. 2011), at 40.
[97] DEREK MCGINNIS, EXIT WOUNDS A SURVIVAL GUIDE TO PAIN MANAGEMENT FOR RETURNING VETERANS & THEIR FAMILIES 106 (2009).
[98] *Id.*, p. 107.

or past history of substance abuse."[99] However, the study the guidelines cited to support this statement did not even evaluate addiction risk by age group. Based on "low quality evidence," the AGS guidelines made the "strong recommendation" that "[a]ll patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy[.]"[100] Drug manufacturers including Defendant Purdue provided grants to AGS for distribution of these guidelines. KOL Dr. Fine, among others, was on the AGS Panel that created the guidelines, and front group AAPM peer reviewed a draft of the guidelines.[101] AGS and AAPM also distributed guidelines sponsored by Defendant Janssen that contained several purported "facts" that were unsupported and/or misleading, including the "[f]act" that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[102]

Importantly, the majority of the material described above was *unbranded*, meaning that Defendants' and their products' names often did not appear on these materials. Such unbranded marketing efforts were part of Defendants' conspiracy to increase opioid prescribing and sales *generally*—that is, to create a market for opioids where no market had previously existed. As explained herein, this concerted unlawful behavior subjects Defendants to joint and several liability for the harm they have caused Oklahoma.

In May 2012, the U.S. Senate Finance Committee, citing "an epidemic of accidental deaths

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[99] AMERICAN GERIATRICS SOCIETY, *Pharmacological Management of Persistent Pain in Older Persons, American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons*, J. AM. GERIATRIC SOC. 57(8):1331-46 (Aug. 2009), *available at* https://www.painbc.ca/sites/default/files/events/materials/AmericanGeriatricSociety-Guidelines2009.pdf, at 1339.

[100] *Id.*, p.1342.

[101] *Id.*, p.1343 ("Panel Members and Affiliations").

[102] *Finding Relief, Pain Management for Older Adults*, PRICARA (2009); *see also, e.g.*, Martha Rosenberg, *Was Prince the Latest Opioid Casualty?*, CommonDreams.org (May 8, 2016), https://www.commondreams.org/views/2016/05/08/was-prince-latest-opioid-casualty (quoting the *Finding Relief* pain guide, "funded by opioid maker Janssen" as stating "'Many studies show that opioids are rarely addictive when used properly for management of chronic pain.'").

and addiction resulting from the increased sale and use of powerful narcotic painkillers," launched an investigation into the financial relationship between drug manufactures, front groups and KOLs. Targets of the investigation included Defendants Purdue and Janssen, and APF, AAPM, APS, AGS, FSMB and JCAHO, and KOLs, Dr. Portenoy, Dr. Fishman, Dr. Fine, and Dr. Webster. The Committee began this investigation based on "growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness."[103] The Committee report drafted from the documents collected during the investigation remains under seal.

Defendants also spent millions on false and deceptive *branded* marketing that minimized the risk of addiction and exaggerated the efficacy of opioid therapy for chronic non-cancer pain in medical journal advertisements, patient brochures, promotional videos, sponsored links on internet search engines and other marketing materials. ¶¶52-57. For example, Defendants mispresented the risk of addiction in its marketing materials by citing "studies" like the "Porter-Jick Letter." ¶56. However, this "study" was actually a 101-word, single-paragraph letter to the editor in a medical journal from 1980, which focused exclusively on hospitalized patients who were given narcotics in a hospital setting. *Id.* It did not establish or support the misrepresentation for which Defendants used it (*i.e.* that addiction is rare from opioid treatment of pain). *Id.*[104] Defendant Purdue even sponsored a study that made the claim that "the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[105] The sole support for this statement was the

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[103] *See e.g.*, Letter from Senators Max Baucus and Charles E. Grassley to John H. Stewart, President and Chief Executive Officer, Purdue Pharma L.P. (May 8, 2012), *available at* https://www.finance.senate.gov/imo/media/doc/Purdue_May_8.pdf.

[104] J. Porter & H. Jick, Letter to the Editor, *Addiction Rare in Patients Treated with Narcotics*, 302(2) NEW ENG. J. MED. 123 (1980), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[105] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, PAIN 105 (2003) 71-78, *available at* https://pdfs.semanticscholar.org/be4f/ff311b5869e11245dbc5ed433e59035d0f9c.pdf, at 72.

"Porter-Jick Letter."[106] And a co-author of the study was an employee of Defendant Purdue.

A June 2017 study published in the *New England Journal of Medicine* noted a sizeable increase in citation to the Porter-Jick Letter after the introduction of OxyContin and that nearly three quarters of the articles referencing the Letter cited it "as evidence that addiction was rare in patients treated with opioids."[107] This study reached the conclusions that the Letter was "heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy."[108] Dr. Jick later explained that his Letter was misused by drug companies "pushing out new pain drugs" to falsely conclude that their opioids were not addictive "[b]ut that's not in any shape or form what we suggested in our letter."[109]

Defendants also trained large sales forces to repeat their false messaging on the low risk of addiction and efficacy of opioids for chronic non-cancer pain directly to health care professionals through office visits, including to Oklahoma medical professionals. ¶54. For example, according to an interview by a former Purdue sales manager from 2003, Defendant Purdue trained its sales representatives for OxyContin "to say things like it is 'virtually' non-addicting...That's what we were instructed to do. It's not right, but that's what they told us to say."[110] This same manager claimed he was trained that OxyContin was "non-habit forming."[111]

Defendants' sales representatives marketed their opioids directly to unsuspecting

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[106] *Id.*
[107] Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376.22 NEW ENG. J. OF MED., 2194-95 (2017), *available at* http://addictiondomain.com/wp-content/uploads/2017/06/A-1980-Letter-on-the-Risk-of-Opioid-Addiction.pdf.
[108] *Id.*
[109] Taylor Haney, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed the Opioid Crisis*, NPR.ORG (June 16, 2017), http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.
[110] Fred Schulte & Nancy McVicar, *OxyContin Was Touted As Virtually Nonaddictive, Newly Released State Records Show*, SUNSENTINEL (Mar. 6, 2003), http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely.
[111] *Id.*

Oklahoma physicians. According to ProPublica's "Dollars for Doctors" investigation, Defendants' sales representatives have frequently visited and preyed upon Oklahoma primary care physicians and specialists, including physicians working at State medical centers, and offered them tens of thousands of dollars per year in food and beverage fees, promotional speaking fees, consulting fees and travel and lodging fees. For example, in 2015 alone, Defendant Purdue visited one Oklahoma high opioid prescribing physician 22 times related to its opioids and paid for food and beverage during each of these visits.[112] Defendant Purdue also paid another frequent Oklahoma opioid prescriber over $57,000 in promotional speaking, consulting, travel and lodging, and food and beverage fees related to its opioids between August 2013 and December 2015.[113] Defendant Cephalon also paid this same prescriber thousands of dollars in promotional speaking fees.[114] Defendant Janssen also visited Oklahoma prescribers for purposes of marketing their opioids and paid for food and beverage during these visits.[115] It was during these visits and others that Defendants directly misled Oklahoma physicians regarding the addictiveness and effectiveness of opioids.

A 2016 study found that providing industry-sponsored meals to physicians was associated with an increased rate of prescribing the brand-named medication being promoted.[116] The study found that physicians receiving meals related to the target drugs on 4 or more days prescribed the

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[112] PROPUBLICA.ORG, *Dollars for Docs*, https://projects.propublica.org/docdollars/doctors/pid/309160 (last visited Oct. 26, 2017).
[113] PROPUBLICA.ORG, *Dollars for Docs*, https://projects.propublica.org/docdollars/doctors/pid/242826 (last visited Oct. 26, 2017).
[114] *Id.*
[115] *See, e.g.*, PROPUBLICA.ORG, *Dollars for Docs*, https://projects.propublica.org/docdollars/doctors/pid/190046 (last visited Oct. 26, 2017).
[116] Collette DeJong, et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, JAMA INTERN. MED. 176(8):1114-1122 (Aug. 1, 2016), *available at* https://www.ncbi.nlm.nih.gov/pubmed/27322350.

drugs from 1.8 times to as much as 4.5 times the rate of physicians receiving no meals.[117] The study found that even a "single industry-sponsored meal with a mean value of less than $20 was associated with prescription of the promoted brand-name drug at significantly higher rates..." and that additional and more costly meals were associated with greater increases in prescribing. [118]

Through its highly coordinated and deceptive marketing campaign, Defendants convinced doctors, pharmacists and consumers nationwide, including in Oklahoma, that despite the instructions on their drug labels and the longstanding practice of prescribing opioids only in limited circumstances, opioids are a safe and effective treatment for chronic non-cancer pain and there is a low risk of addiction with long-term opioid use—representations that were false, deceptive, and unsupported. ¶67. Numerous studies demonstrate the high addiction and abuse risk posed by opioids, including when used to treat chronic pain. ¶69. According to the CDC Guidelines, "[e]xtensive evidence shows the possible harms of opioids," including "opioid use disorder" and "overdose" and "that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." ¶69. The CDC also found, "[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." *Id.* Moreover, the CDC found "[e]xtensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm." *Id.*

Defendants' deceptive marketing campaign caused opioid prescription and consumption to rapidly rise across the country with devastating effects for the nation. Sales of prescription opioids to pharmacies, hospitals and doctors' offices quadrupled since 1999, yet according to the CDC,

[117] *Id.*
[118] *Id.*

there has not been a change in the amount of pain Americans report.[119] As opioid sales skyrocketed, there was a concomitant increase in prescription opioid overdose death and people in treatment for addiction. *See* pp. 5-7 *supra*.

Drug overdose is now the leading cause of death for Americans under 50, reducing life expectancy and killing people at a faster rate than the HIV/AIDS epidemic at its peak.[120] One hundred and forty-five Americans die of drug overdoses every day.[121] From 1999 to 2015, more than 183,000 people have died in the U.S. from overdoses related to prescription opioids.[122] In 2014, almost 2 million Americans abused or were dependent on prescription opioids.[123] And as many as 1 in 4 people prescribed opioids long term for non-cancer pain in primary care settings struggles with opioid addiction.[124] A Blue Cross Blue Shield analysis of 30 million Americans' medical claims showed diagnoses of opioid-use disorder surged nearly 500% over the past seven years.[125]

In short, the impact of Defendants' conduct upon Oklahoma, and the nation, is catastrophic.

IV. THE CORRECT PLEADING STANDARDS

Defendants' motions rely heavily, and inappropriately, on federal case law applying the more stringent federal "plausibility" pleading standard set forth in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007). Oklahoma courts have refused to adopt this standard. *See Edelen v. Bd. of*

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[119] CDC.GOV, *Opioid Overdose, Opioid Basics, Understanding the Epidemic, Record Overdose Deaths*, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Oct. 26, 2017).
[120] Josh Katz, *The First Count of Fentanyl Deaths 2016: Up 540% in Three Years*, THE NEW YORK TIMES (Sept. 2, 2017), https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html.
[121] Keefe, *supra* note 13.
[122] CDC.GOV, *Opioid Overdose, Data, Prescription Opioid Overdose Data, Overdose Data*, https://www.cdc.gov/drugoverdose/data/overdose.html (last visited Oct. 26, 2017).
[123] *Id.*
[124] *Id.*
[125] Anne Steel, *Opioid-Addiction Diagnosis Up Nearly 500% in Past Seven Years, Study Shows*, THE WALL STREET JOURNAL (June 29, 2017), https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603.

Comm'r, 2011 OK CIV APP 116, ¶3, 266 P.3d 660 ("Oklahoma has not adopted this pleading standard...We decline to adopt a different pleading standard here."). But, this case is in state court. Oklahoma pleading laws control.

Defendants' motions also wrongly contend that *all* of the State's claims sound in fraud. At a minimum, the State's claims for public nuisance and unjust enrichment do not sound in fraud and thus are subject to the liberal notice pleading standard. *See Estrada*, 2015 OK CIV APP 19, ¶14 ("[A]n averment of fraud does not exist merely because the modifier 'fraudulent' is used.").

A. The State's Non-Fraud Claims—Nuisance, Unjust Enrichment and OCPA—are Subject to Oklahoma's Liberal Notice Pleading Standard

The Petition's nuisance, unjust enrichment and OCPA claims are governed by notice pleading standards. Since 1984, Oklahoma has been a "notice pleading state." *Gens*, 2008 OK 5, ¶9. "All that is required under notice pleading is that the petition give fair notice of the plaintiff's claim and the grounds upon which it rests." *Id.* "The Pleading Code does not require a plaintiff to set out in detail the facts upon which the claim is based but merely requires 'a short and plain statement of the claim showing that the pleader is entitled to relief; and ... [a] demand for judgment for the relief to which he deems himself entitled.'" *Fanning v. Brown*, 2004 OK 7, ¶19, 85 P.3d 841 (citing 12 O.S. §2008(A)(1) & (2)). "This requirement is not onerous, but is merely to give an opposing party fair notice of the claim and the grounds upon which it rests." *Id.*

Under this standard, a "petition can generally be dismissed only for lack of any cognizable legal theory to support the claim or for insufficient facts under a cognizable legal theory." *Kirby v. Jean's Plumbing Heat & Air,* 2009 OK 65, ¶5, 222 P.3d 21. Motions to dismiss are generally viewed with disfavor under this liberal standard. *Simonson v. Schaefer,* 2013 OK 25, ¶3, 301 P.3d 413; *Indiana Nat'l Bank v. State Dep't of Human Servs.*, 1994 OK 98, ¶4, 880 P.2d 371. When reviewing a motion to dismiss, the court must take as true all of the challenged pleading's

allegations together with all reasonable inferences that may be drawn from them. *Schaefer,* 2013 OK 25, ¶3; *Great Plains Fed. S&L Ass'n v. Dabney,* 1993 OK 4 n.3, 846 P.2d 1088. "A pleading *must not* be dismissed for failure to state a legally cognizable claim *unless* the allegations indicate *beyond any doubt* that the litigant can prove *no* set of facts which would entitle him to relief." *Frazier*, 1989 OK 73, ¶13 (emphasis in original); *see also Schaefer*, 2013 OK 25, ¶3; *Fanning*, 2004 OK 7, ¶4. Further, "the burden to show the legal insufficiency of the petition is on the party moving for dismissal and a motion made under §2012(B)(6) must separately state each omission or defect in the petition; if it does not, the motion shall be denied without a hearing." *Indiana Nat'l Bank*, 1994 OK 98, ¶3 (citing *Curlee v. Norman,* 1989 OK CIV APP 25, ¶4, 774 P.2d 481); *see also Schaefer,* 2013 OK 25, ¶3 ("The party moving for dismissal bears the burden of proof.").[126] Measured by this standard, the Petition more than adequately satisfies the notice pleading requirements of Section 2008.

B. The State's Fraud-Based Claims Satisfy the Requirements of Section 2009(B)

The particularity requirement of Section 2009(B) applies only to the State's common law fraud/deceit claim and arguably to claims brought under the OMFCA and OMPIA. *Gay*, 1988 OK 150, ¶8. Section 2009(B) requires, in pertinent part, that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." 12 O.S. §

[126] Title 12 O.S. 2011, §2012(G) provides "(o)n granting a motion to dismiss a claim for relief, the court shall grant leave to amend if the defect can be remedied and shall specify the time within which an amended pleading shall be filed." The Oklahoma Supreme Court has interpreted the statute as a mandatory duty on trial courts, as long as the defect can be remedied. *See Kelly v. Abbott*, 1989 OK 124, ¶6, 781 P.2d 1188. For courts to dismiss a claim for failure to state a cause of action without giving the plaintiff the opportunity to amend, it must appear that the claim does not exist rather than the claim has been defectively stated. *See Lockhart v. Loosen*, 1997 OK 103, ¶5, 943 P.2d 1074 (which draws a distinction between a petition that is dismissible for want of a cognizable legal theory of liability and one that is dismissible for insufficient facts under a recognized theory). As demonstrated herein, the State's Petition is not "defective" in any way under Oklahoma law. Should the Court, however, disagree and grant Defendants' motions to any degree, the State respectfully requests leave to cure any such "defect" by amendment. *See id.*

2009(B). "While §2009(B) governs *how* such allegations must be made; *what* must be pled is determined by Oklahoma substantive law." *Id.* at ¶7 (emphasis in original).

