



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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

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.,
Defendants.

STATE OF OKLAHOMA } S.S.
CLEVELAND COUNTY }
FILED

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In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816

Honorable Thad Balkman

**DEFENDANTS' JOINT REPLY BRIEF IN SUPPORT OF THEIR
MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM**

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I. INTRODUCTION

The State's Response to Defendants' Joint Motion to Dismiss improperly attempts to supplement its defective Petition with entirely new factual allegations. Those allegations, spread over the first 38 pages of the State's brief, should be disregarded, because the viability of the State's claims must be judged by the allegations in its Petition. Yet even considering the new allegations, the State still fails state a claim. The core pleading deficiencies that entitle Defendants to dismissal are not remediated.

For instance, the State points to alleged efforts by Defendants to minimize the potential for opioid addiction, Resp. 21-24, 34-35, but does not identify a single Oklahoma doctor who wrote a medically unnecessary prescription or a single Oklahoma patient who received one. The State never grapples with this fundamental failure—one laid bare by the State's plea for the Court to excuse it on the assumption that at least one of the Defendants grouped together in the Petition must have caused "at least one" medically unnecessary reimbursement claim to be submitted to Oklahoma Medicaid. *Id.* 64. Oklahoma law requires more.

The State asserts that there is a "dearth of scientific evidence demonstrating opioids are safe and effective for" treating non-cancer related pain, *id.* 19, without mentioning that the federal Food & Drug Administration (FDA) takes a contrary view. The State insists, in turn, that Defendants were wrong to promote opioids for non-cancer pain by sponsoring various key opinion leaders and publications, *id.* 19-20, 27-29, without acknowledging that the promotion was consistent with FDA labeling for long-acting opioids and without explaining why claims based on such allegations are not preempted by federal law.¹ The State takes issue with lobbying by the American Pain

¹ The State filed a separate brief responding to Defendants' Joint Motion to Dismiss Based on Preemption and Joint Motion to Stay This Case Under The Primary Jurisdiction Doctrine. Defendants address those arguments in a standalone reply brief.

Foundation (and impugns Defendants for partially funding the Foundation), *id.* 25-26, but nowhere explains how these actions could form a basis for the claims in the Petition, let alone do so without running afoul of constitutional protections for petitioning activity.

The State also describes Oklahoma working groups and commissions that have initiated studies or developed plans to address opioid abuse, *id.* 7-8, advancing the contention that the existence of these initiatives somehow shows Defendants' alleged fraudulent marketing was "material" to Oklahoma Medicaid's decision to reimburse opioids prescribed to Medicaid beneficiaries, *id.* 65-66. These initiatives add no support for the State's claims, but rather emphasize the complexity of the public health issues surrounding opioids—issues involving numerous actors, including health care providers, law enforcement, public and private health organizations, educators, pharmacists, distributors, federal government agencies, and others.

The various newspaper articles cited by the State in connection with its description of the impact of opioid abuse further underscore the complex factors involved. These sources identify illegal drugs like carfentanil (a veterinary product used on elephants) and illicitly-produced street fentanyl, rather than medications sold by Defendants, as major contributors to overdose deaths²; fault some doctors for not conducting basic checks to determine whether their patients truly needed opioids or had a history of drug addiction before prescribing them³; and describe "patients selling their pills on the black market" and doctors distributing opioid medications illegally through so-

² Katharine Q. Seelye, *As Overdose Deaths Pile Up, a Medical Examiner Quits the Morgue*, New York Times (Oct. 8, 2017) at A16 (cited at Resp. 1 n.5).

³ German Lopez, *How to Stop the Deadliest Drug Overdose Crisis in American History*, Vox (Oct. 26, 2017) (cited at Resp. 1 n.3).

called “pill mills.”⁴ The State offers no explanation for how it might legally connect any Defendant, as opposed to these and numerous other factors, to the harms caused by opioid abuse. Instead, the State incorrectly argues that the Court should excuse its pleading failure because “the questions of causation and damages are fact questions for the jury” that need not be addressed now. *Id.* 95. Oklahoma law says otherwise.

The State’s Response makes clear that opioid abuse and addiction present policy questions about the value of things like public outreach, medical education, prescribing guidelines, training and consultation services for Medicaid-contracted practices, and potential enhancements to the State’s own prescription monitoring program, *id.* 8, through which the State has long had the ability to identify and reduce doctor shopping, prescribing, and the availability of controlled substances. But the existence of policy questions surrounding this public health issue says nothing about whether the State’s Petition contains sufficient allegations to advance beyond the pleading stage. It does not.

II. ARGUMENT

The State’s Petition fails to identify a single medically unnecessary or inappropriate opioid prescription written by an Oklahoma doctor for an Oklahoma patient. The State likewise fails to identify any reimbursement decision by Oklahoma Medicaid that was caused by a Defendant’s fraudulent promotion. These central pleading deficiencies pertain to every cause of action advanced in the Petition—from the Oklahoma Medicaid False Claims Act to the State’s public nuisance claim. They are both fatal to the State’s ability to plausibly allege causation, a required element of each of its claims, and emblematic of a broader failure to allege facts with the specificity

⁴ Patrick Radden Keefe, *The Family That Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017) (cited at Resp. 38 n.121).

required by Oklahoma law. That lack of specificity is also seen in the State's impermissible group pleading, lumping all Defendants together despite the fact that they are competitors who sold different medications at different times. For these and the additional reasons addressed below, the Court should dismiss the State's Petition.

A. The State Fails To Satisfy Section 2009(B)

The State acknowledges that Section 2009(B) requires for its fraud-based claims that “the circumstances constituting fraud or mistake ... be stated with particularity,” including the “*specification of the time, place and content of an alleged false representation.*” Resp. 14, 40 (quoting *Gay v. Akin*, 1988 OK 150, ¶ 18, 766 P.2d 985, 993; emphasis added). But the Response does not point to any allegation in the Petition that satisfies this requirement—because no such allegations exist. Despite repeatedly accusing Defendants of misrepresenting the risks of opioid addiction, Resp. 49, 61, 63, 67-68, 84-85, 87, the Response does not identify the content of a single misrepresentation or omission made by a Defendant in Oklahoma, much less identify when, where, or to whom it was made. Nor does the Response dispute that the Petition fails to connect any purported misrepresentation to any Oklahoma patient, physician, prescription, claim, or reimbursement decision. *See* Joint Motion 10; Resp. 38-41. The failure to plead these basic elements is fatal to all of State's claims.

The State asserts that Section 2009(B)'s heightened standard does not apply to its public nuisance, unjust enrichment, and OCPA claims, arguing they are not fraud claims. Resp. 39. But “the particularity requirement extends to all averments of fraud, regardless of the theory of legal duty,” and an averment of fraud exists “where there is some false suggestion or suppression of the truth—some false representation—by which one can get advantage over another.” *Estrada v. Kriz*, 2015 OK CIV APP 19, ¶¶ 13, 15, 345 P.3d 403, 407-08. The State's public nuisance, unjust enrichment, and OCPA claims are based on exactly the same allegedly fraudulent representations as

every other cause of action.⁵ Pet. ¶¶ 105-114, 118-19, 130-31. And because the Petition does not provide the requisite particularity,⁶ all of the State’s claims fail.

B. All Claims Fail Because the State Does Not Adequately Allege Causation.

Under any pleading standard, the Petition lacks facts sufficient to prove causation. Cause in fact and proximate cause are essential elements for all of the State’s claims. *See* Joint Motion 16; Resp. 95. In this case, the causation element rests on the State’s assertion that Defendants deceived doctors into writing medically unnecessary or excessive prescriptions for opioid medications. The State’s claims for damages arising out of its reimbursements for allegedly unnecessary opioid prescriptions further requires the State to show that its agents were deceived. *See* Joint Motion 16-18; Resp. 95-99. Yet the State’s Response fails to identify any factual, non-conclusory allegations that could establish that a purported misrepresentation actually or proximately caused any prescribing or reimbursement decision. The absence of any such allegations is fatal to every one of the State’s claims.

Recognizing as much, the State suggests that a Petition cannot be dismissed for failure adequately to plead facts supporting causation. Resp. 95. Not so. As the Oklahoma Supreme Court

⁵ The State cites various cases explaining *what* the notice pleading standard entails, Resp. 39-40, yet none of them addresses Defendants’ point that the notice pleading standard is inapplicable here because the claims are based on allegations of fraud.

