**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.



Case No. CJ-2017-816

Honorable Thad Balkman

JURY TRIAL DEMANDED

**DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM**

## MOTION

Defendants Janssen Pharmaceuticals, Inc. ("Janssen")[1] and its parent company Johnson & Johnson ("J&J") join in Defendants' Joint Motion to Dismiss for Failure to State a Claim ("Joint Motion to Dismiss"). Janssen and J&J submit this separate motion to highlight the Petition's particular deficiencies as to them.

Janssen and J&J, by and through their attorneys, file this Motion to Dismiss the State of Oklahoma's Petition pursuant to Sections 2008(A)(1), 2009(B), and 2012 of the Oklahoma Pleading Code. Okla. Stat. tit. 12, §§ 2008(A)(1), 2009(B), 2012. Janssen and J&J seek dismissal of all claims asserted against them for the reasons described below and also for the reasons stated in the concurrently filed Joint Motion to Dismiss. In the alternative, Janssen seeks an order that the State make its Petition more definite and certain in compliance with Oklahoma's pleading requirements, and such other and further relief as the Court deems just and proper.

## BRIEF IN SUPPORT

In support of this Motion to Dismiss, Janssen and J&J show the following:

### I. INTRODUCTION

The State's Petition alleges virtually nothing about Janssen and J&J. Paragraph 19 alleges that Janssen "manufactures, or manufactured in the past," the opioid medications "Duragesic, Nucynta, and Nucynta ER" and "promotes, markets, and sells" them in Oklahoma. Pet. ¶ 20. Paragraph 38 alleges that since 2007, Janssen "caused to be submitted" for reimbursement by the Oklahoma Health Care Authority ("OHCA") "over 2,600 prescriptions" for Janssen opioid medications, for which the Authority paid $1,209,446.77. *Id.* ¶ 38 & Ex. 4. Paragraph 53 contains the Petition's lone allegation asserting that Janssen, by name, engaged in any wrongdoing—a single sentence asserting, without any specifics, that "Defendant Janssen made unsubstantiated repre-

[1] "Janssen" also refers to Janssen Pharmaceuticals, Inc.'s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

sentations that Nucynta was appropriate for broader pain conditions than indicated and downplayed its risks." *Id.* ¶ 53. The Petition contains no allegations at all about Janssen's other opioid medications, Duragesic and Nucynta ER. And it likewise contains no allegations about Janssen's corporate parent, J&J, except the conclusory assertion that Janssen and J&J "acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein." *Id.* ¶ 19.

These skeletal allegations do not begin to state a claim against Janssen or J&J. The Petition does not give Janssen and J&J fair notice of the State's claims against them, as required by section 2008(A), and it fails to particularize the circumstances any alleged fraud, as required by section 2009(B). It does not allege that even one of the Janssen opioid prescriptions reimbursed by OHCA was induced by fraud, medically inappropriate, or harmful to the patient. Nor does it allege that any other Janssen opioid prescription written in Oklahoma was fraud-induced, inappropriate, or harmful. Further, the State's claims cannot overcome the Petition's admission that the labeling for Janssen's opioid medications in fact disclosed "the risk of abuse and addiction." Pet. ¶ 70. And, finally, the Petition pleads no basis whatsoever for parent-company liability against J&J. For all these reasons, in addition to those stated in the Joint Motion to Dismiss, the claims against Janssen and J&J should be dismissed.

## II. ARGUMENT

### A. The Petition Pleads No Actionable Conduct by Janssen.

As discussed in the Joint Motion to Dismiss, Oklahoma law rejects "group pleading"—that is, asserting undifferentiated allegations of wrongdoing against multiple distinct defendants as if they were a single agglomerated entity. *Gay v. Akin*, 1988 OK 150, ¶ 8, 766 P.2d 985, 990; *see also Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1240 (10th Cir. 2013) (affirming dismissal "because [complaint] attribute[d] actions to a large group of collective 'de-

fendants'" and the court could not "tell which defendant is alleged to have done what").[2] Rather, "a plaintiff must plead facts from which fraud may reasonably be inferred as to each defendant." *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990.