To satisfy the pleading requirements of Section 2009(B), "it is unnecessary to plead *each element* of fraud in detail if the *circumstances* constituting fraud are stated with particularity." *Id.* at ¶8 (emphasis in original). Moreover, Section 2009(B) must be read in conjunction with Section 2008, which requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." 12 O.S. §2008(A)(1); *Gay*, 1988 OK 150, ¶17. These two sections must be harmonized:

> [§ 2009(B)'s] demand for greater specificity serves three important purposes: 1) the desire to protect the reputation of the defendants; 2) the need to deter "strike" suits; and 3) the need to afford an opponent adequate notice in order to prepare a responsive pleading. Despite these purposes, the particularity requirement is not unbounded; § 2008 serves as a limitation. With these principles in mind, the purpose and requirements of § 2009(B) become clear. **The section requires only the degree of specificity necessary to enable the opposing party to prepare his responsive pleadings and defenses.** The clear weight of authority holds that Rule 9 requires specification of the time, place and content of an alleged false representation, but not the circumstances or evidence from which fraudulent intent could be inferred. If the circumstances are set out, there is no requirement that the word "fraud" even be used. **"Particularity" does not mean the plaintiff has to plead detailed evidentiary matters.** This interpretation of § 2009(B) harmonizes with the pleading code[.]

Gay, 1988 OK 150, ¶¶17-18. The State's common law fraud, OMFCA and OMPIA claims more than satisfy the specificity required by Section 2009(B).

V. ARGUMENT & AUTHORITIES

A. The Petition Does Not "Group Plead," Nor is Such a Doctrine Applicable

As a threshold matter, Defendants wrongly contend the Petition is defective because it engages in "group pleading." Jt. MTD at 3, 6-8; Teva MTD at 2, 10-11; Purdue MTD at 13; J&J MTD at 2-4. It is disingenuous at best for Defendants to complain that the State "group" pled allegations against 13 Defendants when, in reality, 9 of these companies are branches of only 4

primary corporate Defendants. Further: (i) Defendants acted in concert with one another and acted as agents and/or principals of one another; (ii) Defendants and their co-conspirators engaged in common conduct and utilized the same misrepresentations for their marketing scheme and misinformation campaign; (iii) Defendants and their co-conspirators engaged in a conspiracy to submit false claims under the OMFCA (¶¶73-91), which contains a provision making any person liable who "[c]onspires to defraud the state by getting a false or fraudulent claim allowed or paid" (63 O.S. §5053.1(B)(3), (7)); (iv) the group pleading doctrine is not applicable here, nor has it been adopted by any Oklahoma court; and (v) under Oklahoma law, each Defendant is jointly and severally liable for creating a public nuisance (and other torts) (*see* 23 O.S. §15(B)).

First, Defendants' argument that the State engaged in "group pleading" as to all 13 Defendants "as if they were a single agglomerated whole" is false. Jt. MTD at 7. As summarized in the chart below, these 13 Defendants operate within just 4 "families," as Defendants have admitted. ¶¶13-20. Members of those families acted in concert with each other and the other Defendant families.

Each family is classified by a primary Defendant and drug(s), with corporate family members of the primary Defendant, many of which are wholly-owned subsidiaries of the primary Defendant. Moreover, the Petition alleges that the members of each family "acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein." ¶13 (Purdue), ¶15 (Actavis), ¶17 (Cephalon), ¶19 (Janssen).

Family	Family Members	Drugs Marketed & Sold in OK
Purdue	Purdue Pharma L.P. Purdue Pharma, Inc. The Purdue Frederick Co.	OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER
Actavis	Allergan Plc Watson Laboratories, Inc. (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., f/k/a Watson Pharma, Inc.) Actavis LLC Actavis Pharma, Inc.	Kadian and Norco, and several generic opioids
Cephalon	Cephalon, Inc. (acquired by Teva in Oct. 2011) Teva Pharmaceuticals USA, Inc.	Actiq and Fentora
Janssen	Janssen Pharmaceuticals, Inc. (wholly owned subsidiary of Defendant Johnson & Johnson (J&J)) Johnson & Johnson Ortho-McNeil-Janssen Pharmaceuticals, Inc. (n/k/a Janssen Pharmaceuticals, Inc.) Janssen Pharmaceutica Inc., (n/k/a Janssen Pharmaceuticals)	Duragesic, Nucynta, and Nucynta ER

Second, these families of Defendants are not "unrelated corporate groups" as Defendants contend. Jt. MTD at 7. Nor is it relevant that the 4 families of Defendants manufactured and sold different or competing drugs. *Id.* They ***all*** sold opioids, and they ***all*** misrepresented the risks of addiction and touted unsubstantiated benefits of those drugs and "opioids" generally, not just their own branded drugs, creating a state-wide public nuisance. ¶¶4, 118. Group conduct is not group pleading.

Third, Defendants engaged in a conspiracy to submit false claims under the OMFCA (¶¶73-91), which contains a provision making any person liable who "[c]onspires to defraud the state by getting a false or fraudulent claim allowed or paid." 63 O.S. §5053.1(B)(3), (7).

Fourth, the "group pleading" doctrine pertains to allegations of vicarious liability and is, thus, inapplicable to this case. The group pleading doctrine was established by the Ninth Circuit in 1987—*a federal court having nothing to do with the State of Oklahoma*—in the context of inapplicable ***federal securities fraud cases***. *See Wool v. Tandem Computers, Inc.*, 818 F.2d 1433, 1440 (9th Cir. 1987). This doctrine allows knowledge of falsity (*i.e.*, scienter) to be imputed to officers and directors of companies when the false and misleading information is conveyed in a "group-published" document. *See In re: Williams Sec. Litig.*, 339 F. Supp. 2d 1242, 1260 (N.D. Okla. 2003) ("Plaintiffs are not required to plead the allegedly false and misleading statements made by each individual Defendant or state specific facts demonstrating that they had the requisite scienter.").

This doctrine has no applicability here. This is not a traditional "group pleading" case, where a theory of vicarious liability is necessary to hold individual defendants responsible for the false statements or actions of a corporation. Instead, this is a case about 13 Defendants in 4 corporate families who engaged in a common course of conduct, *i.e.*, "'massive' marketing campaigns that understated the risks and overstated the benefits of opioid therapy for chronic non-cancer pain." Jt. MTD at 6. Because of the alleged relationship among Defendants and their common conduct, the State's claims are "linked by common allegations" and, thus, would actually comply with the inapplicable federal standards Defendants advocate. *See, e.g.*, *Flow Valve, LLC v. Forum Energy Tech., Inc.*, No. CIV-13-1261-F, 2014 U.S. Dist. LEXIS 97736, at *8-9 (W.D. Okla. July 18, 2014) (denying motion to dismiss based on group pleading doctrine under federal pleading standard). Indeed, the Petition describes an overarching scheme by which Defendants collectively defrauded and injured the State, as a whole, in a variety of ways, including by utilizing the same KOLs and front groups. *See, e.g.*, ¶¶63-66; *see also* Section III *supra*.

The Petition also alleges Defendants' collective actions have created a public nuisance permeating the entire State of Oklahoma "that affects ***entire communities, neighborhoods, and considerable numbers of persons***." ¶118. As discussed below, the public nuisance Defendants created gives rise to a "single injury" caused by joint tortfeasors, not "group pleading."

Defendants cite ***no Oklahoma state court authority*** that even uses the phrase "group pleading," much less any that officially adopt the doctrine.[127] Instead, Defendants rely upon *Gay v. Akin* as their only Oklahoma state court authority. *See* Jt. MTD at 6-8; Teva MTD at 10-11; Purdue MTD at 12-13 (incorporating Jt. MTD); J&J MTD at 2-3. But *Gay* actually upheld the plaintiff's "group" pled allegations—a critical fact Defendants fail to mention:

> Under these circumstances, where knowledge of the alleged specific unlawful acts committed by the Institution and the individual Directors is imputed to each of the Directors as a matter of law, ***the allegations of fraud averred against the defendants as a group (without specific reference to each individual defendant) is sufficient to support a reasonable inference of fraud as to each of the individual Directors***.

1988 OK 150, ¶15. Thus, Defendants' sole Oklahoma state court authority does not support their argument.

In sum, the Petition does not engage in "group pleading," nor is the doctrine even applicable here. Instead, the Petition describes how 13 Defendants in 4 corporate families engaged

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[127] Defendants' two federal cases are inapposite. First, they were decided under the more stringent "plausibility" federal pleading standard, which Oklahoma courts have refused to adopt. *See Edelen*, 2011 OK CIV APP 116, ¶3. Second, they are factually distinguishable. In *Burnett v. Mortg. Elec. Registration Sys., Inc.* (Jt. MTD at 6-7), the plaintiff's complaint was deficient because it "attribute[d] actions to a large group of collective 'defendants,' which include[d] fifty *unknown* Doe defendants." 706 F.3d 1231, 1240 (10th Cir. 2013). In *Robbins v. Oklahoma* (Jt. MTD at 7), a §1983 action was dismissed without prejudice because "plaintiffs d[id] not allege facts sufficient to render their claim *plausible* under *Twombly*." 519 F.3d 1242, 1250-51 (10th Cir. 2008). *Robbins* is further distinguishable because "complaints in §1983 cases against individual government actors pose a greater likelihood of failures in notice and plausibility because they typically include complex claims against multiple defendants. The *Twombly* standard may have greater bite in such contexts, appropriately reflecting the special interest in resolving the affirmative defense of qualified immunity 'at the earliest possible stage of a litigation.'" *Id.* at 1249.

in a common course of conduct to defraud the State of Oklahoma, giving rise to a single injury and joint liability. Defendants undoubtedly have fair notice of the State's claims against them.

B. Oklahoma Law Recognizes the Availability of Joint and Several Liability in Actions Brought by or on Behalf of the State for Creating a Public Nuisance and Other Torts

The Petition alleges claims giving rise to joint and several liability. Joint liability remains a viable theory of recovery in "actions brought by or on behalf of the state." 23 O.S. §15(B); *In re Amendments to the Okla. Unif. Jury Instructions – Civ. (Second)*, 2014 OK 17 (Mar. 24, 2014) at Instruction 9.24 (stating joint liability instruction "***should be used only if the action accrued before November 1, 2011, or was brought by or on behalf of the State of Oklahoma***"). To establish such a recovery, the State must only show that Defendants created a "single injury," even if they were not acting in concert:

> The general rule is that where several persons are guilty of separate and independent acts of negligence which combine to produce directly a single injury, the courts will not attempt to apportion the damage, especially where it is impracticable to do so, but will hold each joint tort-feasor liable for the entire result. To make tortfeasors jointly liable, ***there must be a single injury***, there must be community in the wrongdoing and the injury must be in some way due to their joint work. ***It is not necessary that they be acting together or in concert if their concurring wrongful acts occasion the injury.***

Union Tex. Petroleum Corp. v. Jackson, 1995 OK CIV APP 63, ¶60, 909 P.2d 131 (internal citations omitted); *see also Northup v. Eakes*, 1918 OK 652, ¶9, 178 P. 266 ("Where, *although concert is lacking*, the separate and independent acts or negligence of several combine to produce directly a *single injury*, each is responsible for the entire result, even though his act or neglect alone might not have caused it.").

Many Oklahoma courts have applied the single injury rule to public nuisance claims. *Jackson*, 1995 OK CIV APP 63, ¶60; *see also Tidal Oil Co. v. Pease*, 1931 OK 740, ¶14, 5 P.2d 389; *Indian Territory Illuminating Oil Co. v. Bell*, 1935 OK 597, ¶10, 46 P2d 481; *Okla. City v.*

Miller, 1937 OK 164, ¶5, 65 P.2d 990; *British-American Oil Producing Co. v. McClain*, 1942 OK 89 ¶9, 126 P.2d 530. Here, the "single injury" is Oklahoma's opioid epidemic. The Petition pleads the ***entire*** State of Oklahoma has been affected and damaged by Defendants' collective actions. *See* ¶118. Moreover, as demonstrated above, the Petition describes an overarching scheme by which Defendants collectively defrauded and injured the State, as a whole, in a variety of ways. *See, e.g.*, ¶¶63-66 (discussing Defendants' funding and utilization of front groups to distribute "pro-opioid messages for Defendants with the same misrepresentations regarding the risk of addiction and benefits"); *see also* Section III *supra*.

Put simply, Defendants created a public nuisance (and committed other torts) causing a "single injury" that gives rise to the availability of joint and several liability. The Petition pleads the collective actions of all Defendants, whether done in conscious collusion or not, were a cause of Oklahoma's sweeping opioid epidemic.

C. The Petition Alleges a Claim for Public Nuisance

Defendants' actions have created a public nuisance on a greater scale than this State has ever seen, endangering the health, safety, peace, and welfare of the residents of the State of Oklahoma. Despite the Petition's allegations regarding its public nuisance claim, Defendants spend only ***one*** page addressing this claim out of 102 pages of briefing. Defendants buried their response to the State's public nuisance claim because it is subject to Oklahoma's liberal notice pleading standard.

To obtain dismissal of this claim, Defendants must show that the Petition "indicate[s] *beyond any doubt* that the [State] can prove *no* set of facts" that could entitle the State to relief under its public nuisance claim. *Frazier*, 1989 OK 73, ¶13. Defendants have not done so.

The Oklahoma Legislature generally defines a public nuisance as any nuisance[128] that affects an entire community, neighborhood or considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal. 50 O.S. §2. Defendants' actions certainly affect a community, neighborhood or considerable number of persons—they affect the ***entire*** State. Thus, the State is compelled to seek relief and abate the nuisance.

The suppression of public nuisances to protect the public health and morality has been described as one of the "most important duties of government." *Reaves v. Territory*, 1903 OK 92, ¶25, 74 P. 951 (citing *Phalen v. Virginia*, 49 U.S. 163, 168 (1842)). The Oklahoma Legislature has identified a variety of specific types of danger and injury to the public as public nuisances *per se*, such as improper maintenance of an industrial waste facility, smoking in certain public areas, and maintenance of unsafe or unsound foodstuffs.[129]

Historically, public nuisances were treated as crimes against the state; thus, the remedies against public nuisances generally reside with governmental authorities and officials. That is still the case in Oklahoma. *See* 50 O.S. §11 ("[a] public nuisance may be abated by any public body or officer authorized thereto by law."). Under Oklahoma law, the available remedies for public nuisance include: 1) an indictment or information; 2) a civil action; or 3) an abatement. *Id.* at §8. These remedies *are not* mutually exclusive. *See id.* at §6; *McNulty v. State*, 1923 OK 509, ¶10-12,

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[128] In Oklahoma, a nuisance consists of unlawfully doing an act, or omitting to perform a duty, which act or omission "[a]nnoys, injures or endangers the comfort, repose, health, or safety of others[.]" 50 O.S. §1.

[129] *See, e.g.*, 63 O.S. §1-1011 (maintenance of filth or other conditions conducive to the breeding of insects or rodents that might contribute to the spreading of diseases or other conditions adverse to the public health); 69 O.S. §1252, 1258 (improper maintenance of an industrial waste facility); 63 O.S. §1-1105 (maintenance of unsafe or unsound foodstuffs); 21 O.S. §1247 (smoking in certain public areas); 31 O.S. §102 (maintenance of hazardous conditions at airports); 63 O.S. 1-818.7 (maintenance of a group home for handicapped or disabled persons not in compliance with statutory requirements); 63 O.S. §§1-1020 to 1-1021(maintenance of a public bath not in compliance with statutory requirements); 74 O.S. §152.8 (transportation of oil or gas contrary to statutory requirements); and 82 O.S. §926.4 (pollution of waters of the State).

217 P. 467. And, the State may seek to hold Defendants jointly and severally liable for the resulting damages caused by the maintenance of a public nuisance. *See* Section V.B *supra*.[130]

Defendants nevertheless argue that it is not an unlawful act or omission to "market medications for their lawful indications." Jt. MTD at 34. Defendants' argument ignores the allegations in the Petition. The Petition alleges Defendants: unlawfully marketed their medications beyond their lawful indications by, among other things, exaggerating the benefits and understating the risks, ¶¶51-54, 56, 63-71; "engaged in 'deceptive trade practices' in violation of the Oklahoma Consumer Protection Act because Defendants made misrepresentations and omissions in marketing their opioids that deceived or could reasonably be expected to deceive or mislead consumers," ¶105; violated the OMFCA and OMPIA, ¶¶73-101; and "knew their misrepresentations were false and unsupported and "their marketing efforts often contradicted their own labels, which acknowledged the risk of abuse and addiction." ¶70, ¶¶118-119.

Second, Defendants incorrectly argue their actions cannot be a "nuisance" because they are done under the express authority of a statute. Jt. MTD at 34, n. 28. Quite the contrary:

> The fact that a person or corporation has authority to do certain acts does not give the right to do such acts in a way constituting an unnecessary interference with the rights of others. A license, permit or franchise to do a certain act cannot protect the licensee who abuses the privilege by erecting or maintaining a nuisance. The reasonableness or necessity of the acts complained of are for the jury to decide.