⁶ Rather than demonstrate that the Petition alleges fraud with sufficient specificity, the Response tries to sidestep this flaw by arguing that Defendants did not file the appropriate motion to seek relief for the State’s failure—namely, a motion to supply the necessary particulars. Resp. 14-15. But the Oklahoma Supreme Court has dismissed petitions for failure to plead fraud with the necessary specificity under Section 2009(B). *See, e.g., Dani v. Miller*, 2016 OK 35, ¶ 25, 374 P.3d 779, 791; *Gianfillippo v. Northland Cas. Co.*, 1993 OK 125, ¶ 11, 861 P.2d 308, 310-11. Moreover, the Joint Motion plainly seeks, in the alternative, “an order that the State make its Petition more definite and certain in compliance with Oklahoma’s pleading requirements” and argues that the “State should be compelled to provide the requisite factual details of each of its claims, which all sound in fraud.” Joint Motion 1, 8 & n.9; *see A-Plus Janitorial & Carpet Cleaning v. Emp’rs’ Workers’ Compensation Ass’n*, 1997 OK 37, ¶ 36, 936 P.2d 916, 931. The State cannot exempt itself from pleading its deficient claims with sufficient factual detail.

has recognized, even under the more liberal pleading standard that the State contends is applicable to the majority of its claims, “a petition ‘should disclose the existence of the necessary elements of a legally recognized claim or cause of action.’” *Zaharias v. Gammill*, 1992 OK 149, ¶ 6, 844 P.2d 137, 138 (quoting Fraser, George B., *The Petition Under the New Pleading Code*, 38 Okla. L. Rev. 245, 246 (1985)). Thus, when the facts alleged in a petition are insufficient to establish causation, the petition must be dismissed. *See, e.g., Truitt v. Diggs*, 1980 OK 57, ¶ 17, 611 P.2d 633, 637 (affirming dismissal of petition where allegations of essential element of causation were “conclusional in nature and not factual”); *Sanders By & Through Sanders v. Crosstown Mkt., Inc.*, 1993 OK 25, ¶ 16, 850 P.2d 1061, 1064 (affirming dismissal where causal connection between alleged misconduct and alleged injuries was too remote); *TKO Energy Servs., LLC v. M-I LLC*, 539 F. App’x 866, 873 (10th Cir. 2013) (applying Oklahoma law and affirming dismissal of fraud-based claims where complaint failed to allege actual reliance).

1. The Petition Fails to Allege Facts That Could Establish That the Purported Misrepresentations Were the Actual Cause of Any Prescribing Decision.

The State contends it has pled actual causation by alleging that “Defendants conducted their marketing campaign in Oklahoma.” Resp. 96 (citing Pet. ¶¶ 51, 54). But those bare allegations about marketing in Oklahoma, without more, do not show that any providers relied on, or were influenced by, any purported misrepresentation in writing any opioid prescription. Indeed, the State concedes as much. *See* Resp. 95-96. It thus suggests that the Court should compensate for its pleading failure by *inferring* that prescribers relied on Defendants’ marketing and promotional

statements because Defendants intended them to do so. *Id.* 96.⁷ Alleged *intent*, however, does not establish *causation*.⁸

The State also points to a statewide “increase[] [in the] number of opioid prescription claims,” Resp. 86, but that allegation still does not show that Defendants’ alleged misconduct caused that increase. Indeed, the State’s observation is missing the key causation allegation—i.e., that Defendants’ alleged *misstatements* (as opposed to other marketing statements or factors)

⁷ The State relies on *U.S. ex rel. Brown v. Celgene Corp.*, 2014 U.S. Dist. LEXIS 99815 (C.D. Cal. July 10, 2014), an unpublished decision from the Central District of California, for its contention that vague allegations of an “overarching scheme” to defraud satisfy its burden to plead facts to demonstrate a causal connection between Defendants’ alleged misrepresentations, physicians’ prescribing decisions, and the State’s reimbursement decisions. *Celgene* does not stand for that proposition, and in any event, is inapplicable here. In *Celgene*, a former sales representative for the defendant drug manufacturer alleged that the defendant developed an intentional scheme both to encourage prescribers to prescribe its medications for unauthorized uses that expressly violated statutory payment conditions and to pay illegal kickbacks to doctors, and that “almost all” of the sales of the medicines at issue were for these statutorily ineligible uses. *Id.* at *9. Here, the State alleges none of these facts. Given that all of the State’s alleged injuries are premised on allegedly medically *improper* opioid prescribing (notwithstanding that Oklahoma law expressly authorizes opioid prescriptions for chronic pain), the State must allege that Defendants’ alleged misrepresentations caused prescribers to submit, and the State to reimburse, medically improper prescriptions. The “scheme” that the State alleges here does not establish the type of causal connection that is necessary to sustain its claims, as numerous courts have recognized. Joint Motion 16-18 (citing cases).

⁸ Defendants’ cases are materially indistinguishable. *Twyman v. GHK Corp.*, 2004 OK CIV APP 53, ¶ 52, 93 P.3d 51, 61, was, as the State observes, decided following an appeal of a jury trial verdict. Nothing about the principles articulated in that case remotely suggest that causation need not be alleged at the pleading stage. To the contrary, *Twyman* recognized that “proximate causation [is] an *essential element* of [] negligence and nuisance claims.” *Id.* (emphasis added). *Baron v. Pfizer, Inc.*, 820 N.Y.S.2d 841 (2006), is, as the State observes, a New York decision, Resp. 97, but New York law does not materially differ from Oklahoma law on the issue of causation. Like Oklahoma, New York law requires dismissal where “the complaint lacks specific allegations regarding whether plaintiff’s physician either received or relied upon any information from defendant in prescribing [the drug] for plaintiff.” *Id.*; see also *Turner v. Rector*, 1975 Okla. Civ. App. LEXIS 154, at *10-11 (Ct. App. July 8, 1975) (“It is fundamental law that in pleading negligence . . . plaintiff must plead facts sufficient to show . . . [that] the breach was the proximate cause and . . . plaintiff suffered damages.”). *City of Chicago v. Purdue Pharma, L.P.*, 2015 WL 2208423 (N.D. Ill. May 8, 2015), cannot be distinguished on the ground that it was “decided under more stringent federal pleading standards that do not apply here,” Resp. 97, because those standards *do* apply here, see *supra* § II.A.

caused opioids to be improperly prescribed. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010) (rejecting the plaintiff’s attempt to demonstrate causation could be shown by pointing to an increase in the number of prescriptions written following a drug manufacturer’s alleged misrepresentations about the drug, because “[t]he nature of prescriptions . . . means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof”). “Without more specific allegations of reliance by physicians whose prescriptions Plaintiff reimbursed, there is no way to know if any of those prescriptions resulted from deception.” *In re Bextra & Celebrex Marketing Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *7 (N.D. Cal. Aug. 2, 2012); *see id.* (“Because at least some doctors were not misled by [Defendants’] alleged misrepresentations . . . general proof of but-for causation [is] impossible” (quotations omitted)).

2. The Petition Fails to Allege That the Purported Misrepresentations Caused the State to Pay for Opioid Prescriptions.

Claims premised on reimbursement of allegedly unnecessary opioid prescriptions similarly fail, because the Petition does not allege a causal connection between Defendants’ purported misrepresentations and any State agent’s reimbursement decision. *See* Joint Motion 18. The State does not dispute that it was required to allege such a connection and does not contest that the Petition fails to allege that any “employee or agent of the Health Care Authority ever read, heard, or otherwise received a single purported misrepresentation by any Defendant.” Resp. 98 (quoting Joint Motion 18).

The State instead asserts that “at this stage, prior to any discovery, [it] need not allege the number of improper claims reimbursed” or “engag[e] in a doctor-by-doctor analysis of all claims and patients” to establish causation with respect to each reimbursement decision. Resp. 98-99. The State once again misses the mark. Even if the State is not required to identify at the pleading stage

every prescription that it alleges to have been improperly reimbursed, the State must still allege *facts showing* a causal nexus between the purported misrepresentations and the State's reimbursement decisions. The State cannot adequately plead causation with respect to reimbursement decisions absent factual allegations showing that the State's agents were exposed to, and reasonably relied on, Defendants' purported misrepresentations prior to making those decisions. The State now concedes that the Petition did not.

3. The State's Alleged Injuries Are Too Remote As a Matter of Law and Depend on Multiple Intervening Events.

In Oklahoma, as elsewhere, a plaintiff is required to plead and prove proximate causation, and Oklahoma law accordingly precludes liability when the connection between an alleged harm and the challenged conduct is too remote, too attenuated or is broken by superseding intervening causes. Joint Motion 18-20; *see also Woodward v. Kinchen*, 1968 OK 152, ¶ 12, 446 P.2d 375, 377-78. The State's causation theory fails this requirement as well. Any connection between Defendants' alleged misconduct and any reimbursement or prescribing decision is simply too attenuated, punctuated with multiple, independent, intervening factors that break the causal chain—including doctors' decisions whether and how to use opioids, a patient's response to the medications, and the State's decision to reimburse an opioid prescription, not to mention the intervening criminal acts of illegal opioid sale and use. *See* Joint Motion 19. And the State does not dispute that the prescribing physician's independent exercise of medical judgment in assessing and treating each patient serves as an intervening factor that breaks the chain of causation. Resp. 92.

To save its deficient claims, the State argues that the learned intermediary doctrine is limited to product liability claims, Resp. 92, and that proximate causation cannot be resolved on a motion to dismiss, Resp. 99. That simply is not true. Courts across the country routinely dismiss

complaints like the State's for lack of factual allegations plausibly showing proximate cause, including where (as here) learned intermediaries' independent judgment breaks the causal chain. See, e.g., *United Food & Commercial Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (affirming dismissal of action to recover for payments for allegedly improper prescriptions where plaintiffs "failed to plead a cognizable theory of proximate causation" and instead "proffered an attenuated causal chain that involved at least four independent links," including "Medicare's decision to cover" drugs at issue for the alleged misuse, and "doctors' decisions to prescribe [the drugs] for these uses"); see also Joint Motion 19-20 (citing additional cases). The State has no response to these cases.

C. The State's Improper Group Pleading Warrants Dismissal.

In a similar vein, the State's group pleading also warrants dismissal. The State does not offer any serious reason for the Court to accept its assertion that it "[d]oes [n]ot '[g]roup [p]lead.'" Resp. 41. In fact, the State admits that group pleading is spread throughout the Petition, which routinely groups together thirteen different Defendants, including four distinct "primary corporate Defendants," on the ground that they "all sold opioids." *Id.* 42-43 (emphasis omitted).