In the Petition here, the *only* allegation of wrongdoing pleaded against Janssen by name is one sentence: "Defendant Janssen made unsubstantiated representations that Nucynta was appropriate for broader pain indications than indicated and downplayed its risks." Pet. ¶ 53. This is patently inadequate to state a claim. Under Oklahoma law, a pleader must allege claims sounding in fraud with particularity. Okla. Stat. tit. 12, § 2009(B); *Gay*, 1988 OK 150, ¶ 8, 766 P.2d at 990; *see also* Joint Motion to Dismiss at § III.B. On pain of dismissal, the pleader must specify the circumstances of the alleged fraud, including "the time, place, and content of an alleged false representation." *Gianfillippo v. Northland Cas. Co.,* 1993 OK 125, ¶ 11, 861 P.2d 308, 310-11; *Dani v. Miller*, 2016 OK 35, ¶ 25, 374 P.3d 779, 791.[3]

The State's one-sentence allegation does none of those things. It does not identify any person who made such representations about Nucynta, when and where they were made, or to whom they were made. There is no allegation that the alleged representations even occurred Oklahoma or that any Oklahoma prescriber was exposed to such a representation. Nor is there any allegation specifying what was supposedly misrepresented. For what indications did Janssen assert without substantiation that Nucynta was appropriate? What risks did Janssen allegedly downplay? In short, this allegation does nothing whatsoever to put Janssen on notice of the relevant facts of any alleged claim. It thus fails to satisfy the State's pleading burden under either section 2008(A) or 2009(B).

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[2] Because sections 2008(A) and 2009(B) track their federal counterparts, Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure, Oklahoma courts look to federal cases interpreting those Rules as persuasive authority. *See Gay*, 1988 OK 150, ¶ 8 & n.18, 766 P.2d at 990 & n.18.

[3] Alternatively, the State should be compelled to provide the requisite factual details for each of its claims. *See A-Plus Janitorial & Carpet Cleaning v. Emp'rs' Workers' Compensation Ass'n*, 1997 OK 37, ¶¶ 35-36, 936 P.2d 916, 930-31.

Further, this single inadequate allegation concerns only one medication—Nucynta. The Petition nowhere alleges that Janssen misrepresented anything at all about Duragesic or Nucynta ER, the two other Janssen-manufactured opioids mentioned in the complaint. Nor can the Petition state a claim merely by alleging that OHCA reimbursed the cost of some prescriptions for those three medications. *See* Pet. ¶ 38 & Ex. 4.[4] The Petition nowhere alleges that any OHCA-reimbursed prescription for Duragesic, Nucynta, or Nucynta ER was induced by fraud, nor does it allege that any OHCA-reimbursed prescription for those medications was medically inappropriate or harmful. Likewise, the Petition does not allege that any other prescription written in Oklahoma for Duragesic, Nucynta, or Nucynta ER was fraud-induced, inappropriate, or harmful. And it alleges no facts suggesting that any of those three Janssen medications was excessively prescribed, widely abused, or widely misused in Oklahoma or anywhere else. In short, the Petition alleges no facts connecting either Janssen or any of Janssen's medications to any of the State's claims. Dismissal is therefore in order.

### B. Janssen's Product Labels Disclose the Known Risks of Its Opioids and Foreclose the State's Claims.

Dismissal is also in order because, as the Petition acknowledges and the State cannot dispute, the FDA-approved labels for Janssen's opioid medications disclosed "the risk of abuse and addiction" at the center of the State's claims. Schedule II opioids like Duragesic, Nucynta ER,