Briscoe, 1985 OK 43, ¶10. Here, although Defendants had the authority to manufacture, market and sell their opioids, they abused and exceeded that authority by falsely and fraudulently marketing their opioids.

[130] *Okla. City v. Tyetenicz*, 1935 OK 1187, 52 P.2d 849 (Court's syllabus), *overruled on other grounds*; *Okla. City v. Eylar* 1936 OK 614, 61 P.2d 649; *see also Phillips Petroleum Co. v. Vandergriff*, 1942 OK 94, ¶¶13-16, 122 P.2d 1020; *Northup*, 1918 OK 652, ¶9.

Third, Defendants assert that the State does not allege Defendants promoted opioids for unapproved or "off label" conditions in Oklahoma. To the contrary, the Petition alleges Defendants expanded the market for their opioids through a deceptive marketing campaign, including committing various unlawful deceptive and unfair trade practices that caused a devastating public health crisis in Oklahoma. Moreover, it is disingenuous for Defendants to jointly argue the State does not allege facts of any "off-label" promotion, when, among other things, ***all*** Defendants are aware that Defendant Cephalon pled guilty to claims related to promoting its opioid, Actiq, off label in 2008 and paid substantial fines and penalties.[131]

Defendants' suggestion that they have not created a public nuisance or do not have fair notice of the State's claim regarding the public nuisance is simply dishonest. Indeed:

- The President created a national opioid commission and officially declared the opioid epidemic a national public health emergency.[132]
- Senators are investigating various allegations against opioid manufacturers.[133]
- Certain Defendants previously pled guilty to this type of conduct.[134]

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[131] *Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing*, USDOJ.GOV (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (quoting Laurie Magid, acting U.S. attorney for the Eastern District of Pennsylvania at the time as stating, "These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients…*This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgement. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.*").

[132] Ali Vitali & Cory Siemaszko, *Trump Declares Opioid Crisis National Emergency*, NBCNEWS.COM (Aug. 10, 2017), https://www.nbcnews.com/storyline/americas-heroin-epidemic/trump-declares-opioid-crisis-national-emergency-n791576; *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis.

[133] UNITED STATES SENATE COMMITTEE ON FINANCE, *Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups* (May 8, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups; Katelyn Newman, *Senator Reveals First Findings in Opioids Inquiry*, USNEWS.COM (Sept. 6, 2017), https://www.usnews.com/news/national-news/articles/2017-09-06/mccaskill-releases-first-findings-from-opioids-investigation.

[134] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, THE NEW YORK TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html; U.S. Department of Justice Press Release, *Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing*, FDA.GOV (Sept. 29, 2008), https://www.fda.gov/iceci/criminalinvestigations/ucm260715.htm.

- Seven states, plus dozens of counties and cities, country are suing some or all of Defendants for their conduct.
- A bipartisan coalition of 41 attorneys general are investigating Defendants.[135]
- Oklahoma Legislature was forced to create a Commission on Opioid Abuse. ¶33.
- Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. ¶23.
- Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. And, the vast majority of these deaths involved opioids. *Id.*
- In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths. *Id.*
- In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate. ¶24.
- 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. ¶25.
- As of 2015, there were more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined. *Id.*
- In 2016, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident. ¶26.

Defendants have created a public nuisance of epic proportions.

This epidemic did not just appear from thin air. It did not come from a bacteria or virus. It was not spread from animals, insects or airborne agents. Doctors in Oklahoma did not just wake up one morning and decide to start writing more opioid prescriptions. No, the genesis of this epidemic is quite clear. Defendants poured millions of dollars into carefully calculated marketing strategies with reckless disregard for human life and for the peace, tranquility and economic well-being of the State of Oklahoma.

The State's public nuisance claim should not be dismissed.

D. The Petition Adequately Alleges a Claim for Unjust Enrichment

The State's unjust enrichment claim is subject to the liberal notice pleading standard of Section 2008(A) and therefore, "*must not* be dismissed for failure to state a legally cognizable

[135] *A.G. Schneiderman, Bipartisan Coalition of AGs Expand Multistate Investigation Into Opioid Crisis*, NY.GOV (Sept. 19, 2017), https://ag.ny.gov/press-release/ag-schneiderman-bipartisan-coalition-ags-expand-multistate-investigation-opioid-crisis.

claim *unless* the allegations indicate *beyond any doubt* that the litigant can prove *no* set of facts which would entitle him to relief." *Frazier,* 1989 OK 73, ¶13 (emphasis in original). Perhaps that is why, again, Defendants spend only ***one*** page addressing the unjust enrichment claim. Defendants wrongly contend the State's unjust enrichment claim should be dismissed for three reasons: (i) it is "derivative" of the State's other claims and thus fails for the same reasons; (ii) there is no "inequity" because the State was not harmed; and (iii) the State has an "adequate remedy at law" through its other claims. Jt. MTD at 36. These arguments are without merit.

Defendants' first argument—that the unjust enrichment claim is "derivative" of the State's other claims—is based on the assumption that all of the State's other claims will be dismissed. Jt. MTD at 36 (citing *Weaver v. Legend Senior Living, LLC*, No. CIV-16-1230-R, 2017 WL 3088416 (W.D. Okla. July 20, 2017) (dismissing unjust enrichment claim *after* dismissing plaintiffs' other claims)). This assumption is misplaced and premature. As set forth herein, *all* of the claims in the Petition should be upheld. However, even if only a single claim survives, the unjust enrichment claim would also survive under Defendants' "derivative" logic.

Defendants' second argument also fails because the Petition clearly pleads an "inequity that must be rectified," *i.e.*, that the State has been harmed by Defendants' collective conduct. *Id.* This harm is extensively discussed herein and need not be restated here. *See* ¶131. The State is entitled to recover Defendants' ill-gotten gains, which are monies paid for opioid prescriptions that, but for Defendants' deceptive marketing scheme, would never have been prescribed. ¶¶131-32. Thus, the Petition pleads an inequity that must be rectified.

Defendants' third and final argument likewise fails because the State is allowed to plead alternative theories of liability and is not required to prove at this stage of the proceedings that it has no adequate remedy at law. "Oklahoma procedure clearly permits pleading alternative

remedies, just as it allows alternative theories of recovery, as long as plaintiffs are not given double recovery for the same injury." *N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 1996 OK CIV APP 92, ¶24, 929 P.2d 288. Even under the more stringent federal standard, it would be premature to dismiss the State's unjust enrichment claim at this early stage. *See Valley View Agri, LLC v. Producers Cooperative Oil Mill*, No. CIV-15-1297-D, 2017 U.S. Dist. LEXIS 48993, at *7-8 (W.D. Okla. Mar. 31, 2017) (finding summary judgment on unjust enrichment claim "premature, because it has yet to be determined whether [plaintiff] has an adequate remedy at law").

E. The Petition Adequately Alleges Violations of the OMFCA, 63 O.S. §§5053.1-5053.7, Under Oklahoma Law

Defendants next seek to dismiss the State's claim for violation of the OMFCA. Defendants, however, admit there is ***no*** binding Oklahoma precedent that supports their erroneous contention that the Petition fails to state a claim under the OMFCA. Jt. MTD at 21, n.20. Instead, Defendants cherry-pick statements from factually inapposite federal cases to manufacture support for their arguments. *Id.* at 21-26.[136] Defendants offer no rational explanation why, if there is a "paucity of caselaw applying the OMFCA" (*Id.* at n.20), this Court should declare what facts can or cannot support a violation of the OMFCA before any discovery. Indeed, a plain reading of the statute demonstrates the Petition adequately alleges Defendants violated the OMFCA.

> The OMFCA is violated by any person who:
>
> (1) Knowingly presents, or ***causes to be presented***, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
> (2) Knowingly makes, uses, or ***causes to be made or used***, a false record or statement to get a false or fraudulent claim paid or approved by the state; [and]

[136] Citing to federal cases for non-binding insight as to interpretations of the *substantive elements* of claims under the OMFCA's federal counterpart (the False Claims Act or "FCA") is not itself objectionable; however, citing to federal cases for their application of an *evidentiary* requirement at the pleading stage that Oklahoma courts have never adopted is misleading and disingenuous. In reality, as shown below, ample federal cases demonstrate the viability of the State's claims here and that Defendants egregiously misrepresent what federal courts purportedly "require" to plead claims, similar to the ones asserted here, but brought under the federal FCA.

(3) ***Conspires*** to defraud the state by getting a false or fraudulent claim allowed or paid[.]

63 O.S. §5053.1(B)(1)-(3) (2007).

As an initial matter, Defendants wrongly contend the State does not seek relief for any period beyond November 1, 2016, because the Oklahoma Legislature clarified some of the language of the OMFCA by amendment in 2016, and, thus, only the version of the OMFCA in effect from November 1, 2007 through November 1, 2016 applies. Jt. MTD at 21, n.19. Defendants are wrong. The State seeks remedies under the OMFCA for false claims Defendants caused to be submitted from November 1, 2007 through November 1, 2016 and prospective relief (¶¶115, 120, 133), full restitution, damages and penalties through the pendency of this litigation. *Id.* ¶¶35-38, 91, 101. As such, (1) the 2007 version of the OMFCA applies to claims submitted to the State from November 1, 2007 through November 1, 2016, 63 O.S. §5053 *et seq.* (2007), 2007 OKLA. SESS. LAW SERV. CH. 137 (S.B. 889); and (2) the 2016 version of the OMFCA applies to claims submitted to the State ***after*** November 1, 2016. 63 O.S. §5053 *et seq.* (2016), 2016 OKLA. SESS. LAW SERV. CH. 44 (S.B. 1515).

Defendants point to no binding authority suggesting the 2016 amendments were intended to do anything but clarify existing law. To the contrary, the U.S. Congress amended the language in the OMFCA's federal counterpart, the FCA, in 2009 to "***clarify***" the text of the FCA. *See* U.S. SENATE REPORT OF THE JUDICIARY COMMITTEE, S. REP. 111-10, S. REP. NO. 10, 111TH CONG., 1ST SESS. 2009, 2009 U.S.C.C.A.N. 430, 437-42, P.L. 111-21, 2009 WL 787872 (Mar. 23, 2009), at *10-15 (Sect. 4: "***Clarifications*** to the [FCA] to reflect the original intent of the law"). And, the Oklahoma Legislature subsequently adopted these clarifications, effective November 1, 2016. *See* 2016 OKLA. SESS. LAW SERV. CH. 44 (S.B. 1515). Thus, the State respectfully submits the 2016

amendments do not affect the Court's analysis at this stage. Unless otherwise noted, the State cites the 2007 OMFCA herein for clarity and consistency.

Demonstrating the OMFCA's comprehensive scope and purpose, the Oklahoma Legislature broadly defined "knowingly" to mean "actual knowledge," "deliberate ignorance" or "reckless disregard", and made clear that "[n]o proof of specific intent to defraud is required" to find a violation. 63 O.S. §5053.1(A)(1) (2007). And, the Legislature further declared that "[a]ny person who" violates any provision of the OMFCA "is liable to the State of Oklahoma for a civil penalty of ***not less*** than Five Thousand Dollars ($5,000.00) and not more than ***Ten Thousand Dollars ($10,000.00)***, . . . ***plus three times the amount of damages*** which the state sustains because of the act of that person." *Id.* at §5053.1(B) (2007).[137]

Tracking the text and purpose of the OMFCA, the Petition sets forth in detail the fraudulent marketing scheme Defendants and their co-conspirators perpetrated for years to cause Oklahoma medical providers to submit thousands of false claims for reimbursement for unnecessary and excessive opioid prescriptions to Oklahoma Medicaid. ¶¶1-7, 21-91. Accepting these allegations as true, Defendants cannot credibly contend the Petition "indicate[s] *beyond any doubt* that the [State] can prove *no* set of facts" that could entitle the State to relief under the OMFCA. *Frazier*, 1989 OK 73, ¶13. Nor can Defendants truthfully claim they lack sufficient notice of the fraudulent conduct alleged. *Gay*, 1988 OK 150, ¶17. The Petition sufficiently pleads each element of the State's OMFCA claims.

[137] The 2016 amendments to the OMFCA did, however, increase the OMFCA's penalty provisions to require "a civil penalty of not less than Five Thousand Five Hundred Dollars and not more than Eleven Thousand Dollars, plus three times the amount of damages which the state sustains because of the act of that person." 63 O.S. §5053.1(B) (2016). The 2016 amendments also clarified that any person who violates the OMFCA "shall also be liable to this state for the costs of a civil action brought to recover any such penalty or damages." *Id.* at §5053.1(D) (2016).

1. The Petition Adequately Alleges Defendants Caused Medical Providers to Submit False and Fraudulent Claims to Oklahoma Medicaid

Defendants argue the Petition insufficiently pleads the submission of false claims to the State for two purported reasons. Jt. MTD at 21-22. First, they contend the State does not plead "*any* allegations of actual claims for payment," or the specific "details" of any such claim, as supposedly "required by" federal courts. *Id.* Second, Defendants assert the State has not adequately pled that any claim was "false or fraudulent" because the Petition does not state whether the State is asserting a theory of "legal" or "factual falsity." *Id.* at 22. Neither argument is correct.

a. The Petition Adequately Alleges the Details of Defendants' Fraudulent Scheme that Caused the Submission of False Claims to the State

Defendants' first argument is factually misleading and legally wrong. Demonstrating their adequate notice of the State's claims, Defendants contradict their assertion that the Petition contains no "allegations of actual claims for payment" in their own brief. *See* Jt. MTD at 23 (admitting the Petition Exhibits "indicate that the State ***continued to reimburse Medicaid claims*** for extended-release opioids into 2017"). The Petition identifies over *99,000* representative samples of claims for reimbursement for prescriptions of Defendants' branded opioids alone from 2007 to present. ¶¶34-39, Pet. Exs. 1-4. Clearly, the Petition alleges and demonstrates "actual claims for payment" submitted to the State.

Moreover, Defendants deceptively argue that the State has not yet spelled out all the details of each individual false claim. *See* Jt. MTD at 21-22. Defendants point to no Oklahoma authority that so conflates pleading with proof to require such an endeavor at the pleading stage. *Id.* Instead, Defendants argue that certain federal courts purportedly "require" the pleading of specific details about each individual claim submitted to the government under the heightened pleading standards

in federal court. *Id.*[138] But, Defendants egregiously misrepresent what *federal* courts actually "require" to state a federal FCA claim with particularity under the heightened federal pleading standards.

The majority of *federal* courts specifically do ***not*** require the pleading of granular details about individual claims, as Defendants contend, where, as here, a plaintiff alleges the defendants orchestrated a fraudulent scheme that caused third parties to submit false claims to the government:

> We accordingly join our sister circuits in holding that the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint, ***especially not when the relator alleges that the defendant knowingly caused a third party to submit a false claim...The central question, instead, is whether the complaint alleges particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted***...To win his case, a relator does ***not*** need to identify 'exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted.' We ***decline*** to read Rule 9(b) as requiring more factual proof at the pleading stage than is required to win on the merits.

United States ex rel. Health v. AT&T, Inc., 791 F.3d 112, 126-27 (D.C. Cir. 2015) (citing decisions from the U.S. Courts of Appeals for the First, Third, Fifth, Seventh, Ninth and Tenth Circuits).[139]

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[138] Defendants incompletely quote a statement from a Tenth Circuit opinion as purportedly *requiring* the pleading of a laundry list of specific details to state a claim under the heightened federal pleading standards. Jt. MTD at 21 (quoting *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006)). But, a simple reading of the *Sikkenga* opinion reveals that Defendants' altered quotation: (i) pertained only to the plaintiff's claim that the defendant, *itself*, had submitted false claims to the government, not that a defendant's scheme *caused* a third party to submit such claims (as pled here); and (ii) does *not* state the laundry list Defendants quote are mandatory requirements, but instead, are simply examples of "the types of information that may *help* a [plaintiff] to state his or her claims [under this disparate theory] with particularity. *These details do not constitute a checklist of mandatory requirements that must be satisfied for each allegation included in a complaint.*" *Id.* at 727. In fact, *Sikkenga* held the plaintiff adequately alleged the defendant had "caused" a third party to submit false claims to the federal government and found there was "no support for the defendants' position that a *causing to be presented* claim requires a direct order to present a false claim." *Sikkenga*, 472 F.3d at 715, n.17. Moreover, in *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010) (Jt. MTD at 21), the Tenth Circuit *reversed* a district court's dismissal of FCA claims on the pleadings because, even under the heightened federal pleading standards, a plaintiff "need only show the *specifics of a fraudulent scheme* and provide an adequate basis for a *reasonable inference* that false claims were submitted as part of that scheme." *Id.* at 1171.