The State first says that the group pleading rule is unique to "federal securities fraud cases." *Id.* 44. Not so. Defendants do not rely on any type of specialized doctrine, but rather generally-applicable and settled Oklahoma law that when a plaintiff's claims sound in fraud, it may not group multiple defendants together without identifying specific acts against each defendant. *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990 (where a plaintiff asserts a claim sounding in fraud, it "must plead facts from which fraud may reasonably be inferred *as to each defendant*" (emphasis added)); see

also Joint Motion 6-7.⁹ In a similar vein, the State chastises Defendants for citing federal cases, suggesting the federal standard somehow differs from that in Oklahoma. Resp. 14, 38-39, 44-45 & n.27.¹⁰ But the Oklahoma Supreme Court *explicitly* recognized in *Gay* that “the text of Federal Rule 9(b) is incorporated verbatim in the Oklahoma pleading code” and federal decisions should therefore guide the analysis. *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990 & n.21 (citing *Grunwald v. Bornfreund*, 668 F. Supp. 128, 131 (E.D.N.Y. 1987); *Natowitz v. Mehlman*, 542 F. Supp. 674, 676 (S.D.N.Y. 1982)).¹¹

⁹ Contrary to the State’s argument, *all* of its claims are subject to *Gay*’s holding because every cause of action in the Petition hinges on allegations that Defendants disseminated purportedly false or misleading statements and thus sounds in fraud. *See, e.g.*, Pet. ¶¶ 3-5, 75, 78-79, 82-83, 85-90, 94, 99, 105, 107-08, 110-12, 118-19, 121-26, 131. *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990 (explaining that “the particularity requirement extends to *all* averments of fraud, regardless of the theory of legal duty—statutory, tort, contract or fiduciary”) (emphasis in original); *Howard Family Charitable Found., Inc. v. Trimble*, 2011 OK Civ. App. 85 ¶ 47, 259 P.3d 850, 863 (same) (quoting *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990).

¹⁰ The State itself relies on federal cases—a tacit concession that the analysis of Federal Rule of Civil Procedure 9 is persuasive authority. The Response, for instance, cites *Flow Valve, LLC v. Forum Energy Techs., Inc.*, 2014 U.S. Dist. LEXIS 97736, at *8-9 (W.D. Okla. July 18, 2014), in an effort to evade *Gay*’s group-pleading rule. Resp. 44. The case, however, is inapposite on its face, as it did not involve the sprawling allegations at issue here and even included “specific” allegations of misconduct by the defendant. *Flow Valve LLC*, 2014 U.S. Dist. LEXIS 97736, at *8-9 (“The complaint makes specific references to conduct by Mr. Wood...the claims involved in this action are relatively straightforward, involving only three defendants...[i]n these circumstances, the purported “group pleading” is not a deficiency with respect to the misappropriation claim.”).

¹¹ The State suggests that, to the extent *Gay*’s group-pleading rule applies to its claims, the decision there shows that the State’s allegations are not defective. Resp. 45. But in *Gay*, each defendant was “chargeable with all matters pertaining to the corporation’s affairs, of which he has or should have knowledge in the exercise of the duties required of him as a director.” *Gay*, 1988 OK 150, 766 P.2d at 992. In contrast, Defendants here are separate and distinct corporate competitors that manufactured and sold distinct medications, each of which were independently approved FDA, carried different indications, bore different labels and warnings, and were marketed with different promotional strategies.

Despite submitting a 100-page brief, the State has not explained why it should be permitted to treat thirteen different defendants, constituting four disparate corporate families, as a single agglomerated whole, lumping them together in more than 80 of the Petition's 134 paragraphs. *See* Joint Motion 7. The State's improper group pleading violates well-settled Oklahoma law and denies each Defendant fair notice of the claims against it.

Yet the problems run deeper still. In addition to inappropriately lumping all thirteen defendants together, the State ignores the crucial distinctions within the various corporate families.¹² The State claims that it was permitted to do so because the individual companies were "merely" instrumentalities or agents of their parents and because the corporations took on a separate existence to perpetuate a fraud. *See* Resp. 88. But the Petition is devoid of allegations supporting the State's newly-minted theory, and it is axiomatic that a petition must allege facts supporting the plaintiff's efforts to disregard the corporate form. *See, e.g., Keel v. Titan Constr. Corp.*, 1981 OK 148, ¶ 3, 639 P.2d 1228, 1230 ("[t]he burden is upon the Plaintiffs to allege facts essential to establish the existence of the agency relationship and the nature and extent thereof"); *Cherry v. Remington Arms Co., Inc.*, 2012 WL 12862815, at *2 (W.D. Okla. Sept. 4, 2012) (same).¹³

Indeed, the Petition's failing is particularly stark in this case. Within the four identified corporate families, some entities marketed and promoted branded opioids, others manufactured

¹² The State impermissibly (and inaccurately) re-characterizes Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc. and Watson Laboratories, Inc. as "Actavis"; Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. as "Cephalon"; and Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica Inc. as "Janssen." Pet. ¶¶ 15, 17, 19.

¹³ The Petition also alleges that Defendants "acted in concert with one another and acted as agents and/or principals of one another." Pet. ¶¶ 15, 17, 19. That is a legal conclusion entitled to no weight at the dismissal stage, and the Petition lacks any *factual* allegations substantiating the State's theory.

generic drugs without promoting them, and still others, like Johnson & Johnson, did not design, manufacture, sell, or promote any medications at all. Likewise, some entities only became part of a corporate family recently, and have little or no connection to any of the alleged promotional activities in the Petition. *See, e.g.*, Pet. ¶ 15 (alleging that Actavis Plc did not acquire Allergan Plc until March 2015); *id.* ¶ 17 (alleging that Cephalon, Inc. did not become affiliated with Teva Pharmaceuticals USA, Inc. until October 2011). And where individual defendants were involved in the promotion of opioid medications, they manufactured and sold a wide range of medications over an extended period of time, utilizing individualized and vastly different marketing strategies.

Recognizing this failing, the State seeks permission to conduct discovery on the corporate relationships “between and among Janssen/J&J, Cephalon/Teva USA and Allergan Plc/The Acquired Actavis Entities to support its agency and instrumentality theories.” Resp. 90. But the State cannot use *discovery* to satisfy its *pleading* burden. Only adequately pled allegations entitle a plaintiff to discovery, and the Petition does not contain any.

D. The State’s Causes of Action Fail for Additional Claim Specific Reasons.

1. The Oklahoma Medicaid False Claims Act Claim (Cause of Action A) Must Be Dismissed.

The lack of specificity in the State’s Petition directly undercuts its first cause of action under the Oklahoma Medicaid False Claims Act (OMFCA). The State fails to allege the particulars of any false claim and the Petition likewise lacks allegations sufficient to show materiality, presentment of a false claim, or a false statement made to secure payment from the Oklahoma Medicaid program.¹⁴

¹⁴ The State’s OMFCA claim would otherwise be time-barred for claims predating June 30, 2011. The State concedes that claims predating the OMFCA’s November 1, 2007 enactment are barred, *see* Resp. 70 n.151, but argues that the OMFCA’s six-year limitations period does not bar claims predating June 30, 2011, because “it [applies only] to *qui tam* actions brought by private

a. The Petition Fails to Plead the Particulars of Any False Claims.

The State’s principal effort to avoid the consequences of the pleading deficiencies for its OMFCA claim would turn the law on its head. According to the State, because there is a “paucity of case law applying the OMFCA,” this Court should jettison standard Oklahoma pleading law, Resp. 53, and require *Defendants* to show “*beyond any doubt* that the State can prove *no* set of facts” supporting liability, Resp. 55 (emphasis in original, brackets removed). It is not Defendants’ obligation to *disprove* liability, much less “beyond any doubt”; rather, the plaintiff *always* bears the burden of adequately supporting its claims at each stage of the case. *See Brown v. Founders Bank and Tr. Co.*, 1994 OK 130, ¶ 16 n.34, 890 P.2d 855, 864 (noting that plaintiffs ultimately bear the burden of “proof of all the elements required as a prerequisite to recovery”).

The State’s Response also fails to explain how the Petition satisfies Section 2009(B)’s particularity requirement.¹⁵ Defendants do *not* contend, as the State claims, that the Petition must

citizens,” Resp. 71. To be sure, the pre-amendment OMFCA’s limitations provision exempted actions brought by the Attorney General. *See Okla. Stat. tit. 63, §§ 5053.6(B)(1), 5053.3.* But while the previous OMFCA version applies to the *substantive* allegations in the petition, *see* Joint Motion 21 n.19, the current version applies to *procedural* matters, including the statute of limitations. *See Trinity Broad. Corp. v. Leeco Oil Co.*, 1984 OK 80, ¶ 8, 692 P.2d 1364, 1366-67 (holding statute of limitations applicable at time of filing suit applied because “[s]tatutes of limitation are viewed as procedural rather than substantive”). The operative version of the OMFCA at the time the State filed this lawsuit applied the limitations period to *any* “civil action under Section 5053.2 of this title.” Okla. Stat. tit. 63, § 5053.6(B). And Section 5053.2 includes *both* private *qui tam* actions *and* actions brought by the Attorney General. §§ 5053.2(A)-(B). The legislature’s deliberate change unmistakably shows its intent to apply the limitations period to actions brought by the Attorney General. *See* 2016 Okla. Sess. Law Serv. Ch. 44 (S.B. 1515) § 6 (deliberately striking the language exempting Attorney General actions from the limitations bar). Accordingly, the six-year limitations period applies and bars the State’s OMFCA claims predating June 30, 2011.