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[4] Exhibit 4 to the Petition purports to show that over the last ten years, OHCA has paid approximately $1.2 million to reimburse the costs of 2,600 prescriptions for Janssen opioids. In fact, even these very modest numbers are substantially overstated. It is a matter of judicially noticeable public record (*see infra* n.5) that Janssen divested its U.S. rights to Nucynta and Nucynta ER in April 2015. *See* Johnson & Johnson, Quarterly Report (Form 10-Q) (May 1, 2015), available at https://www.sec.gov/Archives/edgar/data/200406/000020040615000019/a1q10q3-29x15.htm ("In April 2015, [Janssen Pharmaceuticals, Inc.] completed the divestiture of its U.S. rights to NUCYNTA®, NUCYNTA® ER and NUCYNTA® oral solution..."). Exhibit 4 mistakenly lists reimbursements of Nucynta and Nucynta ER prescriptions made *after* Janssen's April 2015 divestiture of those medications as reimbursements of Janssen-marketed opioids. Corrected for this error, the total alleged OHCA reimbursements for prescriptions of Janssen opioids would total only about $900,000 to reimburse the cost of 2,100 prescriptions written over a ten-year period.

and Nucynta are among the most closely regulated medications on the market. Patients can lawfully obtain them only from licensed physicians authorized to prescribe controlled substances, *see* 21 C.F.R. §§ 1306.11, 1306.03(a)(1), and must consult with a physician before every prescription renewal, 21 U.S.C. § 829(a). Oklahoma law explicitly permits physicians to prescribe such medications for the treatment of pain, including chronic non-cancer pain. See OAC § 435:10-7-11; 475:30-1-2. And as a learned intermediary, the physician has a "duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product." *McKee v. Moore*, 1982 OK 71, ¶ 8, 648 P.2d 21, 24. To that end, Duragesic, Nucynta ER, and Nucynta—like all opioids—are labeled with extensive FDA-approved prescribing information. That judicially noticeable labeling describes, among other things, (1) the medications' approved indications, (2) the endpoints, duration, and results of the clinical trials supporting those indications, (3) contraindications, warnings, and precautions, and other important risk information, (4) instructions for safe dosing, use, and discontinuation, and (5) safety information for patients.[5]

***Duragesic***, approved since 1990, is not a pain pill like the most commonly prescribed opioid analgesics, but rather a transdermal patch designed to slowly administer a controlled dose of a powerful opioid pain reliever (pharmaceutical fentanyl)[6] through the patient's skin over a

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[5] Footnotes 7 through 13 and 15 through 17, *infra*, cite the current FDA-approved labels for the three identified Janssen opioid medications, available on the FDA's website; older versions of the labels, also available the FDA's website, are similar in all relevant respects. Janssen requests that the Court take judicial notice of these labels because they are all publicly available via the FDA and other government websites and thus are "[c]apable of accurate and ready determination by . . . sources whose accuracy cannot reasonably be questioned." Okla. Stat. tit. 12, § 2202(B)(2); *see also Doe v. First Presbyterian Church U.S.A. of Tulsa, Okla.*, 2017 OK 15, ¶ 8 n.6, __ P. __ (taking judicial notice at motion-to-dismiss stage).

[6] Pharmaceutical fentanyl is a lawful Schedule II controlled substance used in multiple analgesic products; it is not to be confused with illegally manufactured and imported fentanyl powder associated with recent reports of overdose deaths from adulterated street drugs. *See* Centers for Disease Control and Prevention ("CDC"), *Opioid Overdose, Fentanyl,*

period of days.[7] Under its FDA-approved labeling, Duragesic is indicated only for patients who are *already* opioid tolerant, for pain "severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[8]

As a scheduled drug, Duragesic's labeling includes a prominent two-page "boxed warning"—the most serious warning FDA mandates—highlighting its risks, including the following:

> **DURAGESIC exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor regularly for development of these behaviors or conditions.**
> . . .
>
> **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. . . .**
>
> **Accidental exposure to DURAGESIC, especially in children, can result in fatal overdose of fentanyl. . . .**[9]

The rest of the label provides extensive information about these and other risks and instructions for safe use, including warnings that the medication carries "risks of addiction, abuse, and misuse, which can lead to overdose and death," that it contains "a substance with high potential for abuse," and that "addiction can occur in patients appropriately prescribed" opioids.[10]

***Nucynta ER***, first approved in 2011, is a Schedule II extended-release opioid pain reliever administered via oral tablet. Its active ingredient is tapentadol, a medication with characteristics of both an opioid analgesic and a norepinephrine reuptake inhibitor, providing a potential

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https://www.cdc.gov/drugoverdose/opioids/fentanyl.html. Janssen requests that the Court take judicial notice of this document because it is publicly available via a government website and thus is "[c]apable of accurate and ready determination by . . . sources whose accuracy cannot reasonably be questioned." Okla. Stat. tit. 12, § 2202(B)(2); *see also Doe*, 2017 OK 15, ¶ 8 n.6.