[139] *See also, e.g., Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014) (reversing dismissal and explaining: (i) the court "had never held that a plaintiff must identify a specific claim for payment *at the pleading stage* of a case to state a claim for relief"; (ii) the "text of the FCA...does not require that the exact content of the false claims in question be shown"; and (iii) requiring such "detail at the pleading stage would be *one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and*

"Standing alone, raw bills—even with numbers, dates and amounts—are not fraud without an underlying scheme to submit the bills." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189-90 (5th Cir. 2009). It is the fraudulent "scheme in which particular circumstances constituting fraud may be found that make it highly likely that fraud was consummated[.]" *Id.* at 190.

Indeed, scores of federal FCA cases brought against drug manufacturers (including some of the Defendants named here) demonstrate that when the manufacturers allegedly engaged in a scheme that caused medical providers to submit false claims to the government, any analysis of the sufficiency of the pleading must focus on the conduct of the perpetrators of the scheme—*not* the minutia of the individual claims submitted by providers as a result of the scheme. *See, e.g.*, *United States v. Johnson & Johnson*, No. 12-7758, 2017 U.S. Dist. LEXIS 83335, at *4-6, *16-17 (D.N.J. May 31, 2017) (denying Janssen Defendants' motion to dismiss under heightened federal pleading standards, where they were alleged to have utilized a nationwide marketing scheme that misrepresented risks related to drug and caused physicians to write medically unnecessary prescriptions, despite no allegations about any "specific claim for payment" or "reimbursement"). [140] These courts' rationale is straightforward: the FCA seeks to hold

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significantly more than any federal pleading rule contemplates" and one that would undermine the federal FCA's "effectiveness as a tool to combat fraud against the United States"); *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 86-87 (2d Cir. 2017) (refusing to "require" that every federal FCA complaint allege "specific identified false invoices submitted to the government" because, even under the heightened federal pleading standard, "a complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government" and a holding to the contrary would "*render the FCA toothless as to particularly clever fraudulent schemes*"); *United States v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 777 (7th Cir. 2016) ("Our case law establishes that a plaintiff does not need to present, *or even include allegations about*, a specific document or bill that the defendants submitted to the Government.").

[140] *See also, e.g.*, *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2016 U.S. Dist. LEXIS 25723, at *34-44 (E.D. Pa. Mar. 1, 2016) (denying drug manufacturer's motion to dismiss under heightened federal pleading standard where plaintiff alleged "that Defendant's marketing activities created the market for the off-label use of Vfend and that Defendant purposefully encouraged such a use even though it had no credible evidence that Vfend would be effective in that context"); *United States ex rel. Brown v. Celgene Corp.*, No. 10-3165-GHK (SSx), 2014 U.S. Dist. LEXIS 99815, at *33-37 (C.D. Cal. July 10, 2014) (federal FCA plaintiff "is not required to identify representative examples of false claims" particularly where "the defendant is alleged to have induced third parties to submit false claims"); *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 676-79 (E.D. Pa. 2010) (finding

accountable "those who cause the claims or statements to be false in the first place." *Mason v. Medline Indus.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010).

Thus, although the State is not required to meet the federal pleading standards, the State has pled what the weight of federal courts *actually* require to sufficiently put Defendants on notice of the circumstances of the fraud at issue here—details regarding the massive scheme that Defendants and their co-conspirators executed to defraud the State by causing medical providers to submit claims for reimbursement to Oklahoma Medicaid for "unnecessary or excessive opioid prescriptions" and an adequate basis for a reasonable inference that such claims were submitted. ¶¶1-7, 34-39, 51-91, Pet. Exs. 1-4. Nothing more is required under Oklahoma law. *Gay*, 1988 OK 150, ¶8. As such, Defendants' improper invitation to transform the State's pleading burden into an unrealistic evidentiary requirement must be rejected. *See id.* at ¶18.

b. The Petition Adequately Alleges the Claims Defendants Caused to be Submitted to the State were "False" and "Fraudulent"

Defendants next contend the State does not allege that any claim submitted as a result of Defendants' marketing campaign was "false or fraudulent." Jt. MTD at 22. This assertion is demonstrably false, as that is precisely what the Petition alleges. *See* ¶¶75, 82, 83, 89-90. Defendants' real argument is that the State is required to lay out the details of the legal theories and strategies the State intends to pursue at trial to demonstrate ***why*** these claims were false. Jt. MTD at 22 (claiming the State was required to plead whether Defendants' conduct fits within a theory of "factual" or "legal falsity").[141] This is incorrect.

"no authority" in the Third Circuit requiring a *qui tam* relator "to identify in his Complaint a specific false claim actually submitted to the Government...especially where, as here, the Relator has alleged that the Defendant itself did not submit the false claims, but induced the third parties to do so").

[141] Defendants' lone case, *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162 (10th Cir. 2016), was a summary judgment opinion decided based on a fully developed evidentiary record and, thus, the court there necessarily weighed and considered the evidence against the specific theories alleged. Imposing such evidentiary demands at the pleading stage here would fly in the face of the pleading standards under Oklahoma law.

Defendants cite no Oklahoma law suggesting a petition must delineate the minute details of a specific legal theory to proceed into discovery. *Id.* The exact opposite is true. The Oklahoma Supreme Court expressly holds that "to withstand a motion to dismiss it is ***not*** necessary for a plaintiff to either identify a specific theory of recovery or set out the correct remedy or relief to which he/she may be entitled." *Indiana Nat'l Bank*, 1994 OK 98, ¶4. Moreover, even under the heightened federal pleading standard (which Oklahoma courts have refused to adopt), "a plaintiff need ***not*** plead his legal theory of fraud in the complaint; the complaint must plead only the facts that form the basis for the fraud[.]" *United States v. Honeywell Int'l, Inc.*, 798 F. Supp. 2d 12, 19 n.1 (D.D.C. 2011) (rejecting the argument that any pleading rule "requires a plaintiff to explain in its complaint ***why*** a particular statement is fraudulent to survive a motion to dismiss") (collecting cases); *see also United States ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1036 (S.D. Cal. 2012) (finding defendants' argument that plaintiff's claims must fit into two "narrow categories" was "unpersuasive and unsupported by the statute, its history, and the Supreme Court's interpretation of the FCA" (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) ("The FCA reaches beyond claims which might be legally enforced, to ***all*** fraudulent attempts to cause the government to pay out sums of money.")); *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (the FCA reaches "***all*** types of fraud, ***without qualification***, that might result in financial loss to the government.").

Defendants' quibbling over the precise *legal theory* the State will present at trial is a red herring, for "fraud is fraud," and "[a]ll that matters is whether the false statement or course of conduct causes the government to 'pay out money or to forfeit moneys due.'" *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174-77 (9th Cir. 2006). The Petition alleges the details of Defendants' knowingly fraudulent conduct that caused medical providers to submit

claims to the State under false pretenses. *See* ¶¶51-66; *see also* Section III *supra*. Nothing more is required.

Nevertheless, even if the Court viewed the Petition through the lens of the "legal theories" in which Defendants attempt to cabin the State's claims, Defendants' arguments still fail. *First*, the claims Defendants caused to be submitted to the State were "factually false" because they sought reimbursement for drugs that did not do what Defendants claimed they did and contained risks Defendants claimed they did not contain. *Cf.* Jt. MTD at 22. The Petition's core allegation is that Defendants and their co-conspirators convinced the medical industry that each Defendant's opioids safely and effectively could be prescribed more frequently, to a broader range of patients, without (or with a limited) risk of addiction. ¶¶1-6, 51-72. Oklahoma medical providers, thus, wrote and filled these prescriptions and, for Oklahoma Medicaid beneficiaries, submitted claims to the State for reimbursement. ¶¶34-40. Such claims were infected by Defendants' deception. ¶¶34, 75-101. For example, each reimbursement claim for an opioid prescription described a drug that, according to Defendants and their co-conspirators, carried with it a risk that "less than 1%" of its users would become addicted to the drug. ¶61. This description, like the multitude of other representations Defendants made during their scheme, was false. ¶¶67-71. And, by inducing providers to prescribe their drugs based on false descriptions of the medical efficacy of the drugs, Defendants caused the submission of claims for reimbursement to the State that incorrectly described the goods provided. A contrary conclusion at this stage necessarily would require the Court not to accept the Petition's allegations as true, which is not the appropriate standard. *Indiana Nat'l Bank*, 1994 OK 98, ¶3.

Second, the Petition alleges Defendants' disinformation campaign "caused" the submission of claims for reimbursement for "***unnecessary or excessive opioid prescriptions***" to Oklahoma

Medicaid. ¶¶34-39, 75-101. The claims Defendants caused to be submitted to the State were "legally false" because they sought reimbursement for costs that were not reimbursable by Oklahoma Medicaid. *See, e.g., United States ex rel. Galmines v. Novartis Pharms. Corp.*, No. 06-3213, 2013 U.S. Dist. LEXIS 83100, at *30-31 (E.D. Pa. June 13, 2013) ("claims may be false if they claim reimbursement for services or costs that...are not reimbursable"); *see also, e.g., Celgene*, 2014 U.S. Dist. LEXIS 99815, at *15 ("the falsity here lies in the submission of non-reimbursable claims...And courts are in broad agreement that a claim for reimbursement from Medicare or Medicaid is 'false' when it is statutorily ineligible for such reimbursement.").

The federal Medicaid statutes grant exclusive authority to the states to define what is sufficiently "***medically necessary***" to receive Medicaid coverage and, in Oklahoma, that definition is supplied by the Oklahoma Health Care Authority ("OHCA") in Oklahoma Administrative Code ("OAC") §317:30-3-1. *Pharmcare Okla., Inc. v. State Health Care Auth.*, 2007 OK CIV APP 5, ¶¶23-26, 152 P.3d 267.[142] Oklahoma Medicaid legally cannot reimburse claims for products or services that do not meet this definition. OAC §317:30-3-1(d). Therefore, "***[i]n order to be eligible for payment***" for any reimbursement from Oklahoma Medicaid, *every* medical provider must enter a standard form Provider Agreement, OAC §317:30-3-2, under which *every* medical provider expressly "certifies with each claim for payment that the services or products for which payment is billed by or on behalf of Provider were ***medically necessary as defined by OAC 317:30-3-1(f)***" and complies with both the OMFCA and OMPIA.[143] Through this Provider Agreement, "the

[142] The OHCA also retains the authority to review any pharmacy claims for reimbursement to "insure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results." *Id.*, ¶25 (citing OAC §317:30-5-86).

[143] OHCA General Provider Agreement ("Provider Agreement") at ¶4.3(g). The Provider Agreement is a standard, uniform form that is publicly available on the OHCA's website. *See* OHCAPROVIDER.COM, https://www.ohcaprovider.com/Enrollment/Prod/LegalDocs/General_Agreement_2017-1.pdf (last visited Oct. 26, 2017). Moreover, with every claim for reimbursement submitted to Oklahoma Medicaid by a physician who prescribed Defendants' opioids to an Oklahoma Medicaid beneficiary, the physician must expressly certify: "I certify that the

provider certifies all information submitted on claims is accurate and complete, assures that the State Agency's requirements are met and assures compliance with all applicable Federal and State regulations." OAC §317:30-3-2. Such certifications are, by law, a material condition to the payment of any claim by Oklahoma Medicaid. *Id.* And, the OHCA defines "[m]edical necessity" as an assessment that considers, *inter alia*, the following:

> (3) ***Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes***;
> (4) Services must be ***necessary to alleviate a medical condition*** and must be required for reasons other than convenience for the client, family, or medical provider;
> (5) Services must be delivered in the ***most cost-effective manner*** and most appropriate setting; and
> (6) Services must be ***appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity***.

OAC §317:30-3-1(f). As such, by operation of law, *every* claim for reimbursement related to opioids submitted to Oklahoma Medicaid (including each of the more than 99,000 identified in the Petition) necessarily was based on Oklahoma medical providers' certifications that the "services or products" provided (*i.e.*, prescription opioids) met the OHCA's definition of "medical necessity." *See, e.g.*, Provider Agreement at ¶4.3(g); *see also* OAC §317:30-3-2.

Here, however, the false representations Defendants and their co-conspirators imbedded in the Oklahoma medical community prevented providers from being able to accurately and completely assess the "medical necessity" of Defendants' drugs for any patient in the first place. ¶¶1-4, 34, 51-72. As a result, these providers' compliance certifications to Oklahoma Medicaid were based on a false understanding of the true characteristics and safety of Defendants' drugs,

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services listed above were medically indicated and necessary to the health of the patient..." *See* CMS.GOV, Form 1500, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. Just like the Provider Agreement, the CMS Form 1500 is a standard, uniform form that is publicly available on the Centers for Medicare and Medicaid's website. *See id.*

rendering the claims for reimbursement they submitted non-reimbursable under Oklahoma Medicaid regulations—or, in other words, "legally false." As such, Defendants fraudulently caused "the Oklahoma Medicaid program to approve and pay [legally] false claims." ¶¶98, 73-101.

Moreover, based on the extent of Defendants' misinformation campaign, the statistical increase in prescriptions for Defendants' opioids and the unprecedented epidemic that has overcome this State as a result of Defendants' scheme, it is impossible to infer that *all 99,000-plus* claims for reimbursement for prescriptions of Defendants' opioids identified in the Petition actually were prescribed for "medically necessary" purposes, as required for reimbursement under Oklahoma Medicaid regulations. *See, e.g., Novartis*, 2013 U.S. Dist. LEXIS 83100, at *30-31 (denying motion to dismiss where complaint alleged fraudulent marketing scheme caused "at least some of the claims submitted to government healthcare programs" for reimbursement for prescriptions of defendant's drugs to not be "reimbursable"); *see also* OAC §317:30-3-1(f) (defining factors that determine "medical necessity"). If the Petition's allegations that Defendants caused the submission of false claims for "unnecessary or excessive opioid prescriptions" (¶¶34-40) that "would not have been submitted and would not have been paid by the Oklahoma Medicaid program but for Defendants' improper false marketing" (¶99) are taken as true, the only logical inference that can be drawn is that *at least one* of the reimbursement claims Defendants caused to be submitted to the State was for a "medically unnecessary" purpose and, thus, was non-reimbursable or "legally false." *See, e.g., Novartis*, 2013 U.S. Dist. LEXIS 83100, at *30-31.[144]

[144] The fact that the FDA has approved a drug for certain treatments does not render a prescription for that drug "medically necessary" and, thus, reimbursable under Medicare or Medicaid. *See, e.g., Johnson & Johnson*, 2017 U.S. Dist. LEXIS 83335, at *12-14 (denying Janssen Defendants' motion to dismiss where, "despite FDA approval," relators contended marketing scheme caused submission of reimbursement claims for drugs that may not have been "reasonable and necessary" under Medicare/Medicaid); *see also, e.g., United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (although "a product may be sufficiently 'safe' and 'effective' to secure FDA approval for a given use,...its use might nonetheless not be sufficiently 'reasonable and necessary' for patient care to warrant Medicare reimbursement for its use."); *Int'l Rehabilitative Scis., Inc. v. Sebelius*, 688 F.3d 994,

2. The Petition Adequately Alleges OMFCA Materiality

Next, Defendants argue their fraudulent marketing scheme was not "material" to the State's reimbursement of claims submitted to Medicaid. *See* Jt. MTD at 23-24. Defendants are wrong.

Under the OMFCA, "'[m]aterial' means having a natural tendency to influence or be capable of influencing the payment or receipt of money or property[.]" 63 O.S. §5053.1(A)(3) (2016). The Petition specifically alleges that "false claims would not have been submitted and would not have been paid by the Oklahoma Medicaid program but for Defendants' improper false marketing[,]" (¶99), and that Defendants purposefully concealed the truth about their campaign from the State (¶72)—two facts the Court would have to disregard to endorse Defendants' argument. Defendants' argument is based entirely on federal *qui tam* cases filed by private citizen-whistleblowers in which the allegedly defrauded governmental entity chose ***not*** to intervene, thus, allowing those courts to infer the government believed it was not defrauded by the conduct alleged.[145] That inference is impossible here, for the State itself has brought this action. Nothing could be more probative of whether the State deems Defendants' conduct to be "material."

Further, the State has demonstrated the "materiality" of the epidemic Defendants thrust onto Oklahoma citizens by taking unprecedented actions:

- The Oklahoma Legislature is actively working to pass stricter legislation to combat opioid over-prescription. ¶29.
- The Governor's and Attorney General's Task Force on Mental Health, Substance Abuse and Domestic Violence has specifically endeavored to determine the economic impact of this epidemic on the State. ¶33.