¹⁵ The State asserts, without citation, that “Oklahoma courts have refused to adopt” “the heightened federal pleading standard” for fraud claims. Resp. 60. Not so: “Oklahoma adopted the federal rule verbatim.” *Gianfillippo*, 1993 OK 125, ¶ 11, 861 P.2d at 310; *see* Okla. Stat. tit. 12, § 2009(B) (echoing Fed. R. Civ. P. 9(b) nearly verbatim). As for the OMFCA in particular, there simply are not any published Oklahoma appellate cases discussing it—so it is misleading to say,

contain “the minutiae of the individual claims.” Resp. 58. However, the State must provide *some* basic level of detail—“the ‘who, what, when, where and how’ of the alleged fraud.” *United States ex rel. Sikkenga v. Regence Blue Cross Blue Shield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006). In fact, the State’s own case, *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126-27 (D.C. Cir. 2015), required the plaintiff to “allege[] *particular details* of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that *[[false] claims were actually submitted.*” Resp. 57. Here, the Petition is bereft of *any* allegation of actual claims for payment, much less allegations that meet the particularity requirement.

In attempting to circumvent its pleading requirements, the State cites to a string of inapposite cases, Resp. 57-59 nn.138-40, applying a “lenient” pleading standard where the claim information at issue was not readily available to the relator plaintiff. *See United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 89 (2d Cir. 2017) (considering *qui tam* claims). But the State’s failure is inexcusable here, because *only it has access to its own reimbursement data*. And the cited opinions still required even relator plaintiffs to plead their claims with enough specificity to give rise to an inference that actual false claims were submitted to the government.¹⁶

as the State does, that courts have “refused” to adopt the heightened pleading standard in this context. And in any case, general Oklahoma law—which clearly holds that claims *sounding* in fraud are governed by Section 2009(B)—applies fully to the OMFCA.

¹⁶ *See* Resp. 57-59 nn.138-40, citing *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010) (holding relator plaintiffs’ FCA claims met Rule 9(b) standard by “providing factual allegations regarding the who, what, when, where, and how of the alleged claims,” and showing “the *specifics of a fraudulent scheme* and...an adequate basis for a reasonable inference *that false claims were submitted as part of that scheme*” (emphasis added)); *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 158 (3d Cir. 2014) (same); *United States ex rel. Chorches*, 865 F.3d at 86-87 (same); *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 777 (7th Cir. 2016) (same); *United States v. Johnson & Johnson*, 2017 U.S. Dist. LEXIS 83335, at *16-17 (D.N.J. May 31, 2017) (same); *United States ex rel. Brown v. Pfizer, Inc.*, 2016 U.S. Dist. LEXIS 25723, at *34-44 (E.D. Pa. Mar. 1, 2016) (same); *United States ex rel. Brown v. Celgene Corp.*, 2014 U.S. Dist. LEXIS 99815, at *33-37 (C.D.

The State similarly argues that it need not “delineate the minute details of a specific legal theory” to allege “false or fraudulent” claims within the meaning of Okla. Stat. tit. 63, § 5053.1(B)(1). Resp. 60. But, again, under any legal theory that could support false claims liability, more is required. *See* Joint Motion 22. With respect to factual falsity, the Petition does not allege that any claim contained “an incorrect description of goods or services provided”—for instance, a claim for prescription opioids when the pharmacy in fact provided sugar pills—or sought “reimbursement for goods or services never provided,” as required to plead factual falsity. Joint Motion 22 (citing *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1168 (10th Cir. 2016)). The State’s only response is that even if each and every claim *accurately* described the “goods or services provided”—namely, a prescription opioid—it is nevertheless factually false because opioids in general “did not do what Defendants claim they did and contained risks that Defendants claimed they did not contain.” Resp. 61. That sweeping theory fails for the reasons described above, *see supra* § II.A, and is preempted insofar as FDA expressly determined that opioids are effective and can be marketed for long-term treatment of chronic pain.

The similar contention that “*every* claim for reimbursement,” “including each of the more than 99,000 identified in the Petition” are false “by operation of law,” Resp. 62-63, fails for the same reasons. The State does not dispute that FDA has approved many of the drugs at issue for the treatment of chronic pain, including chronic non-cancer pain. *See* Joint Motion 10-11. And Oklahoma law expressly allows—in fact “encourages”—physicians to prescribe opioids and other controlled substances for pain relief. Okla. Stat. tit. 63, § 2-551(B) (“The State of Oklahoma encourages physicians to view effective pain management as a part of quality medical practice for

Cal. July 10, 2014) (same); *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 676-79 (E.D. Pa. 2010) (same).

all patients with pain, acute or chronic.”); *see also* Joint Motion 10 (citing OAC § 435:10-7-11; 475:30-1-2 (permitting physicians to prescribe controlled substances for the treatment of chronic pain)).¹⁷ The State’s theory of falsity—that *every single opioid prescription* submitted to Oklahoma Medicaid for reimbursement is somehow “false”—runs headlong into these determinations. And the State does not dispute that *some* opioids were in fact properly prescribed, negating a claim that *all* prescriptions were false.

The State’s alternative theory—i.e., that “at least one of the reimbursement claims Defendants caused to be submitted to the State was for a ‘medically unnecessary’ purpose,” Resp. 64—also fails. The predicates for that theory are the State’s allegations of a “statistical increase” in opioid prescriptions and “the unprecedented epidemic,” *id.*, but to plead legal falsity, the State must allege that a claim contained a false assertion of “compliance with a regulation or contractual provision.” Joint Motion 22 (citing *United States ex rel. Thomas*, 820 F.3d at 1168). It is not enough to declare that “it is impossible to infer that *all 99,000-plus* claims ... were prescribed for ‘medically necessary’ purposes, as required for reimbursement.” Resp. 64. The State’s theory, if accepted, would have sweeping ramifications for false claims law, as the State’s argument boils down to the contention that the greater number the claims, the more likely it is that one might be false. But an allegation that, at some point, at least one false claim must have been submitted is entirely speculative, and falls well short of the State’s burden to plead facts showing that an actual false claim was submitted.

¹⁷ In addition, the United States Supreme Court has recognized that off-label prescribing and use of medicines “often is essential to giving patients optimal medical care.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 n.5 (2001) (internal citations omitted).

b. The Petition Does Not Plead Facts That Plausibly Support Materiality.

The State does not dispute that materiality is an essential element of an OMFCA claim, or that the Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* precludes a finding of materiality here because "the Government regularly pays a particular type of claim [i.e., for prescription opioids] in full despite actual knowledge" of Defendants' marketing activities. 136 S. Ct. 1989, 2003-04 (2016). The State attempts to distinguish *Escobar* and its progeny on the ground that the government did not intervene in those cases. *See* Resp. 65-66. But that is a distinction without a difference; no relevant part of *Escobar* turned on the government's participation in the case.

The State's interpretation of *Escobar* would also read the materiality requirement out of the statute. According to the State, the lawsuit *itself* would be proof of materiality, Resp. 65, rendering actual proof of materiality unnecessary. Of course, that is not how the FCA works. Materiality is judged not by the government's *ex post* willingness to sue, but by whether the government would, in actuality, have withheld payment had it known the statement at issue was false. *Escobar*, 136 S. Ct. at 1996, 2002-04 & n.6. Here, Oklahoma Medicaid paid *and continues to pay* for prescription opioids, as exemplified by Exhibits 1 and 4 to the Petition. That the legislature is "actively working to pass stricter legislation to combat [future] opioid *over-prescription*" by physicians, Resp. 65 (emphasis added), has no bearing on whether the prescriptions that ultimately *were* filled are reimbursable. The other "facts" alleged in support of the State's materiality argument, *see* Resp. 65-66, are similarly irrelevant: they concern the State's alleged damages, not materiality with respect to its reimbursement decisions. Without any allegation of materiality with respect to *payment decisions*, the State's theory of liability, *see* Resp. 63, 66-67, fails as a matter of law. *See Escobar*, 136 S. Ct. at 2003 ("A misrepresentation cannot be deemed material merely because the

Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.”).

c. The State Fails to Plead Presentment of Any False Claim (“Count 1”).

To address the presentment requirement, the State merely points to generic allegations in its Petition that Defendants caused the submission of claims for the reimbursement of opioid prescriptions by Oklahoma Medicaid, but nowhere does the Petition allege that any of those submitted claims were false claims. Resp. 67 (citing Pet. ¶¶ 34-39, 99 & Pet. Exs. 1-4). This does not suffice to plead that Defendants “[k]nowingly...caus[ed] to be presented, [to an officer or employee of the State of Oklahoma], a false or fraudulent claim for payment or approval.” Okla. Stat. tit. 63, § 5053.1(B)(1); Pet. ¶ 75.

d. The State Fails to Plead Any False Statement to Secure Payment (“Count 2”).

As explained, the Petition does not adequately plead a false statement in connection with a claim for payment. Joint Motion 9-10, 24-25. Nor does the Petition plead the requisite purpose and intent—i.e., intent “to get a false or fraudulent claim paid or approved by the State.” Okla. Stat. tit. 63, § 5053.1(B)(2). *Allison Engine Co. v. United States ex rel. Sanders* holds that the phrase “to get” as used in the FCA means the defendant must have “the *purpose* of getting a false or fraudulent claim ‘paid or approved by the Government’” and “must *intend* that the Government itself pay the claim” to be liable. 553 U.S. 662, 668-69 (2008).

The State urges this Court to ignore that construction of the “to get” clause based on a *subsequent* amendment to the FCA by Congress in 2009 and the Oklahoma legislature in 2016. Resp. 69; *see also id.* 54. But that is an unheard-of form of statutory interpretation. Legislatures are free to enact new or amended legislation to *change* the law, but cannot retroactively “overturn” a conclusive judicial interpretation of the *previous* law. *See Plaut v. Spendthrift Farm, Inc.*, 514

U.S. 211, 218 (1995); *Equity Ins. Co. v. Garrett*, 2008 OK CIV APP 23, ¶ 12, 178 P.3d 201, 204 (“where [the former statute’s] meaning had been judicially determined, the amendment may reasonably indicate that the intention of the legislature was to *alter* the law” (emphasis added)). The State separately asserts that it can bypass the purpose and intent requirement because the eventual submission of Medicaid claims was the “natural, ordinary and reasonable consequenc[e]” of Defendants’ “scheme,” Resp. 70, but none of the cases it cites actually support that proposition. *See* Resp. 70 n.150. Two of the four cited cases predate *Allison Engine*. *See United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243-44 (3d Cir. 2004). The other two involved bribes and kickbacks, which are already illegal under federal law and which Congress has said are FCA violations *notwithstanding* a lack of “actual knowledge or specific intent.” 42 U.S.C. §§ 1320a-7b(a)-(d), (g), (h); *see United States ex rel. Nevyas v. Allergan, Inc.*, 2015 U.S. Dist. LEXIS 86243, at *16 (E.D. Pa. July 2, 2015); *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 740-51 (N.D. Ill. 2010).

2. The Oklahoma Medicaid Program Integrity Act Claim (Cause of Action B) Must Be Dismissed.

The Oklahoma Medicaid Program Integrity Act (OMPIA), Okla. Stat. tit. 56, §§ 1001 *et seq.*, is a criminal statute that does not provide for civil liability except in the limited circumstances outlined in Section 1007(B). Resp. 71; *see* Joint Motion 26-27. Section 1007, in turn, applies *only* to a “person who receives payment for furnishing goods or services under the Oklahoma Medicaid Program.” §§ 1007(A), (B)(1), (B)(2). The State concedes that Defendants did not directly receive payment from Oklahoma Medicaid, Resp. 72, but contends that *everyone* in the supply chain—not only pharmacies and medical providers, but also pharmacy benefit managers, wholesalers, distrib-

utors, and manufacturers alike, no matter how far removed from the Medicaid program—has “receive[d] payment” from Medicaid. *Id.* The State’s proffered interpretation of the OMPIA is inconsistent with Oklahoma law.

In Oklahoma, as elsewhere, “[s]tatutes are to be construed according to the plain and ordinary meaning of their language.” *Johnson v. State*, 2013 OK CR 12, ¶ 10, 308 P.3d 1053, 1055; Okla. Stat. tit. 25, § 1. And the plain meaning of the phrase “a person who receives payment ... under the Oklahoma Medicaid Program” is someone who *actually* receives payment *under* the Medicaid Program, not entities several steps removed in the supply chain with no relationship to the Medicaid Program whatsoever.¹⁸ The State offers no citation to support its novel and expansive theory of liability, which would in essence rewrite the statute to eliminate the requirement that the defendant actually “receiv[e] payment” from Medicaid. *Cf. Allison Engine*, 553 U.S. at 670 (false claims must be paid by the government “and not by another entity”).

Even setting aside this fatal flaw, the Petition fails to plead a substantive violation of the OMPIA. *See Joint Motion 27 & n.23.* The Response identifies only one potentially applicable provision, Okla. Stat. tit. 56, § 1005(A)(1), which makes it unlawful for any person to “willfully and knowingly ... cause to be made a claim, knowing the claim to be false.” Resp. 72-73. But the Petition fails to plead that Defendants acted “willfully and knowingly,” as required by the statute. *See Joint Motion 27.* The State asserts that “willfully and knowingly” means the same thing as “knowingly” in the OMFCA. Resp. 73. But the Supreme Court of Oklahoma disagrees. Where, as

¹⁸ The State also asserts that Defendants qualify as “person[s]” under the statute because they “provid[e] goods or services *to a provider* under the Oklahoma Medicaid Program for which the provider submits claims.” Resp. 72 (quoting Okla. Stat. tit. 56, § 1002(8) (emphasis added)). But a “provider” is a “person who has applied to participate or who participates in the Oklahoma Medicaid Program,” Okla. Stat. tit. 56, § 1002(9), and the Petition contains no allegation that any Defendant sells opioids to such a participant (as opposed to distributors and wholesalers).

here, a statute requires a defendant to have acted *both* willfully *and* knowingly, the plaintiff must show “not only conscious, purposeful violations of the [statute], but also deliberate disregard of the law by those who know, or should have known, of the requirements of” the statute. *Estes v. ConocoPhillips Co.*, 2008 OK 21, ¶ 22, 184 P.3d 518, 527.

The Petition contains no such allegation. Nor does the Petition allege that any Defendant knowingly encouraged Oklahoma doctors to submit “false” claims for reimbursement, let alone that Defendants even caused “claims” to be submitted under the OMPIA at all. Resp. 73. The State attempts to repurpose its argument that Defendants caused claims to be submitted under the OMFCA, but “claims” means very different things under the two statutes. While “claims” in the OMFCA means “any request or demand for money ... presented to an officer, employee or agent of the state,” Okla. Stat. tit. 63, § 5053.1(A)(1), “claim” in the OMPIA means “a communication ... which is utilized to identify a good, item or service as reimbursable ..., or which states income or expense and is or may be used to determine a rate of payment” under the state’s Medicaid program, Okla. Stat. tit. 56, § 1002(3). The State ignores that critical textual difference, and the Petition contains no allegations that Defendants caused to be made any “claim” *as defined by the OMPIA*. See Joint Motion 27. The State does not—and cannot—argue otherwise.

3. The Oklahoma Consumer Protection Act Claim (Cause of Action C) Must Be Dismissed.

The State’s only support for its deceptive trade practices claim is the conclusory allegation that “Defendants deceived or reasonably expected to mislead the State, Oklahoma physicians, and Oklahoma residents.” Resp. 78.¹⁹ That bare legal conclusion does not carry the State’s

¹⁹ The State’s contention that it is “[i]t is of no import that physicians were the conduit” for any purported misrepresentations is an attempt to obscure the crucial point. As Defendants have noted numerous times, the State’s theory that prescribers were deceived by Defendants’ conduct

pleading burden, which required it to identify actual “misrepresentation[s], omission[s], or other practice[s] that ha[ve] deceived or could reasonably be expected to deceive or mislead” physicians in Oklahoma, *see* Joint Motion 31 (citing Okla. Stat. tit. 15, § 752). The State’s conclusory assertion that it meets the statutory definition of “unfair trade practice” with its allegations of a nationwide marketing campaign, Resp. 76, is similarly insufficient to survive a motion to dismiss. Joint Motion 30-31.²⁰ As explained below, the State fails to allege any Oklahoma consumer transaction in support of its OCPA claim. Moreover, even if the State had identified an Oklahoma consumer transaction, the OCPA safe harbor provision would bar the claims here and the Petition fails to state a claim for damages or penalties under the OCPA.

a. The State Does Not Allege a “Consumer Transaction.”

The Response, like the Petition, fails to identify a single qualifying “consumer transaction” under the OCPA. *Walkabout v. Midland Funding LLC*, 2015 WL 2345308, at *2 (W.D. Okla. May 14, 2015) (dismissing claim because transaction at issue was not a “consumer transaction”). The key requirement here is that the consumer transaction must occur in *Oklahoma* to trigger the OCPA. *See Steinbeck v. Dollar Thrifty Auto. Grp., Inc.*, 2008 WL 4279798, at * 3 (N.D. Okla.

is simply unworkable, given that every physician who prescribes opioids has a duty to know the risks disclosed in the opioid products’ labels. *See infra* § III.E.

²⁰ The State takes issue with the fact that Defendants have looked to the FTC Act for guidance on the meaning of an “unfair trade practice.” Resp. 76. But the Oklahoma Supreme Court has made clear that the OCPA does not “specifically define what constitutes an unfair trade practice,” *Patterson v. Beall*, 2000 OK 92, ¶ 34, 19 P.3d 839, 847, and because the OCPA is modeled after the FTCA, it is appropriate to look to the FTC Act for guidance determining what conduct constitutes “unfair” conduct. *Id.*; Joint Motion 30.

Sept. 15, 2008).²¹ Yet the State asserts only that “Defendants have engaged in a massive, *nation-wide* marketing and advertising campaign,” arguing that it “directly falls within the definition of ‘consumer transaction.’” Resp. 76 (emphasis added). The State’s argument is a non-sequitur. The State’s failure to identify any Oklahoma consumer transaction is fatal to its OCPA claim.

b. The OCPA Claim Is Barred by the Safe-Harbor Provision for Regulated Activity.²²

The OCPA safe harbor shields from liability conduct “regulated under laws administered by . . . any regulatory body . . . acting under statutory authority of this state or the United States,” as the State rightly acknowledges. Resp. 80 (citing Okla. Stat. tit. 15, § 754(2)). The State incorrectly contends that the safe harbor does not apply to its claims because the Petition complains in part about “unbranded marketing materials” that are “not regulated by the FDA.” Resp. 81.