1002 (9th Cir. 2012) ("FDA clearance, however, is *necessary*, but not *sufficient*, for Medicare coverage."); *Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012) ("While FDA approval may thus inform the Secretary[of Health and Human Services]'s decision as to whether a device is 'reasonable and necessary,' it cannot tie the Secretary's hands.").

[145] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1998 (2016) (Jt. MTD at 23) (*qui tam* suit in which the "United States declined to intervene"); *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (Jt. MTD at 23) (finding, where government "declined to intervene" and relator conceded the Government would have paid claims with full knowledge of the alleged fraud, the court did "not think it appropriate for a private citizen to enforce these regulations through the [FCA]"); *United States v. Catholic Health Sys. of Long Island Inc.*, No. 12-cv-4425 (MKB), 2017 U.S. Dist. LEXIS 50696, at *2 (E.D.N.Y. Mar. 31, 2017) (Jt. MTD at 23) ("The United States and the State of New York declined to intervene").

- The State has invested substantial funds in developing comprehensive prescription drug abuse education, intervention and prevention programs. ¶46.
- The State has expended significant public resources to enhance its opioid prescribing and dispensing guidelines, public health surveillance systems and hospital emergency department protocols. ¶¶47-49.

Such comprehensive actions demonstrate the "influence" Defendants' fraudulent scheme has had on the State of Oklahoma. *See* 63 O.S. §5053.1(A)(3) (2016).

The federal cases Defendants cite stand for the unremarkable proposition that when a private citizen files suit on the government's behalf **that the government later refuses to endorse**, courts should rigorously analyze the allegations to ensure false claims liability is not extended to "minor or insubstantial" noncompliance with regulations that even the government does not intend to enforce, despite its "actual knowledge" of their violation. *See Escobar*, 136 S. Ct. at 2003-04. These cases do not involve a suit in which the government *itself* seeks recompense for the defendants' fraud; nor do they address a scheme of the magnitude alleged here. But, they do make clear the "materiality" requirement is met when the alleged misrepresentations go to the "very essence of the bargain" entered with the government, which is undoubtedly present here.[146]

In sum, a material condition to any payment by Oklahoma Medicaid is the provider's certification of compliance with all of the "State Agency's requirements" set forth above. *See* Section V.E.1.b *supra*; *see also* OAC §317:30-3-2. The State expressly conditions ***all*** reimbursement payments on medical providers' certifications "that the services or products for which payment is billed...were medically necessary as defined by OAC 317:30-3-1(f)[,]" Provider Agreement at ¶4.3(g). These requirements represent the "very essence of the bargain" struck by

[146] *See, e.g., United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 109-10 (1st Cir. 2016) (applying U.S. Supreme Court's "materiality test" on remand to find claims under federal FCA sufficiently pled because misrepresentations about medical providers' licenses went to the "very essence of the bargain" struck by government to provide Medicaid coverage).

the State in providing Medicaid coverage for its citizens. *See Escobar*, 842 F.3d at 109-10. Defendants' collusive scheme to flout these requirements was and is material to the State.

3. The Petition Demonstrates that Defendants Caused False and Fraudulent Claims to be Presented to the State

Defendants argue the State does not allege any false claim was "presented" to the State. Jt. MTD at 24. Defendants are wrong. The Petition specifically alleges Defendants caused thousands of claims to be presented to the State. ¶¶34-39, 73-101 & Pet. Exs. 1-4. And, the Petition goes further by showing the State, in fact, reimbursed these claims. ¶¶34-39, 99 & Pet. Exs. 1-4.

4. The Petition Adequately Alleges Defendants' Made False Representations to Get False and Fraudulent Claims Paid by the State

Defendants next argue the State's claims under sub-section 5053.1(B)(2) of the OMFCA should be dismissed for failure to adequately allege (i) "a false statement" or (ii) "the requisite purpose and intent" to have any false or fraudulent claims paid or approved. Jt. MTD at 24-25 (citing 63 O.S. §5053.1(B)(2) (2007)). Defendants are wrong again on both accounts.

First, Defendants' "false statement" argument fails. As shown above, the Petition alleges Defendants' scheme caused numerous "false or fraudulent claim[s]" to be submitted to and "paid or approved by the" State. ¶¶34-39, 74-101. Moreover, the Petition states several examples of false "records" Defendants and their co-conspirators "made" or "used" to further their campaign and false statements made by Defendants to cause medical providers to prescribe more opioids. ¶¶54-57, 61-65, 67-70. Defendants offer no argument to refute these allegations and no reason for the Court to disregard them. *See* Jt. MTD at 25.

Instead, Defendants isolate certain statements from paragraph 53 of the Petition and contend these statements, *alone*, are not "actionably *false*." *Id.*[147] This argument misses the forest for the trees. The Petition alleges Defendants colluded to perpetrate a scheme of unprecedented scope and magnitude for decades and specifically identifies a plethora of false statements and false records Defendants made and used to pull it off. ¶¶54-57, 61-70. Analyzing these statements in isolation would require the Court to ignore the 134 other paragraphs of the Petition entirely. Because Defendants do not challenge the falsity of the vast majority of the statements and records pled, much less their fraudulent course of conduct as a whole, this argument fails outright.

Second, Defendants' "purpose and intent" argument likewise fails. The OMFCA expressly does *not* require "proof of specific intent to defraud." 63 O.S. §5053.1(A)(1) (2007). Instead, the statute defines "knowingly" as "actual knowledge," "deliberate ignorance" and "reckless disregard of the truth or falsity of the information[.]" *Id.*[148] The Petition specifically alleges Defendants and their co-conspirators acted "knowingly," (¶¶75, 83) and pleads detailed facts demonstrating the purpose of this scheme was to increase Defendants' opioid sales, no matter the cost. ¶¶2-4, 23-72, 75-101. Section 2009(B) states, "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally." *See* 12 O.S. §2009(B). Thus, the Petition's allegations of Defendants' "purpose and intent" exceed what is required at this stage.

Nonetheless, Defendants contend the State was required, and allegedly failed, to plead that Defendants specifically intended that the State "rely" on Defendants' statements to medical providers as a condition of paying providers' claims. Jt. MTD at 25-26. This argument ignores the

[147] Defendants' arguments about these statements are unsupported by any pertinent authority. Jt. MTD at 25. For example, Defendants' statement that "a lack of evidence supporting a statement does not necessarily make it *false*" is belied by common sense, any reasonable construction of the word "false" and the OMFCA's prohibition against acting in "deliberate ignorance" and "reckless disregard" of the truth. 63 O.S. §5053.1(A) (2007).
[148] The OMFCA's conspiracy provision does not impose any intent element. 63 O.S. §5053.1(B)(3) (2007).

Petition. ¶¶2-6, 75-81, 83-89. And, it ignores the text of the OMFCA, which does not require "specific intent to defraud[.]" 63 O.S. §5053.1(A)(1) (2007).

Defendants' lone authority, *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (Jt. MTD at 25-26), does not save their argument. According to the U.S. Congress, the *Allison Engine* court so wrongly interpreted the elements of the federal FCA that Congress amended the federal FCA to "clarify and correct" this "erroneous interpretation" of the statute:

> In *Allison Engine*, the Supreme Court held that Section 3729(a)(2) of the FCA requires the Government to prove that "a defendant must intend that the Government itself pay the claim," for there to be a violation. 128 S. Ct. at 2128. As a result, even when a subcontractor in a large Government contract knowingly submits a false claim to general contractor and gets paid with Government funds, there can be no liability unless the subcontractor intended to defraud the Federal Government, not just their general contractor. This is contrary to Congress's original intent in passing the law and creates a new element in a FCA claim and a new defense for any subcontractor that are inconsistent with the purpose and language of the statute.[149]

The Oklahoma Legislature similarly amended the OMFCA to clarify its language in 2016. *See* Section V.E *supra*. Thus, this Court is neither bound by nor beholden to the *Allison Engine* court's "erroneous" interpretation of the language in the federal FCA. And, the Oklahoma Legislature's 2016 amendments to the OMFCA demonstrate that, like Congress, the Legislature does not approve of the "erroneous" creation of a specific intent element that defeats the purpose of the statute. The Court should reject Defendants' invitation to read this "new element" into the law.

But, even if this erroneous reading of the statute applied, *Allison Engine*'s holding was limited to the principle that "a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct." 553 U.S. at 672. Here, the Petition alleges Defendants made their misrepresentations to Oklahoma medical providers with the specific intent

[149] S. REP. 111-10, S. REP. NO. 10, 111TH CONG., 1ST SESS. 2009, 2009 U.S.C.C.A.N. 430, 437-42, P.L. 111-21, 2009 WL 787872 (Mar. 23, 2009), at *10-15.

that providers prescribe more opioids to patients and with actual knowledge that these providers "had treated and would continue to treat Oklahoma Medicaid patients." ¶¶76, 85. Moreover, numerous federal courts correctly have found that the "natural, ordinary and reasonable consequences" of a medical product manufacturer's false information scheme is the submission of claims for reimbursement to Medicare and Medicaid.[150] The Petition sufficiently alleges Defendants' "purpose and intent."

5. The State's Claims Are Not Barred by any Statute of Limitations

Finally, Defendants wrongly claim the State's OMFCA claims should be partially dismissed based on Defendants' statute of limitations affirmative defense. Jt. MTD at 26; *see, e.g.*, *Moneypenney v. Dawson*, 2006 OK 53, ¶2, 141 P.3d 549 (petition should not be dismissed on limitations grounds "unless the face of the petition shows ***beyond doubt*** the action is time-barred").[151] None of the State's OMFCA claims are limited in any way by the OMFCA's purported "six-year statute of limitations." Jt. MTD at 26 (citing 63 O.S. §5053.6(B)(1) (2007)).

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[150] *See, e.g.*, *United States ex rel. Nevyas v. Allergan, Inc.*, No. 09-432, 2015 U.S. Dist. LEXIS 86243, at *16 (E.D. Pa. July 2, 2015) (finding submission of claims to government funded healthcare programs for reimbursement for prescriptions was the "natural consequence" of scheme to induce physicians to write prescriptions for manufacturer's drugs); *Medline Indus.*, 731 F. Supp. 2d at 740-41 (where "natural and reasonable consequence" of surgical supplies manufacturer's scheme was healthcare providers' claims for reimbursement to government, *Allison Engine* scienter requirement met); *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007) ("Given the significant proportion of medical care in this country that is financed by Medicare and Medicaid, relators have drawn a reasonable inference that claims for reimbursement regarding off-label uses of Lovenox were submitted to the federal government or the State of Illinois for payment."); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243-44 (3d Cir. 2004) (reversing district court's dismissal on pleadings, where plaintiff alleged defendant "created and pursued a marketing scheme that it knew would, if successful, result in the submission by [health systems] and others similarly situated of compliance certifications required by Medicare.").

[151] Defendants' related argument that "conduct predating the OMFCA's enactment is plainly non-actionable" is baseless. Jt. MTD at 26. Through its *OMFCA* claims, the State seeks the remedies provided under the OMFCA for claims submitted from November 1, 2007, the OMFCA's effective date, through the present. *See, e.g.*, ¶¶34-39, 73-91. For the false claims Defendants and their co-conspirators caused to be submitted to the State prior to November 1, 2007, the State seeks the remedies provided under the OMPIA, which has prohibited the same conduct as that prohibited by the OMFCA since July 1, 1989, and is not limited by any statute of limitations or repose. *See* 56 O.S. §§1001 *et seq.*; *see also* Section V.F *infra*; ¶¶92-101. Moreover, every action Defendants and their co-conspirators took to further their conspiracy clearly will be relevant to proving the State's claims at trial. *See* 12 O.S. §2401.

The State brought this action in its sovereign capacity to vindicate public rights and to recover costs. ¶7. Because "statutes of limitation do not apply to a government entity seeking in its sovereign capacity to vindicate public rights," Defendants' limitations argument fails. *Okla. City Mun. Improvement Auth. v. HTB, Inc.*, 1988 OK 149, ¶5, 769 P.2d 131. The only exception to this rule is where "a statute of limitations specifically provides" that it applies to the State. *State ex rel. Okla. DOT v. Bd. of Cty.* 2007 OK CIV APP 126, ¶8, 174 P.3d 1010. But, the "six-year statute of limitations" in the 2007 OMFCA, upon which Defendants rely, expressly does *not* apply to actions brought *by* the State; it only applies to *qui tam* actions brought by private citizens. *See* 63 O.S. §5053.6(B)(1) (2007) (limitations periods apply only to civil actions brought "under subsection B of Section 3 of this act" or §5053.3(B), the provision allowing for a private citizen to file a *qui tam* suit without government involvement). As such, no statute time-bars any of the State's OMFCA claims. *See, e.g., HTB, Inc.*, 1988 OK 149, ¶5.

F. The Petition Adequately Alleges Violations of the OMPIA, 56 O.S. §§1001-1008

Defendants' arguments for dismissal of the State's OMPIA claims also are meritless. *See* Jt. MTD at 26-28. Though disjointed, Defendants appear to raise two arguments. First, Defendants contend they are not subject to civil liability under the OMPIA. *Id.* Second, Defendants argue the State fails to state a claim for violations of the OMPIA. *Id.* Defendants' arguments fail.

1. Defendants are Subject to Civil Liability Under the OMPIA

Defendants' argument that "the OMPIA is a criminal statute that does not authorize a civil claim against Defendants" is wrong. *Id.* Quite the contrary, "[a] criminal action ***need not*** be brought against the person before ***civil liability*** attaches under" section 1007(B) of the OMPIA. 56 O.S. §1007(B)(2). The OMPIA imposes civil liability, separately from and in addition to, criminal penalties, on "any person who receives payment for furnishing goods or services under the

Oklahoma Medicaid Program" in violation of "paragraphs 1 through 6 of subsection A of Section 1005." *Id.* at §1007(B). In turn, like the OMFCA, section 1005(A)(1) of the OMPIA is violated by any person who "willfully and knowingly" makes or "cause[s] to be made a claim, knowing the claim to be false, in whole or in part, by commission or omission[.]" *Id.* at §1005(A)(1). The Petition alleges precisely that. ¶94. And, the OMPIA expressly authorizes the "Office of the Attorney General" to investigate and bring civil actions for Medicaid fraud in that violates the OMPIA. 56 O.S. §1003. Under the plain language of the statute, Defendants cannot escape "civil liability" for violating the OMPIA.

Defendants, however, argue the OMPIA is not intended to reach their conduct because they do not ***directly*** receive payments from Oklahoma Medicaid. Jt. MTD at 26. But, they cite no authority to support this narrow reading of the statute. The OMPIA applies to "any ***person***" who receives any "payment for furnishing goods or services under the Oklahoma Medicaid Program" and does not state that such payment must be made directly by Medicaid. 56 O.S. §1007. And, the OMPIA expressly defines "person" to include anyone "who is ***not*** a provider under the Oklahoma Medicaid Program but ***who provides goods or services to a provider under the Oklahoma Medicaid Program for which the provider submits claims to the Oklahoma Medicaid Program*** or its fiscal agents[.]" *Id.* at §1002(8). Defendants perfectly fit this definition. Moreover, Defendants' construction effectively would read the phrase "cause to be made" entirely out of the OMPIA's unlawful acts provision. *See Id.* at §1005(A)(1).

The Petition specifically alleges Defendants ***caused*** "providers" to submit to the State claims for unnecessary and excessive opioid prescriptions that "would not have been submitted and would not have been paid by the Oklahoma Medicaid program but for Defendants' improper false marketing." ¶99. Defendants' suggestion that the OMPIA allows the orchestrators of a

scheme, who caused such false claims to be made in the first place, to violate the OMPIA with impunity cannot be credited. Defendants are subject to the civil liability provisions of the OMPIA.