As an initial matter, the State has not alleged unbranded promotional activity occurring in Oklahoma, and so its effort to parse that alleged conduct out from its other allegations is of no moment for application of the statutory safe harbor provision.²³ Just as significantly, the State’s

²¹ The State suggests that, because it is not a private plaintiff, it need not allege all elements of an OCPA claim, but rather merely an “unlawful practice.” Resp. 75 (citing Okla. Stat. tit. 15, § 761.1(C)). But the statute’s text lends no support to the State’s interpretation.

²² The State erroneously contends that the Court cannot resolve the safe harbor issue at this stage. Resp. 82. But whether the safe harbor bars the State’s claims is a question of law, apt to resolution at the pleading stage. The State’s lone case, *Money v. Bristol-Myers Squibb Co.*, 2009 U.S. Dist. LEXIS 121094 (D.N.J. Dec. 30, 2009), is *not* to the contrary. There, the court proceeded with discovery due to a complete “absence of adequate briefing from the parties as to [the applicability of the statutory exemption],” and because the parties “failed to provide the Court with *any* factual information or legal analysis involving the regulatory scheme at issue.” *Id.* at *20-21 (emphasis added). Here, the issue has been thoroughly briefed and the only question is whether, as a matter of law, the safe harbor bar applies.

²³ To the extent the State’s general averments about sales representatives, Pet. ¶ 54, and the provision of certain studies to physicians, *id.* ¶ 56, implicate action in Oklahoma (as non-specific as those allegations are), the alleged conduct is directly regulated by FDA. *See, e.g.*, U.S. Food and Drug Administration, *Final Guidance, Good Reprint Practices for the Distribution of Medical*

argument ignores the fact that in its capacity as the Defendant manufacturers' federal regulator, FDA has specifically addressed what physicians should be told about the risks and benefits of chronic opioid treatment. *See* Joint Motion 13-15; *see also* Letter from FDA to PROP (Sept. 10, 2013) ("FDA Response") at 2 & nn.4-6, available at <https://www.regulations.gov/document?D=FDA-2012-P-0818-0793> (concluding, contrary to State's claim, that scientific evidence supports the use of opioids for treatment of chronic pain). Moreover, the specific transaction targeted by the State's OCPA claim—the sale of a prescription-only opioid medication—is directly regulated by FDA, which mandates that prescription medications have FDA-approved labeling that describes their risks and benefits.

As a result, the State's effort to distinguish *Arnett v. Mylan, Inc.*, 2010 WL 2035132 (S.D. W.Va. May 20, 2010), on the ground that "Defendants' conduct in this case occurred outside any regulatory scheme of the FDA" fails. Resp. 82. The State's reliance on *Sisemore v. Dolgencorp, LLC*, 212 F. Supp. 3d 1106, 1110 (N.D. Okla. 2016); *Robinson v. Sunshine Homes, Inc.*, 2012 OK CIV APP 87, 291 P.3d 628; *Conatzer v. Am. Mercury Ins. Co.*, 2000 OK CIV APP. 141, 15 P.3d 1252, and *In re Gen. Motors Corp*, 2005 WL 1924335 (W.D. Okla. Aug. 8, 2005) for this proposition, *see* Resp. 81, is unavailing for the same reason.

c. The State's Claim for Damages and Penalties Fails.

The State's claim for OCPA damages and penalties is triply deficient. First, the State's overarching failure to identify specific prescriptions caused by allegedly unlawful conduct extends to its failure to identify any individual consumer "aggrieved." To show that a consumer is aggrieved, the State is required to allege something more than "his or her payment of the purchase

Journal Articles and Medical or Scientific References Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices 3 (2009); *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012).

price for that product.” *Walls v. Am. Tobacco Co.*, 2000 OK 66, ¶ 13, 11 P.3d 626, 630. Indeed, even payment for an allegedly “worthless product” has been held to be insufficient under one of the State’s cases. *See Sisemore*, 212 F. Supp. 3d at 1110. The Court should reject the State’s contention that it need not satisfy the OCPA’s plain text. The statute requires the State to allege facts showing that a particular Oklahoma consumer suffered “actual injury or damage caused by a violation of the OCPA.” *Walls*, 2000 OK 66, ¶ 13, 11 P.3d at 630.

Second, the State cannot recover alleged damages or penalties on its own behalf because it is not a “consumer”—i.e., “one who consumes or uses economic goods”—under the OCPA. *See Lumber 2, Inc. v. Illinois Tool Works, Inc.*, 2011 OK 74, ¶ 20, 261 P.3d 1143, 1149; *see also Cent. Reg’l Employees Ben. Fund v. Cephalon, Inc.*, 2009 WL 3245485, at *3 (D.N.J. Oct. 7, 2009) (applying rule under analogous New Jersey statute).²⁴ The State says that it is not required to “prove consumer status,” but that is exactly what the statute says. The State offers no reason why the statute’s plain text should be disregarded, and its novel effort to recover its alleged consequential damages should be dismissed. Resp. 80 (identifying “costs ... above and beyond the cost of the medications themselves”).

Third, the plain language of the OCPA also precludes the State from seeking relief on behalf of multiple individuals at once, Joint Motion 32—the statute makes clear that an action for damages and penalties may only be brought “on behalf of an aggrieved consumer, in an individual action only.” Okla. Stat. tit. 15, § 756.1(A)(3); *see also Fed. Trade Comm’n v. Mylan Labs., Inc.*, 99 F. Supp. 2d 1, 9 (D.D.C. 1999) (addressing rule). The State has not identified a single instance

²⁴ The State attempts to distinguish *Lumber 2, Inc.*, by pointing to the fact that the plaintiff purchased goods for resale and the Court noted that, under “different facts,” liability may attach. Resp. 78. However, the court also held that those “different facts,” would require that “the purchase would have to involve goods which Lumber 2 bought to use in its own business.” *Lumber 2, Inc.*, 2011 OK 74, ¶ 21, 261 P.3d at 1149. That is clearly not the case here.

where it was allowed to proceed on an OCPA claim for damages and penalties on behalf of more than one consumer. The State attempts to confuse the issue by citing language from the OCPA that addresses the *type of relief* that can be awarded in an individual action only—not the logically antecedent issue of *on whose behalf* the action may be brought in the first instance. Resp. 79 (quoting Okla. Stat. tit. 15, § 756.1(C)(3) (identifying relief that court may order)); cf. *Phillips v. Hedges*, 2005 OK 77, ¶ 12, 124 P.3d 227, 231 (if statutory language conflicts, the specific controls over the general language). The OCPA’s express limitation to individual actions demonstrates a clear intent by the Legislature to prevent the Attorney General from bringing quasi-class actions through the State’s consumer protection statute. The Court should not countenance his effort to circumvent the requirements of Okla. Stat. tit. 12, § 2023 in this case.

4. The Public-Nuisance Claim (Cause of Action D) Must Be Dismissed.

The State’s public-nuisance claim fails for multiple, independently dispositive reasons. To state a nuisance claim, a plaintiff must allege an act or omission that “[a]nnoys, injures or endangers the comfort, repose, health, or safety of others.” Okla. Stat. tit. 50, § 1. The State fails to identify a single act committed by Defendants in Oklahoma that was unlawful or breached any duty. The Petition does not plead a single interaction between Defendants and any Oklahoma physician, Oklahoma patient, or the State itself. And the State’s conclusory allegations repeating the elements of its cause of action are not sufficient to state a claim. *Sinclair Refining Co. v. Roberts*, 1949 OK 103, ¶ 16, 206 P.2d 193, 197 (“[M]ere conclusions are insufficient”).²⁵

²⁵ The State’s reliance on *Briscoe v. Harper Oil Co.*, 1985 OK 43, 702 P.2d 33 is misguided. Resp. 49. In *Briscoe*, a *private nuisance* case, the defendant overstepped the authority granted to it by a private contract. Here, by contrast, Defendants’ marketing and promotion of opioids was expressly permitted by State and federal law. Okla. Stat. tit. 50, § 4 (“[n]othing which is done or maintained under the express authority of a statute can be deemed a nuisance.”).

Nor is it sufficient for the State simply to identify the existence of a public health problem, no matter how serious it might be. In order to state a claim for public nuisance, a plaintiff must allege facts sufficient to show that the defendant proximately caused the public nuisance. *Twyman*, 2004 OK CIV APP 53, ¶ 52, 93 P.3d 51, 61; *see also* Joint Motion 16. The State cites what clearly are serious consequences of opioid and other drug abuse in Oklahoma and elsewhere. *See, e.g.*, Resp. 1-2. Yet notwithstanding the State’s criticism of Defendants’ promotional activity, the Petition does not tie Defendants’ allegedly unlawful actions to opioid-related problems in Oklahoma. Indeed, while the State’s Petition describes an “opioid epidemic” facing Oklahoma, that does not mean that Defendants, who sold legally-marketed, prescription-only, FDA-approved medications, are legally responsible for the social costs of the complex opioid abuse problem in the State. The State’s Petition does not allege facts sufficient to sustain its public nuisance claim. *See Butler v. Oklahoma City Pub. School Sys.*, 1994 OK CIV APP 22, 871 P.2d 444, 446 (proximate cause exists only if conduct causes injury “in a natural and continuous sequence, unbroken by any independent cause”).