2. The Petition Adequately Alleges a Claim Under the OMPIA

Defendants next contend the State fails to state a claim under the OMPIA, arguing the State does not sufficiently plead (i) that Defendants acted "willfully" or (ii) the "existence of a false 'claim,'" as defined under the OMPIA. Jt. MTD at 27-28. Both arguments fail for the same reasons as Defendants' nearly identical arguments regarding the OMFCA claim. *See supra* Section V.E.1 (addressing the claims Defendants caused to be submitted), (4) (addressing how Defendants acted "knowingly").[152]

G. <u>The Petition Adequately Alleges Violations of the OCPA</u>

Defendants next seek to dismiss the State's OCPA claim. As an initial matter, despite Defendants' arguments, the State's OCPA claim is not subject to the heightened particularity standard for averments of fraud under Section 2009(B). Rather, the Oklahoma Supreme Court has applied Oklahoma's liberal notice pleading standard under Section 2008 to OCPA claims. *See e.g. Estate of Hicks v. Urban E., Inc.*, 2004 OK 36, ¶5, ¶26 92 P.3d 88, 90 (in evaluating dismissal of claims for "fraudulent and misleading solicitations" under the OCPA, the Court explained "the general rule is that a petition should not be dismissed for failure to state a cause of action unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle her to relief."). Under the correct notice pleading standard, Defendants have not shown the State can prove "no

[152] Contrary to Defendants' perfunctory claim, the Petition alleges Defendants "willfully" violated the OMPIA. *See*, e.g., ¶93 (alleging Defendants "willfully and knowingly" violated the OMPIA); *see also, e.g.*, 12 O.S. 2009(B) (state of mind "may be averred generally"). Defendants' lone authority, *Estes v. ConocoPhillips Co.* (Jt. MTD at 27), does not support their attempt to hide behind "ignorance of the law." There, interpreting a different statute, the Court held it "is axiomatic, that in most instances, ignorance of the law is no excuse, and every person is presumed to know the law." 2008 OK 21, ¶22, 184 P.3d 518. Defendants offer no response to the State's allegations that Defendants made their statements to the medical community with "deliberate ignorance" and "reckless disregard of the truth" to improve their own bottom line. *See id.*; *see also* ¶¶2-4, 21, 70, 79, 87.

set of facts" which entitle the State to relief under the OCPA.

The purpose of the OCPA, 15 O.S. §§751, *et seq.*, is to protect citizens from unfair and deceptive trade practices. *See Patterson v. Beall*, 2000 OK 92, ¶27, 19 P.3d 839. "Because the OCPA is remedial in nature ***it is to be liberally construed to effectuate its underlying purpose.***" *Id.* at ¶28. To effectuate this purpose, the OCPA prohibits certain trade practices, including when a person:[153]

> (2) Makes a false or misleading representation, knowingly or with reason to know, as to the source, sponsorship, approval, or certification of the subject of a consumer transaction;
>
> * * *
>
> (5) Makes a false representation, knowingly or with reason to know, as to the characteristics, ingredients, uses, benefits, alterations, or quantities of the subject of a consumer transaction or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith;
>
> * * *
>
> (20) Commits an unfair or deceptive trade practice as defined in Section 752 of this title;

15 O.S. §753(2), (5), (20). Remedies for violations of the OCPA includes actual damages sustained and costs of litigation, including reasonable attorney's fees (§761.1(A)), a maximum penalty of $2,000 for each violation if the violator's acts were unconscionable (§761.1(B)), a maximum penalty of $10,000 for each violation of an injunction or court order (§761.1(C)), reasonable expenses, attorney's fees and investigation fees incurred by the Attorney General in administering and pursuing OCPA claims (§761.1(D)), and/or criminal liability (§761.1(E)).

The Petition alleges conduct by Defendants falling squarely within the purview of the OCPA. However, Defendants allege the State's OCPA claims should be dismissed because: (a) the

[153] A "person" under the OCPA is defined as a "natural person, corporation, trust, partnership, incorporated or unincorporated association, or any other legal entity." 15 O.S. §752(1).

State fails to establish the elements of an OCPA claim; and/or (b) the exemption set forth in 15 O.S. §754(2) applies. Both of these arguments fail.

1. The Petition Alleges all Necessary Elements Under the OCPA

As Defendants arguu, to state a claim under the OCPA, a *private plaintiff* must allege certain elements, including: (1) the defendant engaged in an unlawful practice, (2) that occurred in the course of defendant's business operations, (3) the plaintiff, in his capacity as a consumer, was injured, and (4) the injury was caused by the unlawful practice. Jt. MTD, citing *Steinbeck v. Dollar Thrifty Auto. Grp., Inc.*, No. 08-CV-0378-CVE-PJC, 2008 WL 4279798, at *1 (N.D. Okla. Sept. 15, 2008). However, in actions brough by the State, the State need not prove these specific elements, but may recover civil penalties from "[a]ny person who is found to be in violation" of the OCPA. 15 O.S. §761.1(C). That is, the State need only show that Defendants engaged in an unlawful practice under the OCPA to recover civil penalties. *See id.* The State is expressly permitted to petition a court for penalties *after* a private citizen has shown a defendant violated the OCPA in a separate individual action. *See id.* Thus, the State is not required to allege or prove the elements required in an individual OCPA suit filed by a private citizen. For this reason, the State also need not show "consumer status" as Defendants argue.

In any event, the Petition adequately alleges all such elements. *First*, Defendants wrongly argue the State "fails to plead facts about a single Oklahoma prescription written because of some false or misleading statement" to a "single Oklahoma resident" who was harmed by such prescription. Jt. MTD at 28-29. Defendants attempt to place a singularity requirement on the OCPA that does not exist. Consistent with the principle that the OCPA is to be liberally construed, a "consumer transaction" is broadly defined as "the "advertising, offering for sale or purchase, sale, purchase, or distribution of any services or any property, tangible or intangible, real, personal, or

mixed, or any other article, commodity, or thing of value wherever located, for purposes that are personal, household, or business oriented." 15 O.S. §752(2).

Here, the Petition alleges Defendants have engaged in a massive, nationwide marketing and *advertising* campaign that has caused the State and its citizens to bear enormous social and economic costs. *See, e.g.*, ¶¶31, 34-43; *see also* Section III *supra*. Such alleged conduct directly falls within the definition of "consumer transaction," which includes "*advertising*" generally. No money need change hands as a result of such advertising. Defendants cite no authority stating otherwise. The Petition sets forth countless "consumer transactions"—*i.e.*, Defendants' massive marketing and *advertising* campaign—as defined by the §752(2).

Second, Defendants argue the State fails to allege an "unfair trade practice." Jt. MTD at 30. However, the OCPA defines "unfair trade practice" broadly as "any practice which offends established public policy or if the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." 15 O.S. §752(14). Ignoring this definition, Defendants look to the Federal Trade Commission Act ("FTCA") instead to argue that, because any claimed injury was "reasonably avoidable" and "not outweighed by countervailing benefits to consumers," the State has not alleged an unfair trade practice in accordance with federal FTCA case law. Jt. MTD at 30-31.

This case has nothing to do with the FTCA. The authority Defendants cite is wholly inapplicable. Under the OCPA, the Petition more than adequately alleges that Defendants engaged in unfair trade practices that "offend[] established public policy" and are "immoral, unethical, opprisive, unscrupulous or substantially injurious to consumers." That is all that is required.

Specifically, the Petition alleges Defendants engaged in a massive deceptive marketing and advertising campaign to downplay the risks associated with opioids and falsely promote their

efficacy, and to even prescribe more opioids when signs of addiction arose. *See, e.g.*, ¶¶51-72; Section III *supra*. The Petition further alleges Defendants misrepresented their drugs ***contrary to*** their own labels. *See, e.g.*, ¶67. Based on Defendants' marketing scheme, the injury claimed by the State and its residents was not "reasonably avoidable" because there was nothing "free and informed" about their choices with respect to opioid abuse. Defendants created a system whereby their blatant misrepresentations to the medical community about the efficacy and risks associated with opioids stripped the State and its residents of any informed choice over their purchases.

In addition, the State has provided dozens of facts in support of its position that the harm to the State and its residents due to opioid abuse far outweighs any potential benefit to consumers. *See, e.g.*, ¶¶21-30, 69; Section III *supra*. Regardless, "[w]hether alleged conduct constitutes an unfair trade practice under the OCPA is a fact question that the trial court must determine on a case by case basis." *Patterson*, 2000 OK 92, ¶35; *see also GxG Mgmt., LLC v. Young Bros. & Co.*, 457 F. Supp. 2d 47, 51 (D. Me. 2006) (whether a claimed injury was "reasonably avoidable" can be determined at trial with the benefit of a more complete record). The State has set forth sufficient facts in its Petition to withstand dismissal, and it should be allowed to proceed with discovery.

Third, Defendants argue the State does not allege a "deceptive trade practice" because it fails to allege that any physician (as opposed to consumer) was deceived or misled by their misrepresentations, and physicians are the target of Defendants' marketing tactics. Jt. MTD at 31. Again, Defendants are inserting limitations on the OCPA that do not exist. The OCPA broadly defines "deceptive trade practice" as "a misrepresentation, omission, or other practice ***that has deceived or could reasonably be expected to deceive*** or mislead a person to the detriment of that person." 15 O.S. §752(13). This provision further states that "[s]uch a practice may occur before, during or after a consumer transaction is entered into and may be written or oral[.]" *Id.* The Petition

alleges Defendants' marketing campaign included misrepresentations and omissions that deceived or could reasonably be expected to deceive or mislead consumers. *See, e.g.*, ¶¶104-05, 108-09. Regardless of whether Defendants' actions targeted physicians or patients themselves (they did both), Defendants deceived or reasonably expected to mislead the State, Oklahoma physicians, and Oklahoma residents.

It is of no import that physicians were the conduit for Defendants' misrepresentations. This "straw man" argument is belied by the words of the statute itself. The OCPA makes it an unlawful practice for a person to make a "false or misleading representation, knowingly or with reason to know, as to the characteristics, uses, benefits, alterations, or quantities of the subject of a consumer transaction...." 15 O.S. §753(5). This statute says nothing of the identity of the person to whom the statement was made, merely requiring a knowing misrepresentation as to the subject of a consumer transaction. If Defendants' position were correct, anyone could unlawfully misrepresent products to a middle man to relay his message and shield himself from liability.

Fourth, Defendants argue the State's OCPA claim should be dismissed because its request for damages fails. The State need not prove damages under the OCPA, but may seek civil penalties instead of or in addition to damages. Thus, Defendants' argument is easily dispensed with here as a basis for dismissal. Further, relying on *Lumber 2, Inc. v. Illinois Tool Works, Inc.*, 2011 OK 74, 261 P.3d 1143, Defendants first argue the State cannot recover damages on its own because it is not a "consumer" who "consumes or uses economic goods." Jt. MTD at 32.[154] However, again, the State need not prove consumer status because the State has standing to enforce the provisions and purpose of the OCPA to protect citizens from unfair and deceptive trade practices. *See*

[154] Moreover, in *Lumber 2*, the goods were purchased by plaintiff for resale, and the Court specifically stated that its holding did not mean that plaintiff, "as a corporate entity, could never be a consumer under different facts." 2011 OK 74, ¶21. Its holding was limited to situations where a plaintiff was seeking relief under the OCPA for "purchasing goods for resale to its customers," which is inapplicable here. *Id.*

Patterson v. Beall, 2000 OK 92, ¶27. Nonetheless, it so happens that the State did in fact purchase opioids as a result of Defendants false and misleading marketing campaigns.

Defendants also argue that to the extent the State is seeking damages on behalf its residents, it is precluded from seeking relief on behalf of multiple individuals at once. *See* Jt. MTD at 32-33. Defendants rely on the language of §756.1(A)(3), which provides that the Attorney General may bring an action "[t]o recover actual damages, and in the case of unconscionable conduct, penalties as provided by this act, on behalf of an aggrieved consumer, in an individual action only, for violation of the Consumer Protection Act...." Defendants' position ignores the fact that 15 O.S. §756.1(A), which is written in the disjunctive, provides multiple avenues for relief, all of which have been pled in this case. More specifically, §756.1(A) also allows the Attorney General to:

(a) obtain a declaratory judgment that an act violates the OCPA, §756.1(A)(1);
(b) enjoin or obtain a restraining order that violations have/will occur, §756.1(A)(2); or
(c) recover reasonable expenses and investigation fees. §756.1(A)(4).

None of these provisions prohibit the Attorney General from proceeding on behalf of multiple consumers at one time, and the Petition pleads them all. *See* ¶115. Section 756.1 further provides that in any action brought by the Attorney General, the court may "[m]ake such orders or judgments as may be necessary to compensate any person for damages sustained." §756.1I(2). It also states that the court may "[m]ake such orders or judgments as may be necessary to carry out a transaction in accordance with consumers' reasonable expectations." §756.1(C)(4). This plurality language undermines Defendants' arguments and authorizes the Attorney General to file OCPA claims on behalf of more than one consumer.

Defendants also claim that because the State only paid the purchase price of a product, it cannot establish actual injury or damages. *See* Jt. MTD at 33. The State does not dispute that an "aggrieved customer" must have suffered some detriment caused by a violation of the OCPA.

Walls v. Am. Tobacco Co., 2000 OK 66, 11 P.3d 626. The State disagrees, however, that such damages have not been pled or that the State's damages are limited to that an aggrieved customer under the OCPA. The Petition alleges Defendants' caused:

(a) Catastrophic damage to the State, including expenses for health care, criminal justice, and lost work productivity;
(b) Staggering damage to businesses and communities;
(c) Costs and losses for substance abuse treatment services, ambulatory services, inpatient hospital services, and emergency department services;
(d) Expenses for education and prevention programs to combat opioid abuse; and
(e) Disproportionate impact to Oklahoma in sales and overdoses.

See ¶¶5, 23-32, 40-46. These costs go far above and beyond the cost of the medications themselves. Just by way of example, the State was forced to create an Opioid Commission directly aimed at reversing the opioid epidemic in Oklahoma and dealing with the damages Defendants caused. The funds and man-hours the State has had to devote to this epidemic is more than enough to show damages, support the statutory penalties, and the injunctive relief required. *See* Sections I, III *supra*. The Petition pleads sufficient damages and penalties under the OCPA.

2. The "Safe-Harbor" Exemption Does Not Apply

The OCPA does not "apply to…[a]ctions or transactions regulated under laws administered by… the Corporation Commission or any other regulatory body… acting under statutory authority of this state or the United States." 15 O.S. §754(2). Defendants wrongly argue that this "safe-harbor" exemption precludes the State's OCPA claim because it is "based upon the marketing and sale of prescription medicines—conduct that is regulated by the FDA." Jt. MTD at 30.

The application of the OCPA exemption depends on the specific conduct alleged and the regulatory scheme at issue. "The OCPA safe harbor 'does not apply when a defendant's conduct at issue is not within the scope of the agency's authority.'" *Sisemore v. Dolgencorp, LLC*, 212 F.

Supp. 3d 1106, 1109 (N.D. Okla. 2016) (citing *Conatzer v. Am. Mercury Ins. Co.*, 2000 OK CIV APP 141, ¶¶8-14). Several applicable Oklahoma cases address this important distinction.

For example, in *Sisemore,* the plaintiff alleged a store violated the OCPA with respect to the labeling of obsolete motor oils and their product placement near other non-obsolete motor oils. 212 F. Supp. 3d at 110. The court held the regulatory scheme relied on by the defendant only addressed product labeling—not product placement. *Id.* Because the plaintiff alleged deceptive conduct with respect to both, the Court held the statutory exemption did not require dismissal. *Id*; *see also Robinson v. Sunshine Homes, Inc.*, 2012 OK CIV APP 87, ¶¶30-37, 291 P.3d 628; *Conatzer v. Am. Mercury Ins. Co.*, 2000 OK CIV APP 141, ¶¶8-9, 15 P.3d 1252; *In re Gen. Motors Corp.*, No. MDL 04-1600, 2005 WL 1924335 (W.D. Okla. Aug. 8, 2005).

Here, the Petition alleges conduct that is not regulated by the FDA. The FDA does not regulate unbranded marketing materials. *See, e.g.*, 21 U.S.C. §352(a); 21 C.F.R. §§1.21, 99.101, 202.1 (listing regulations related to prescription drug advertisements for specific drugs). The Petition alleges Defendants relied extensively on unbranded marketing materials to perpetuate their scheme. *See* ¶¶58-66. For example, the Petition alleges Defendants paid doctors to give speeches and seminars to promote the use of "opioids" and further spread Defendants' misrepresentations regarding their addictiveness and efficacy. *Id.* The Petition further alleges Defendants paid doctors to spread the concept of "pseudoaddiction" to convince prescribers to treat classic signs of addiction with more opioids. *Id.* In this form of unbranded marketing, Defendants avoided the FDA's regulatory framework related to branded prescription drug advertisements by referring generally to opioids, rather than referring to their specific drugs by name. *Id.* As in *Sisemore*, and *GMC*, the Petition alleges conduct that falls ***outside*** of any regulatory scheme and violates the OCPA.