Nor can the State hold Defendants jointly and severally liable for an alleged public nuisance claim. To do so, “there must be a single injury.” *Union Texas Petroleum Corp. v. Jackson*, 1995 OK CIV APP 63, ¶ 60, 909 P.2d 131, 150. The State attempts to argue that “the ‘single injury’ is Oklahoma’s opioid epidemic,” Resp. 47, but merely alleging damages does not satisfy the State’s burden to also allege facts showing causation.²⁶

²⁶ *See, e.g., Price v. Purdue Pharma Co.*, 920 So. 2d 479, 485-86 (Miss. 2006); *Kaminer v. Eckerd Corp. of Florida, Inc.*, 966 So. 2d 452, 454-55 (Fla. Ct. App. 2007); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 704-05 (E.D. Ky. 2003).

5. The Common-Law Fraud and Deceit Claim (Cause of Action E) Must be Dismissed.

The State's Petition fails to plead the essential elements of its common law fraud claims, the absence of any one of which is "fatal to recovery." Joint Motion 35 (quoting *Miller v. Long*, 1949 OK 186, ¶ 14, 2010 P.2d 147, 150). Nothing in the State's Response shows otherwise.²⁷

a. The Petition Fails to State a Claim for Actual Fraud.

For the reasons described above, the State does not adequately plead any affirmative misrepresentation that any Defendant made to any Oklahoma prescribers or State agents charged with deciding whether to reimburse a particular opioid prescription. *See supra* §§ II.B.1-2. This alone requires dismissal of the State's fraud claim. The State argues that Defendants employed a "deceptive marketing and advertising campaign" that "misrepresent[ed] the risks of addiction and abuse and tout[ed] unsubstantiated benefits of opioid treatments for chronic, non-cancer pain," Resp. 84, but does not dispute that Oklahoma law expressly permits physicians to prescribe controlled substances for chronic non-cancer pain, or that FDA has approved most of Defendants' opioids for that very indication. *See supra* § II.D.1.A; Joint Motion 10. The State fails to explain how Defendants can be found to have made unlawful misrepresentations by marketing their products for their lawfully approved indications.

The State also fails to plead the materiality element of its fraud claim. The State argues that Defendants' alleged "misrepresentations are undoubtedly material, as they speak directly, (albeit

²⁷ The State once again asserts that the Court can ignore its pleading failures because, it argues, "failure to plead fraud with specificity is not a ground for dismissal," and a petition "need not plead detailed evidentiary matters." Resp. 83 (internal quotations omitted). Those contentions are incorrect. In any event, the State's pleading failures with respect to its common law fraud claims extend beyond its failure to plead its claim with the particularity required under Section 2009(B). As set forth below, the Petition fails to allege even basic facts to plead the essential elements of fraud.

falsely) to the factors physicians consider in prescribing pain medication: risks and benefits.” Resp. 84.²⁸ But the State fails to explain how any such misrepresentations could be material to physicians’ prescribing decisions when viewed in the context of Defendants’ widespread dissemination of risk information through FDA-mandated disclosures. Joint Motion 11-12. Nor does the State allege any basis to conclude that physicians would abandon their medical obligations and judgment and rely on promotional and marketing materials to the exclusion of the extensive product-specific risk information Defendants disseminated. The State’s conclusory argument that any alleged misrepresentations were “undoubtedly material” to physicians’ prescribing decisions does not cure the Petition’s pleading defects with respect to materiality.²⁹ Likewise, the State’s casual assertion that “the Petition alleges Defendants intended their materially false statements to be relied upon and acted on by Oklahoma physicians,” Resp. 85 (citing Pet. ¶ 122), fails because, as discussed above, given the full context of Defendants’ disclosures, the State has failed to allege a single statement that would mislead.

The State’s arguments regarding the reliance element of its fraud claim are also unavailing. The State asserts that the “Petition alleges Defendants engaged in a sweeping fraudulent marketing and advertising scheme” that “reached and influenced virtually everyone.” Resp. 85. From that, the State argues that 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

²⁸ The Response’s assertion that the Petition “lists specific misrepresentations made by each Defendant,” Resp. 84 (citing Pet. ¶¶ 52-72), does nothing to cure the fundamental flaw in the State’s argument: that the State does not, and cannot, allege that these statements would mislead reasonable physicians.

²⁹ As demonstrated above, *see supra* § II.D.1.b, the State also fails to plead materiality with respect to the State Health Care Authority’s decisions to reimburse any allegedly unnecessary opioid prescriptions.

Defendants' fraudulent conduct." *Id.* In a similar vein, the State argues that the Petition alleges that "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." *Id.* 86. But as explained above and in Defendants' Joint Motion, allegations of a general increase in opioid prescribing do not, as a matter of law, plead reliance or causation. *See, e.g., UFCW Local 1776*, 620 F.3d at 135; *see also supra* § II.B.1; Joint Motion 17-18. Although the State may not be required "to identify in the Petition every single State employee whom Defendants misled," Resp. 86, it still obligated to plead non-conclusory allegations of reliance by prescribing physicians—but it has not shown that even one prescribing physician was misled. *See, e.g., TKO Energy Servs.*, 539 F. App'x at 873 (applying Oklahoma law and dismissing fraud-based claim where the "allegations fail to state that [plaintiff] actually relied on any allegedly false representation and do not identify specific false statements meant to lure [plaintiff] into detrimental reliance"); *see also supra* § II.B.

The State's reliance argument as to reimbursement similarly fails. Indeed, the State all but concedes that its Petition lacks such allegations, stating only that it is "likely" that the alleged misrepresentations "reached members of the Drug Utilization Review Board that determines which medications are eligible for reimbursement under Oklahoma Medicaid." Resp. 86. Setting aside the entirely speculative nature of this argument, it does not, in any way, establish that members of the Drug Utilization Review Board or any other State agents relied on any alleged misrepresentations in making their reimbursement decisions. This is fatal to any fraud claims premised on allegedly improper reimbursements. *See TKO Energy Servs.*, 539 F. App'x at 873; *supra* § II.B.

b. The Petition Fails to State a Claim for Constructive Fraud.

The State's claim for constructive fraud—which in large part simply "incorporates by reference" the same deficient allegations discussed in connection with its actual fraud claim, Resp.

87—suffers from these same pleading defects. Indeed, other than the fraud allegations that the State “incorporate[s] by reference,” the State cites only one paragraph in its Petition that supposedly supports its constructive fraud claim. *Id.* (citing Pet. ¶ 72). Now, the State argues that *Patel v. OMH Med. Ctr., Inc.*, 1999 OK 33, 987 P.2d 1185, should ease its pleading burden, claiming that the decision holds that a claim for constructive fraud can lie “regardless of the actor’s intent” and that “the bar for alleging and proving constructive fraud is lower than actual fraud.” Resp. 86-87. But *Patel* still requires an alleged statement or omission to *actually mislead*. *Id.* 86. And as with the State’s allegations with respect to its actual fraud claim, the allegation in paragraph 72 fails: (i) to identify a single omission made or “partial” truth told to any prescribing physician; (ii) to allege that any such omissions or “partial” truths were material to, or in any way impacted, physicians’ prescribing decisions; and (iii) to connect any such omissions to any decision by a State agent to reimburse any opioid prescriptions. For the same reasons discussed above and in Defendants’ Joint Motion, the State’s constructive fraud claim must be dismissed.

6. The Unjust-Enrichment Claim (Cause of Action F) Must Be Dismissed.

The State does not attempt to refute Defendants’ argument that the unjust enrichment claim is “derivative” of the State’s other claims. Indeed, the State concedes that unless at least one of its other claims survive, the unjust enrichment claim cannot. *Id.*; *see also* Joint Motion 36 (citing *Weaver v. Legend Senior Living, LLC*, 2017 WL 3088416, at *4 (W.D. Okla. July 20, 2017)). Defendants’ “assumption that all of the State’s other claims will be dismissed” is not “misplaced and premature,” Resp. 52, but rather based on Oklahoma law and the averments in the State’s Petition.

Nor does the State dispute that on the merits of its unjust enrichment claim, the Petition must allege some inequity that must be rectified. *See* Joint Motion 36 (citing *Harvell v. Goodyear Tire & Rubber Co.*, 2006 OK 24, ¶ 18, 164 P.3d 1028, 1035; *Teel v. Pub. Serv. Co. of Okla.*, 1985

OK 112, ¶ 23, 767 P.2d 391, 398). Although the State declares that it “has been harmed by Defendants’ collective conduct,” Resp. 52 (citing Pet. ¶ 131), it never identifies any legally cognizable inequity or how it might be rectified, and its generalized allegation in any event fails for reasons previously described. *See supra* § II.B; Joint Motion § III.E.

Finally, the State contends that it is not required to “prove at this stage of the proceedings that it has no adequate remedy at law,” because it is allowed to plead alternative theories of liability. Resp. 52. The State’s cases stand only for the unremarkable proposition that pleading in the alternative is permissible. *See id.* 53 (citing *N.C. Corff Partnership Ltd. v. OXY USA, Inc.*, 1996 OK CIV APP 92, ¶ 24, 929 P.2d 288; *Valley View Agri, LLC v. Producers Cooperative Oil Mill*, 2017 U.S. Dist. LEXIS 48993, at *7-8 (W.D. Okla. Mar. 31, 2017)). But pleading in the alternative still requires the State to properly plead *each* of its alternative theories of liability. For the reasons explained, the State does neither here.