Defendants rely heavily on *Arnett v. Mylan, Inc.*, No. 2:10-cv-00114, 2010 WL 2035132 (S.D. W.Va. May 20, 2010), in support of their position that the State's claims are barred by the OCPA. This ***federal*** district court case ***from West Virginia*** is inapposite. *Mylan* was a products liability action wherein the plaintiff alleged the defendant had defectively labeled the drug and withheld information from the FDA. *Id.* at *1, 4. This case is not a product liability case. Here, the Petition alleges, in part, that Defendants misrepresented their drugs in unbranded advertising and ***contrary to*** their labels. *See, e.g.*, ¶67. In other words, Defendants' conduct in this case occurred ***outside*** any regulatory scheme of the FDA.

Federal courts also have found that dismissal of an OCPA claim based on the safe-harbor exemption is improper prior to discovery and development of the record. For example, in *Money v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1100 (FLW), 2009 U.S. Dist. LEXIS 121094 (D.N.J. Dec. 30, 2009), the plaintiff brought claims for the defendant's alleged improper marketing practices related to the drug Plavix. *Id.* at *1-2. The court emphasized the need for answers to certain fact questions before the §754(2) exemption could be applied to the plaintiff's OCPA claim, stating "[t]he fact that the FDA regulates the labeling and marketing of pharmaceuticals is not a *fait accompli* to the application of the exemption." *Id.* at *20. "While the FDA may indeed regulate the promotion and marketing of Plavix, the parties have failed to provide the Court with any factual information or legal analysis involving the regulatory scheme at issue." *Id.* "If...Defendants' promotional materials were not authorized by the FDA's regulatory scheme in that they were either not in compliance or are not among the type of materials that the FDA monitors then the statutory exemption would be inapplicable." *Id.* at *21. Here, discovery is in its infancy (and Defendants continue to delay it) and the record has not been fully developed. As such, dismissal of the State's OCPA claim is improper.

H. The Petition Alleges Claims for Actual and Constructive Fraud With the Particularity Required by Section 2009(B)

Defendants jointly and severally argue the Petition fails to plead fraud with sufficient particularity as to each of them. *See* Jt. MTD at 8-10; Teva MTD at 11-14; Purdue MTD at 12-14; J&J MTD at 2-4. Defendants also jointly argue the State has failed to "adequately plead the elements of its common-law fraud and deceit claim." Jt. MTD at 35.

Defendants' particularity argument suffers from the same fatal procedural flaw because, as discussed in detail in section IV.B, *supra*, "[f]ailure to plead fraud with specificity is not a ground for dismissal." *Muller*, 2013 OK CIV APP 90, ¶10; *Estrada*, 2015 OK CIV APP 19, ¶23. Therefore, Defendants' motions to dismiss the State's common fraud/deceit claims should be denied on this basis alone. Further, should the Court consider Defendants' request for dismissal, Section 2009(B) only requires "the degree of specificity necessary to enable [Defendants] to prepare [their] responsive pleadings and defenses," and a petition need not "plead detailed evidentiary matters."*Gay*, 1988 OK 150, ¶¶17-18. Here, the Petition identifies "circumstances constituting fraud" such that Defendants were able to prepare their responsive pleadings. *See id.*; 12 O.S. §2009(B). That is all that is required. *See also supra* Section IV(B). In addition, the Petition pleads a complex fraudulent scheme perpetrated by Defendants collectively and individually and, thus, subjects Defendants to joint and several liability. *See* 23 O.S. §15(B) (preserving joint and several liability in "actions brought by or on behalf of the state.").

1. The Petition Adequately Alleges a Claim for Actual Fraud

To state a claim for actual fraud the State must plead: (1) a false material misrepresentation, (2) made as a positive assertion which is either known to be false or is made recklessly without knowledge of the truth, (3) with the intention that it be acted upon, and (4) which is relied on by the other party to his or her own detriment. *Bowman v. Presley*, 2009 OK 48, ¶13, 212 P.3d 1210.

Defendants incorrectly argue the State fails to allege each element. Jt. MTD at 35.

First, the Petition alleges Defendants made material misrepresentations. For example, the Petition alleges Defendants employed a massive and unprecedented deceptive marketing and advertising campaign to influence the Oklahoma medical community's and Oklahoma consumers' perception of prescription opioids by misrepresenting the risks of addiction and abuse and touting unsubstantiated benefits of opioid treatment for chronic non-cancer pain. ¶51. Defendants' alleged misrepresentations are undoubtedly material, as they speak directly (albeit falsely) to the factors physicians consider in prescribing pain medication: risks and benefits. The Petition then lists specific misrepresentations made by each Defendant and explains the various media through which these misrepresentations were made, including sales representatives, brochures, video advertisements, KOLs, and front groups. ¶¶52-72; *see also* Section III *supra*. Thus, the Petition adequately pleads particular, material misrepresentations.

Second, the Petition alleges "Defendants knew [their misrepresentations] were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such assertions." ¶122. The Petition includes specific examples of Defendants' knowledge of the falsity of their statements. For example, the Petition alleges that each Defendant touted the "Porter and Jick Study" as a comprehensive clinical trial finding that less than 1% of patients become addicted to opioids. ¶56. But, Doctors Porter and Jick did not perform a "study" of opioid use outside a hospital at all; they wrote a 101-word letter to the editor of the New England Journal of Medicine in 1980. *See id.* No reasonable person would describe Porter and Jick's letter as a comprehensive study. The many other examples in the Petition, if taken as true, as they must be, allow a reasonable inference that Defendants knew their marketing claims were false or recklessly disregarded their falsity. ¶¶57-72. Thus, the Petition sufficiently pleads the second element of actual fraud.

Third, the Petition alleges Defendants intended their materially false statements to be relied upon and acted on by Oklahoma physicians. ¶122. The Petition lists several specific misrepresentations and omissions made, which "Defendants intended healthcare providers working for the State to rely upon" and which "had a tendency to deceive." ¶¶122-24. Indeed, the entire point of Defendants' false marketing scheme was to sell more opioids, and the only way for Defendants to sell more opioids was to convince doctors that their respective drugs—unlike the opioids of the past—were not addictive. Thus, the Petition sufficiently pleads the third element of actual fraud.

Fourth, the Petition alleges physicians relied on Defendants' false statements to the detriment of the State. *See* ¶122. Indeed, the Petition alleges Defendants engaged in a sweeping fraudulent marketing and advertising ***scheme*** carried out over many years through branded and unbranded marketing with the intended purpose of changing physicians' perception of opioids to treat chronic non-cancer pain and thereby influence their prescribing habits. ¶¶51-66. Defendants' fraudulent scheme reached and influenced virtually ***everyone*** in the Oklahoma medical community including physicians, hospitals and pharmacists. It is as a matter of public record (and, thus, subject to judicial notice) that Defendants' sales representatives called on—and even wined and dined—physicians throughout the State, including physicians working for or with privileges at Oklahoma State-funded hospitals, such as the OU Medical Center and OSU Medical Center. Even so, given the breadth and reach of Defendants' marketing and advertising campaign in the State, the only reasonable inference that can be drawn is that physicians working for or with privileges at Oklahoma State-funded hospitals were among the doctors influenced by Defendants' fraudulent conduct. ¶¶51-66; Section III *supra*. However, it is not necessary for the State to identify in the

Petition every single State employee whom Defendants misled through their sweeping fraudulent scheme.

Moreover, the Petition states:

> Through the misrepresentations and omissions described above, Defendants *convinced* doctors and consumers that, despite the instructions on their drug labels and the longstanding practice of prescribing opioids in limited circumstances, there is a low risk of addiction with long-term opioid use. Additionally, Defendants *convinced* doctors and consumers, through their misrepresentations and omissions, that opioids are effective treatment for chronic, non-cancer pain and signs of addiction could actually be signs of "pseudoaddiction" requiring heavier doses of opioids. *Defendants convinced **Oklahoma** doctors and consumers of these same misrepresentations*.

¶67. And, the Petition alleges, "[h]ealthcare providers working for the State did in fact rely on Defendants' false representations, as seen by the increasing number of opioid prescription claims that have been submitted to and paid by Oklahoma Medicaid." ¶125. The enormous increase in opioid sales, persons addicted and overdose deaths demonstrates prescribers—including State prescribers—relied on Defendants' fraudulent statements. ¶¶23-27; Section III *supra*. Defendants' misleading marketing likely reached members of the Drug Utilization Review Board that determines which medications are eligible for reimbursement under Oklahoma Medicaid.

In reliance on Defendants' fraud, the State experienced severe and widespread damage as explained above. *See* ¶¶31-50; *see also* Sections I, III, V.G.1 *supra*. Thus, the Petition sufficiently pleads the fourth and final element of actual fraud—that the State relied on Defendants' misrepresentations to the State's own detriment.

2. The Petition Adequately Alleges a Claim for Constructive Fraud

The Petition also adequately pleads a claim for constructive fraud. The definition of "constructive fraud" in Oklahoma is "any breach of a duty which, regardless of the actor's intent, gains an advantage for the actor by misleading another to his prejudice." *Patel*, 1999 OK 33, ¶34.

Patel clearly explains that constructive fraud "does not necessarily involve any moral guilt, intent to deceive, or actual dishonesty of purpose." *Id.* As such, the bar for alleging and proving constructive fraud is lower than actual fraud.

The facts related to the State's claim for actual fraud are the same for the State's claim for constructive fraud: Defendants omitted material information related to the addictiveness of their opioids in statements made to State prescribers with the intention that the State prescribe and pay for more opioids. The State incorporates those allegations and arguments by reference here. *See* Section V.H.1 *supra.* In addition, because constructive fraud does not require an affirmative assertion, Defendants' omissions of truth also support the State's constructive fraud claim. For example, Section D of the Petition, titled "Defendants Concealed the Truth About their Campaign" explains:

> The nature of Defendants' marketing scheme required Defendants to conceal the truth for it to be effective. Thus, Defendants operated from behind the scenes, spreading their deceptive misrepresentations through KOLs and third-party groups to conceal their own involvement. Defendants also concealed the falsity of their misrepresentations regarding addiction risk and the benefits of long-term opioids.

¶72. The Petition also contains specific examples of these omissions. Given the highly addictive nature of their opioids, Defendants were under an obligation to disclose the high risk of addiction each time they marketed or pitched their opioids. As alleged further in the Petition, "Defendants, having chosen to speak and make representations to healthcare providers working for the State regarding their opioids, were under a duty to disclose the whole truth, and not disclose partial and misleading truths." ¶123. Defendants chose not to disclose the truth. For a claim of constructive fraud, it matters not whether Defendants' misleading behavior "involve[d] any moral guilt, intent to deceive, or actual dishonesty of purpose." *Patel*, 1999 OK 33, ¶34. Therefore, the Petition more than sufficiently pleads a claim for constructive fraud with particularity under Section 2009(B).

As explained above, based on the allegations in the Petition, and the reasonable inferences drawn therefrom, the Petition adequately pleads claims for actual and constructive fraud. In any event, "[f]ailure to plead fraud with specificity is not a ground for dismissal." *Muller*, 2013 OK CIV APP 90, ¶10. Thus, Defendants' motions to dismiss these claims should be denied. The State should be permitted to proceed with discovery on these claims and show that Defendants are jointly and severally liable for their acts of actual and constructive fraud and deceit.

I. The State Adequately Alleges Claims against J&J, Teva USA, and the Acquired Actavis Entities

Defendants Janssen and J&J argue that the State's "barebones agency allegations do not support a claim against J&J." J&J MTD at 9. Defendants Teva USA and The Acquired Actavis Entities similarly argue the State's claims against them should be dismissed because it fails to allege any wrongdoing by Teva USA or The Acquired Actavis Entities and fails to connect these entities to a single prescription for which the State paid. *See* Teva MTD at 19-20. Defendants are wrong for several reasons.

First, Defendants' position is inconsistent with Oklahoma's notice pleading standard, which requires only that the Petition "give fair notice of the plaintiff's claim and the grounds upon which it rests." *Gens v. Casady Sch.*, 2008 OK 5, 177 P.3d 565, 569. Here, the State alleges that:

(a) Defendant Janssen "is a wholly owned subsidiary" of Defendant J&J, and that these Defendants "acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein." ¶19;

(b) Defendant Teva USA was acquired by Defendant Cephalon in October 2011, and that these Defendants "acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein." ¶17; and

(c) The Acquired Actavis Entities are all part of or were acquired by Defendant Allergan Plc, and that these entities "acted in concert with one another and as agents and/or principals of one another in relation to the conduct described herein." ¶16.

These allegations put Defendants on notice of the State's claims and its intent to disregard the

corporate form based on agency theories. *See Estrada*, 2015 OK CIV APP 19, ¶ 16 (reversing trial court's dismissal of claims based on alter-ego theory, where the plaintiff alleged the individual defendant operated other corporate entities as the alter-ego of the named corporate defendant).

Second, Oklahoma law does not require the State to provide evidence of control at the pleading stage of the litigation. Oklahoma law provides that "[o]ne corporation may be held liable for the acts of another under the theory of alter-ego liability if (1) the separate existence is a design or scheme to perpetrate a fraud, or (2) one corporation is merely the instrumentality or agent of the other." *Gilbert v. Sec. Fin. Corp. of Okla., Inc.*, 2006 OK 58, ¶22, 152 P.3d 165, 175. "If one corporation is but an instrumentality or agent of another, corporate distinctions must be disregarded and the two separate entities must be treated as one." *Frazier*, 1989 OK 73, ¶16; *Oliver v. Farmers Ins. Grp. of Cos.*, 1997 OK 71, ¶8, 941 P.2d 985 (same).

As Defendants Janssen and J&J point out, the Court in *Frazier* lists ten non-exclusive factors to be considered when deciding whether to disregard the corporate form, but those are "[f]actors which may be considered at trial...." *Frazier*, 775 P.2d at 288 (emphasis added).[155] The only case Defendants Janssen and J&J cite in support of their position that the *Frazier* factors should be considered when evaluating the sufficiency of the Petition is a federal case. *See* J&J MTD at 9-10 (citing *Lewis v. Am. Gen. Assur. Co.*, No. CIV-00-1520-W, 2001 WL 36160929, at *2 (W.D. Okla. Feb. 26, 2001)). However, Oklahoma has not adopted the federal pleading standards set forth in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). *See Edelen*, 2011 OK CIV APP 116, ¶3. Moreover, the State has alleged

[155] These factors are whether: (1) the parent corporation owns all or most of the subsidiary's stock; (2) the corporations have common directors or officers; (3) the parent provides financing to its subsidiary; (4) the dominant corporation subscribes to all the other's stock; (5) the subordinate corporation is grossly undercapitalized; (6) the parent pays the salaries, expenses or losses of the subsidiary; (7) almost all of the subsidiary's business is with the parent or the assets of the former were conveyed from the latter; (8) the parent refers to its subsidiary as a division or department; (9) the subsidiary's officers or directors follow directions from the parent corporation; and (10) legal formalities for keeping the entities separate and independent are observed. *Id.*

that Defendant Janssen is a wholly owned subsidiary of J&J, which speaks to the first *Frazier* factor regarding ownership by the parent company. Defendants Janssen and J&J's assertion that the Petition is devoid of any discussion of the *Frazier* factors is inaccurate.

Third, this case is in its infancy and Defendants have blocked discovery to date. The State should be allowed to conduct discovery on the relationship between and among Janssen/J&J, Cephalon/Teva USA and Allergen Plc/The Acquired Actavis Entities to support its agency and instrumentality theories. In *Fanning v. Brown*, 2004 OK 7, 85 P.3d 841, the Oklahoma Supreme Court reversed the court's dismissal of plaintiff's claim to disregard the defendant's corporate structure, emphasizing Oklahoma's liberal notice pleading and the need for discovery:

> Fanning has asserted legal theories of negligence and breach of contract. Fanning seeks to pierce the corporate veil of [the facility] and hold the individual shareholders liable for the obligations and conduct of the facility. **Fanning has given the defendants fair notice of her claims and the grounds upon which they rest. Whether Fanning can prevail on her claim against the shareholders remains to be seen. However, Fanning must be afforded an opportunity to complete discovery so that the court will have a fully developed factual record to determine the issue. At this stage of the proceedings it does not appear beyond a doubt that Fanning can prove no set of facts in support of her theories of recovery**. Accordingly, the trial court erred in dismissing Fanning's petition.

Id. at ¶22. The same result should be reached here.