E. The Petition Itself Disproves The State’s Claims.

In the end, the State’s claims falter on its own allegations. The State’s claims rest on two central contentions: (1) that Defendants deceptively promoted opioids as safe and effective for long-term treatment of chronic non-cancer pain; and (2) that Defendants concealed opioids’ risks. See Joint Motion 4-6; Resp. 93. But the Petition itself acknowledges key facts that directly refute those accusations, showing beyond doubt that the Petition cannot support a claim for relief. *See* Joint Motion 10-12; Resp. 93.

The State concedes that FDA has expressly approved Defendants’ ER/LA opioids for long-term treatment of chronic non-cancer pain. *See* Joint Motion 10-12; Resp. 93. The State also concedes that opioids require a prescription; that Oklahoma law explicitly permits physicians to prescribe opioids for chronic pain; that FDA-mandated labels and REMS programs accurately “disclose the risks” and approved indications for opioids, Resp. 94; and that physicians have long

known that opioids “are highly addictive, habit-forming drugs,” and are obligated to know and discuss such risks with patients before writing any opioid prescription, Pet. ¶ 1; *see also* OAC § 435:10-7-11(2)-(4). In the face of these concessions, the State cannot claim that Oklahoma doctors lacked information about the proper use of opioid medications to treat their patients.

The State attempts to avoid this consequence by arguing that “Defendants cannot rely on their labels as disclaimers for fraudulent misrepresentations.” Resp. 94. Defendants do not claim that FDA labeling acts as a general liability disclaimer.³⁰ The point is that the labeling conveyed accurate and complete information about opioids’ benefits and risks that doctors were required by law to read and heed. *See* Pet. ¶ 70; *see also id.* ¶¶ 53, 67, 124; *McKee v. Moore*, 1982 OK 71, ¶ 8, 648 P.2d 21, 24 (physician has “duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients”)³¹; *see also Indiana/Kentucky/Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498 (E.D. Pa. May 21, 2014) (rejecting false marketing claim against opioid manufacturer regarding use of

³⁰ The State cites *Murray v. D & J Motor Co.*, 1998 OK CIV APP 69, ¶ 10, 958 P.2d 823, 827, but that case involved an actual liability disclaimer that advised “the vehicle was being sold ‘as is’ and ‘with all faults’ and that express and implied warranties were disclaimed.” The court held that the disclaimer did not insulate the defendant from liability for representations that were likely to mislead. Here, by contrast, FDA-mandated disclosures must be read and followed by trained and licensed doctors, which show that doctors *are not* likely to be misled. This distinction between prescription-only pharmaceuticals and consumer products matters a great deal. Ordinary consumers buying ordinary consumer goods have no obligation to apprise themselves of risk information. Doctors, by contrast, owe a duty to their patients and are required by law to apprise themselves of all risks before prescribing medications.

³¹ While the State’s Response relies on *City of Chicago v. Purdue Pharma, L.P.*, 2015 U.S. Dist LEXIS 60587 (N.D. Ill. May 8, 2015) for the proposition that label disclosures, alone, do not preclude fraud claims, that is not Defendants’ position. Rather, Defendants assert that (1) the Petition fails to allege a single instance of affirmative misrepresentation with sufficient specificity; and (2) that the labels embody and disclose the very concepts the State accuses Defendants of concealing or downplaying. *See* Joint Motion 10, 15.

opioid for non-cancer pain because “physician-prescribers are presumed to have knowledge of a drug label’s contents [which state the FDA-approved indications and FDA-required risks]”).

That full and accurate information in the medications’ labels includes the benefits and risks that the State alleges were misrepresented. In light of the labeling and the obligation of Oklahoma doctors to heed that information, it is not surprising that the State fails to identify a single Oklahoma physician who was deceived by any Defendant’s promotion. *See* Joint Motion 10; Resp. 93-95.

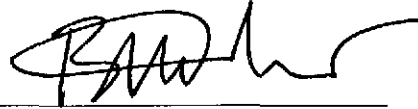
III. CONCLUSION

For all the reasons stated above, the Court should dismiss the Petition in its entirety for failure to state a claim.

Dated: November 27, 2017

Respectfully submitted,

By:



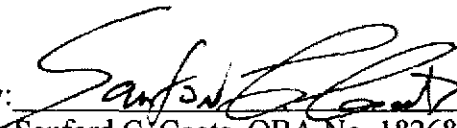
Benjamin H. Odom, OBA No. 10917
John H. Sparks, OBA No. 15661
ODOM, SPARKS & JONES, PLLC
HiPoint Office Building
Suite 140
2500 McGee Drive
Oklahoma City, OK 73072
Telephone: (405) 701-1863
Facsimile: (405) 310-5394
Email: odomb@odomsparks.com
Email: sparksj@odomsparks.com

Charles C. Lifland
Jennifer D. Cardelús
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
Telephone: (213) 430-6000
Facsimile: (213) 430-6407
Email: clifland@omm.com
Email: jcardelus@omm.com

Stephen D. Brody
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
Telephone: (202) 383-5300
Facsimile: (202) 383-5414
Email: sbrody@omm.com

***COUNSEL FOR DEFENDANTS JANSSEN
PHARMACEUTICALS, INC., JOHNSON &
JOHNSON, JANSSEN PHARMACEUTICA,
INC. N/K/A JANSSEN PHARMACEUTI-
CALS, INC., AND ORTHO-MCNEIL-
JANSSEN PHARMACEUTICALS, INC.
N/K/A/ JANSSEN PHARMACEUTICALS,
INC.***

By:



Sanford C. Coats, OBA No. 18268
Cullen D. Sweeney, OBA No. 30269
CROWE & DUNLEVY, P.C.
Braniff Building
324 N. Robinson Ave., Ste. 100
Oklahoma City, OK 73102
Telephone: (405) 235-7700
Facsimile: (405) 272-5269
Email: sandy.coats@crowedunlevy.com
Email: cullen.sweeney@crowedunlevy.com

Of Counsel:

Sheila Birnbaum
Mark S. Cheffo
Hayden A. Coleman
QUINN EMANUEL URQUHART &
SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Telephone: (212) 849-7000
Facsimile: (212) 849-7100
Email: sheilabirnbaum@quinnemanuel.com
Email: markcheffo@quinnemanuel.com
Email: haydencoleman@quinnemanuel.com

Patrick J. Fitzgerald
R. Ryan Stoll
SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP
155 North Wacker Drive, Suite 2700
Chicago, Illinois 60606
Telephone: (312) 407-0700
Facsimile: (312) 407-0411
Email: patrick.fitzgerald@skadden.com
Email: ryan.stoll@skadden.com

*Counsel for Defendants Purdue Pharma L.P.,
Purdue Pharma Inc., and The Purdue Frederick
Company Inc.*

By: Robert G. McCampbell
Robert G. McCampbell, OBA No. 10390
Travis V. Jett, OBA No. 30601
GABLEGOTWALS
One Leadership Square, 15th Fl.
211 North Robinson
Oklahoma City, OK 73102-7255
Telephone: (405) 235-5567
Email: rmccampbell@gablelaw.com
Email: tjett@gablelaw.com

Of Counsel:

Steven A. Reed
Harvey Bartle IV
Jeremy A. Menkowitz
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Email: steven.reed@morganlewis.com
Email: harvey.bartle@morganlewis.com
Email: jeremy.menkowitz@morganlewis.com

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131
Telephone: (305) 415-3416
Email: brian.ercole@morganlewis.com

*Attorneys for Defendants Cephalon, Inc., Teva
Pharmaceuticals USA, Inc., Watson Laborato-
ries, Inc., Actavis LLC, and Actavis Pharma, Inc.
f/k/a Watson Pharma, Inc.*

CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), this is to certify on November, 27, 2017, a true and correct copy of the above and foregoing has been served via the United State Postal Service, First Class postage prepaid, to the following:

Mike Hunter
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver
Ethan Shaner
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
313 NE 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246
Emails: abby.dillsaver@oag.ok.gov
ethan.shaner@oag.ok.gov

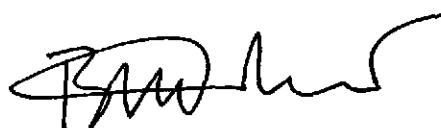
Michael Burrage
Reggie Whitten
WHITTEN BURRAGE
Suite 300
512 North Broadway Avenue
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Bradley Beckworth
Jeffrey Angelovich
NIX, PATTERSON & ROACH, LLP
Suite 200
512 North Broadway Avenue
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: bbeckworth@nixlaw.com
janglovich@npraustin.com

Glenn Coffee
GLENN COFFEE & ASSOCIATES, PLLC
915 North Robinson Avenue
Oklahoma City, OK 73102
Telephone: (405) 601-1616
Email: gcoffee@glenncoffee.com

Tracy Schumacher
SCHUMACHER & STANLEY, PLLC
114 East Main Street
Norman, OK 73072
(405) 701-1882
(405) 7015833 fax
tracy@schumacherstanley.com

ATTORNEYS FOR PLAINTIFF



Benjamin H. Odom, OBA #10917
John H. Sparks, OBA #15661
ODOM, SPARKS & JONES, PLLC
Suite 140
HiPoint Office Building
2500 McGee Drive
Norman, OK 73072
Telephone: (405) 701-1863
Facsimile: (405) 310-5394
odomb@odomsparks.com
sparksj@odomsparks.com

ATTORNEYS FOR DEFENDANTS

**JOHNSON & JOHNSON, JANSSEN
PHARMACEUTICALS, INC.,
JANSSEN PHARMACEUTICA, INC.
N/K/A JANSSEN PHARMACEUTI-
CALS, INC., AND
ORTHO-MCNEIL-JANSSEN PHAR-
MACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.**