The State has placed Defendants on notice of its claims, and it is clearly *not* legally impossible for the State to establish a claim against J&J, Teva USA, and/or The Acquired Actavis Entities. As such, Defendants' Motions must be denied. *See Frazier*, 775 P.2d at 287 (pleading must not be dismissed for failure to state a legally cognizable claim unless the allegations indicate beyond any doubt that the litigant can prove no set of facts which would entitle him to relief) .[156]

[156] In the alternative, if the Court is inclined to grant Defendants' Motion as to J&J, the State must be allowed leave to amend its Petition to satisfy any purported deficiencies in its claims against J&J. *See Fanning*, 2004 OK 7, ¶23 (trial court erred in dismissing the case without providing plaintiff with an opportunity to amend her complaint); *Kelly*,

J. The Content of Janssen's Opioid Labels Is Not the Basis of the State's Claims

In its separate motion, Janssen argues that the disclosures on its labels absolve it from liability, but this argument ignores the nature of this case. *See* Section V.K *infra*. This case is not about product labelling. It is about Defendants' marketing and advertising practices targeting the medical community and consumers in Oklahoma, and the public nuisance Defendants created. *See generally*, Petition. Indeed, the Petition expressly states that Defendants' false and deceptive marketing and advertising to doctors and consumers ***often contradicted their own labels***. ¶¶67, 70. Because the issue is not whether Janssen's opioids were labelled or prescribed appropriately, but whether they were marketed and advertised truthfully, the content of their labels is not a basis to dismiss.

Janssen's argument also contradicts Oklahoma law. "It is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warnings. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty." *Edwards v. Basel Pharm.*, 1997 OK 22, ¶17, 933 P.2d 298. Even if this case was a failure-to-warn case about labelling, which it is not, compliance with the FDA's labelling guidelines would not warrant dismissal. *See id.* ("[W]here a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise [prescription drug] users of inherent risks, the manufacturer should not be shielded from liability by such compliance.").

1989 OK 124, ¶6 (12 O.S. §2012(G) places a mandatory duty on trial courts to grant leave to amend if the defect can be remedied); *Lockhart*, 1997 OK 103, ¶5 (drawing a distinction between a petition that is dismissible for want of a cognizable legal theory of liability and one that is dismissible for insufficient facts under a recognized theory). "The policy of the Oklahoma Pleading Code of deciding cases on the basis of the substantive rights involved rather than technicalities requires a plaintiff to be given every opportunity to cure a formal defect in his pleading." *Brown v. Founders Bank & Trust Co.*, 1994 OK 130, ¶8 n.9, 890 P.2d 855, 961.

Finally, Janssen's and the other Defendants' attempt to hide behind the learned intermediary doctrine by blaming physicians for the fallout of the opioid epidemic is unavailing. *See, e.g.*, Jt. MTD at 19. Defendants claim that physicians are "learned intermediaries" and, as such, are ultimately responsible for any errors in prescribing. *Id.* This, again, ignores the Petition's allegations that Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. This argument also ignores that Oklahoma adopted the learned intermediary doctrine in products liability cases only. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). As such, the learned intermediary doctrine is inapplicable.

Even if the learned intermediary doctrine did apply to the State's claims here, it would not shield Defendants from liability. The doctrine shields manufacturers of prescription drugs from liability "***if the manufacturer adequately warns the prescribing physicians of the dangers of the drug***." *Edwards*, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, ***a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk*** subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors throughout Oklahoma and the country. ¶¶51–72. Moreover, the Petition alleges sufficient facts indicating Defendants' marketing scheme did impact prescribers' habits and caused unnecessary opioid prescriptions. *See, e.g.*, ¶¶3, 6, 73-101, 125, 131.

K. The Petition's Allegations Are Not Inherently Contradictory

Defendants incorrectly argue the Petition's allegations are "inherently self-contradictory." Jt. MTD at 10. Defendants argue that because (1) Oklahoma law permits physicians to prescribe opioids, (2) certain opioids are approved for long term treatment, and (3) the labels disclose the risks, then there can be no fraud as a matter of law. *Id.* Defendants are incorrect.

Defendants rely on authority stating that representations "that 'generally comport with [a medication's] approved label' are 'not misleading as a matter of law.'" *Id.* Tellingly, Defendants do not cite the Petition for any allegation that Defendants simply marketed or advertised their drugs consistent with their labeling, as the Petition pleads the opposite. *See generally id.*

The Petition alleges unlawful conduct on a massive scale by Defendants and specifically ***contrary to*** their own FDA-approved labels through numerous means. ¶¶67, 70, 124. A drug label is not a license to make whatever misrepresentations a company desires outside of the label, nor does it wholly immunize a company from fraud claims where the company misrepresents aspects of the drug separate from the label. *See City of Chi. v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 U.S. Dist. LEXIS 60587, at *33 (N.D. Ill. May 8, 2015) ("But, as the cases cited by defendants illustrate, drug labels do not preclude fraud claims based on misrepresentations of the label information, which is what the City alleges."). For example, while the labels include language regarding the risks of addiction, Defendants' marketing efforts told a different story and fraudulently downplayed the risks of addiction by making statements such as: the risk of addiction was "much less than 1%" or "less than 1%", the drugs were "virtually non-addicting," addiction is "less likely if you have never had an addiction problem," "addiction, when treating pain, is distinctly uncommon." *See, e.g.*, ¶¶53, 56, 61; *see also* Section III *supra.*

Defendants cannot rely on their labels as disclaimers for fraudulent misrepresentations. A party cannot disclaim liability for fraud with a label. To hold otherwise would grant any drug company a license to commit fraud. *See Murray v. D&J Motor Co.*, 1998 OK CIV APP 69, ¶¶28, 35-37, 958 P.2d 823 ("Fraud, if practiced by a seller, cannot be avoided on the ground that seller has disclaimed the very matter out of which the fraud arises."). Defendants' argument regarding "fatal internal inconsistencies" therefore fails; no inconsistencies exist.

Further, Defendants downplay the significance of their massive marketing efforts by stating that the "primary channel" for communicating information to doctors and patients is through the label. Jt. MTD at 11. If such an argument were true, why did Defendants spend millions of dollars on marketing and advertising efforts to promote their drugs? Defendants intend their marketing efforts to have an effect. For example, Defendant Purdue considers its sales force its "most valuable resource," ***not*** its proprietary drug formulations. Defendant Purdue's goals were, among other things, to "increase the number of prescriptions for strong opioids," "convince health care professionals to use OxyContin earlier in the patient's treatment cycle," "enhance the acceptance of opioids for non-cancer pain," "[a]ttach an emotional aspect to non-cancer pain so physicians treat it more seriously and aggressively," "enhance the acceptance of opioids for non-cancer pain through educational efforts," and "[c]onvince health care professionals…to aggressively assess and treat both non-cancer pain and cancer pain." Defendants' efforts had their intended effect and continued beyond 2006. Sales of prescription opioids quadrupled nationwide since 1999. ¶22.

Defendants cannot credibly contend their marketing efforts have zero effect on prescribing habits when they invest millions of dollars a year on such efforts:

> To suggest that [the defendant's] alleged expansive, multi-faceted efforts to create an off-label market for [its drugs] did not cause physicians to prescribe [its drugs] for non-

reimbursable uses strains credulity. ***It is implausible that a fraudulent scheme on the scope of that alleged by [the plaintiff] would be entirely feckless.***

Celgene Corp., 2014 U.S. Dist. LEXIS 99815, at *31-32. It would be unreasonable and illogical to infer otherwise, and all reasonable inferences must currently be drawn in the State's favor. Thus, Defendants' arguments fail.

L. The Petition Adequately Alleges Causation

Defendants incorrectly argue all of the State's claims must fail because the State has not alleged any "causal connection between any supposed misrepresentation and any prescription or reimbursement decision in Oklahoma." Jt. MTD at 16; *see also* Teva MTD at 14-17. Defendants do not focus this argument on any particular claim and argue the State has not alleged any facts in support of causation on *any* claims. The questions of causation and damages are fact questions for the jury. *See, e.g.*, *Delbrel v. Doenges Bros. Ford*, 1996 OK 36, ¶13, 913 P.2d 1318 ("Whether or not the actions of the appellee were the proximate cause of the injury to the appellant, or merely established a condition is a fact question, and therefore one for the jury to decide."); *Bowman*, 2009 OK 48, ¶30 (holding reliance in fraud claims is "reserved for the trier of fact").

Indeed, the State, at this stage, must only "give fair notice of the plaintiff's claim and the grounds upon which it rests." *See* Section IV *supra*.

1. The Petition Alleges Defendants' Conduct Affected Prescribing Decisions by Oklahoma Physicians

Defendants first argue that "the State does not identify any Oklahoma physician who prescribed an opioid for chronic pain—let alone one who did so improperly or as a result of any Defendant's conduct." Jt. MTD at 16. Defendants seek to impose a level of specificity on ***all*** of the State's claims that does not exist for ***any*** of the State's claims, particularly the public nuisance and unjust enrichment claims. The Petition includes significant and substantial allegations of an

overarching, intentional scheme to misrepresent the risks and benefits of their drugs. *See, e.g.*, ¶¶51-71; *see also* Section III *supra*. The intended result of the scheme was to cause physicians to change their prescribing habits. ¶¶2-4, 57. It would otherwise be pointless. *See, e.g., Celgene Corp.*, 2014 U.S. Dist. LEXIS 99815, at *31-32 ("It is implausible that a fraudulent scheme on the scope of that alleged by [the plaintiff] would be entirely feckless.").

The Petition similarly alleges that, as a result of Defendants' massive scheme, physicians' prescribing decisions were affected, the State paid for opioid prescriptions and other services they otherwise would not have paid for, scores of victims became addicted, substantial harm was caused to the health and safety of the people of Oklahoma, and such people continue to be endangered as a result of Defendants' conduct. *See, e.g.*, ¶¶3, 6, 73-101, 118-19, 125, 131.

Defendants argue that other intervening factors were the cause of the injury or the total number of prescriptions and services the State should not have paid for. But these arguments are premature. *See Celgene Corp.*, 2014 U.S. Dist. LEXIS 99815, at *31-32 ("rather than showing a lack of proximate causation, [the defendant's] argument presents a question...regarding the total number of prescriptions that were attributable to [the defendant's] actions" which is "premature at this stage"). Such erroneous arguments also wholly ignore (once again) the State's nuisance claims and unjust enrichment claims. The Petition alleges substantial conduct by Defendants that caused this public nuisance in their efforts to drive up profits and expand the market for opioids.

Defendants next incorrectly argue the State does not allege any facts that "*any* Oklahoma physician *ever* heard, read, or otherwise received" their misrepresentations. Jt. MTD at 16. The Petition, however, plainly alleges that Defendants conducted their marketing campaign in Oklahoma. ¶¶51, 54; *see also* Section III *supra.* Oklahoma is one of the states where Defendants have caused the worst harm. ¶¶21-50. Further, Defendants' "reliance" arguments are based on

cases that are wholly inapposite, based on other states' laws, and/or inapplicable federal pleading standards. *See* Jt. MTD at 16-17.

For example, Defendants cite *Twyman v. GHK Corp.*, which was not decided at the motion to dismiss stage but, rather, following an appeal of a jury trial verdict. 2004 OK CIV APP 53, ¶52, 93 P.3d 51. Defendants also cite *Baron v. Pfizer, Inc.*, a New York state court decision that has no bearing on this case. *See* Jt. MTD at 17. In *Baron*, an individual patient brought a putative class action alleging the defendant's off-label marketing of Neurontin caused her injury. 820 N.Y.S.2d 841 (2006). The claim was dismissed because the plaintiff did not allege any facts that ***her*** prescription was impacted by false marketing. *Id.* Here, in this Oklahoma (*not* New York) case, because the plaintiff is the State, the issue is entirely different. The State pays for massive amounts of prescriptions. The State need not allege each prescription it paid for as a result of Defendants' conduct; even under more stringent federal pleading standards, it is sufficient to allege that, based on the scope of Defendants' scheme, the State paid for prescriptions that resulted from Defendants' false marketing. *See, e.g.*, *Celgene*, 2014 U.S. Dist. LEXIS 99815, at *31-32, ("To suggest that [the defendant's] alleged expansive, multi-faceted efforts to create an off-label market for [its drugs] did not cause physicians to prescribe [its drugs] for non-reimbursable uses strains credulity."). Finally, the *City of Chicago* case on which Defendants so heavily rely was decided under more stringent federal pleading standards that do not apply here. *See City of Chi.*, 2015 U.S. Dist. LEXIS 60587.

Defendants argue the State "cannot satisfy its pleading burden" by alleging a statewide increase in opioids prescriptions. Jt. MTD at 17. But, Defendants cite no Oklahoma cases to support this statement. Instead, they rely on two distinguishable federal cases. Defendants rely on *UFCW Local 1776 v. Eli Lilly & Co.* to argue that the State cannot rely on "generalized data." *Id.*

(citing 620 F.3d 121, 133 (2d Cir. 2010)). Defendants ignore that *UFCW Local 1776* was not decided at the motion-to-dismiss phase even under the stricter federal pleading standard. 620 F.3d at 130. Thus, Defendants' argument is premature. And, in *UFCW Local 1776*, the Court held the only evidence in the record was that the prescribing physicians did not rely on the purported misrepresentations. *Id.* at 133. No such evidence exists here and, taking the State's allegations as true, Defendants' marketing efforts did impact prescribing decisions.

At bottom, Defendants frequently try to overcomplicate and confuse the State's allegations. The Petition alleges Defendants misrepresented the risks and benefits of opioids to encourage physicians to prescribe them more than they otherwise would have. The Petition alleges Defendants were wildly successful and convinced both the public and doctors that opioids were not as addictive as once believed. Defendants had a supply and they created a new demand through their misconduct that led to over-prescription and deadly addiction. As a result, Defendants created a public nuisance the State is forced to deal with, lined their pockets with State money, and endangered the lives and livelihoods of thousands. The Petition more than sufficiently alleges causation at this stage given the scope of Defendants' alleged scheme.

2. The Petition Alleges Defendants' Scheme Caused the State to Pay Claims for Opioid Prescriptions

While unclear, Defendants' argument regarding submission of claims to the State appears to relate only to the State's OMFCA and OMPIA claims. *See* Jt. MTD at 18. Defendants misstate the issue and wrongly assert the only way the State may pay for a claim for opioid prescriptions based on a purported misrepresentation by Defendants is if an "employee or agent of the Health Care Authority ever read, heard, or otherwise received a single purported misrepresentation by any Defendant." *Id.* This distorts the issue. *See* Section V.E *supra*. At this stage, prior to any discovery, the State need not allege the number of improper claims reimbursed. *See Celgene Corp.*, 2014 U.S.

Dist. LEXIS 99815, at *32. Further, to the extent Defendants argue that the only way to both allege and ultimately prove causation under the OMFCA or OMPIA is by engaging in a doctor-by-doctor analysis of all claims and patients, Defendants are incorrect. Even under the federal pleading standard, this is not required. *See id.*; *see also* United States Statement of Interest Regarding Defendant's Motion to Dismiss, *United States ex. rel Brown v. Celgene*, Docket No. 129 (June 12, 2014) ("Like any other element of a case, causation can be established by circumstantial evidence sufficient to allow a reasonable jury to conclude that it is more likely than not that a causal connection existed...a jury could infer that a defendant drug manufacturer's off-label promotion was a substantial factor in the physician's decision to prescribe the drug off-label for uses which are not 'medically accepted indications.'"). Such a heightened level of pleading prior to any discovery is certainly not required under the more liberal Oklahoma pleading requirements.

3. The State's Alleged Injuries Are Not Too Remote

Lastly, Defendants argue the State's alleged injuries are "too remote and depend on multiple intervening events." Jt. MTD at 18; *see also* Teva MTD at 17-19. This is incorrect; and it is a question for the jury. Defendants intended to change prescribers' habits. ¶¶2-4. Defendants intended the State's Medicaid program to pay for the additional prescriptions that resulted. Defendants cannot escape liability just because their conduct had its intended result. To argue otherwise, or put the blame on others, is insulting. Under Defendants' analysis, no pharmaceutical company would ever be liable for fraudulent representations regarding their drugs as long as they are approved by the FDA. Clearly, that is not the law.

Finally, Defendants attempt to avoid liability for the fallout of their conduct by claiming that certain damage categories alleged by the State are too "attenuated." Jt. MTD at 20. Again, this is not an issue for a motion to dismiss; that is a jury question on causation. Moreover, Defendants

ignore that they do not just face liability for damages, but also steep statutory penalties—up to $11,000 per violation under the OMFCA and up to $10,000 per violation under the OCPA before even determining damages. *See* 63 O.S. §5053.1 (2016); 15 O.S. §761.1(C). Now is not the time to attempt to exclude damage categories from any of the Petition's allegations. The Petition undoubtedly alleges severe injuries, which is sufficient at this stage.

Defendants' arguments regarding causation fail and raise fact questions for the jury following discovery.

VI. CONCLUSION

Defendants should not be permitted to delay this case any further. Dismissal is inappropriate. This case should proceed to discovery and trial before twelve jurors.

Dated: October 30, 2017

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