[7] *See generally* FDA, Duragesic Prescription Labeling (Dec. 2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019813s069lbl.pdf.

[8] *Id.* at 1.

[9] *Id.*

[10] *Id.* at 1, 12, 32.

second pathway for pain relief.[11] Like Duragesic, Nucynta ER is indicated only for pain "severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[12] And like Duragesic, it comes with detailed risk information in its FDA-approved labeling, including a boxed warning similar to Duragesic's boxed warning:

> **NUCYNTA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing NUCYNTA ER, and monitor all patients regularly for the development of these behaviors or conditions. . . .**
>
> **Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA ER. Monitor for respiratory depression, especially during initiation of NUCYNTA ER or following a dose increase. . . .**[13]

Nucynta ER was also the first FDA-approved opioid to be launched with an FDA-mandated Risk Evaluation and Mitigation Strategy ("REMS"), an educational program designed to reduce adverse outcomes resulting from inappropriate prescribing, misuse, or abuse of extended-release opioid analgesics;[14] REMS are now required for all opioid analgesics. *See* Joint Motion to Dismiss at 12 n.14.

***Nucynta***, an immediate-release formulation of tapentadol, was approved by the FDA in 2008 and first marketed in 2009. Like Nucynta ER, Nucynta is a Schedule II opioid pain reliever administered via oral table or oral solution.[15] But unlike both Nucynta ER and Duragesic, Nu-

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[11] *See generally* FDA, Nucynta ER Prescription Labeling (Dec. 2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/200533s014lbl.pdf.

[12] *Id.* at 1.

[13] *Id.*

[14] *See* FDA, Risk Evaluation and Mitigation Strategies for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics (REMS), *available at* https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17. Janssen requests that the Court take judicial notice of this document because it is publicly available via the FDA website and thus is "[c]apable of accurate and ready determination by . . . sources whose accuracy cannot reasonably be questioned." Okla. Stat. tit. 12, § 2202(B)(2); *see also Doe*, 2017 OK 15, ¶ 8 n.6.

[15] *See generally* FDA, Nucynta (tablet) Prescription Labeling (Dec. 2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022304s016lbl.pdf ("Nucynta Tablet Label"); FDA, Nucynta (oral solution) Prescription Labeling (Dec. 2016), *available at*

cynta is a short-acting opioid and is indicated only for the management of acute pain, not chronic pain.[16] Like the FDA-approved labeling for Janssen's other opioids, Nucynta's FDA-approved labeling prominently and extensively explains the medications' risks, including addiction and life-threatening respiratory depression.[17]

Given this prescribing environment and the risk disclosures in Janssen's product labels and FDA-mandated REMS, none of the misrepresentations alleged in the State's Petition is misleading, as a matter of law, and thus none can support the State's claims. *See* FTC Policy Statement on Deception, 103 F.T.C. 110, 4 n.32.[18] ("The tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context."); *id.* at 4 (to determine whether a representation is deceptive, a court must examine "the entire mosaic, rather than each tile separately"); *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1120 (10th Cir. 1997) (recognizing "the unremarkable proposition that statements must be analyzed in context" when determining whether they rise to the level of a misrepresentation); *Gilbert v. Nixon*, 429 F.2d 348, 356 (10th Cir. 1970) (requiring consideration of purported misrepresentations in their "full context").[19] For this reason, too, the Petition should be dismissed.

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https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203794s004lbl.pdf ("Nucynta Solution Label").

[16] Nucynta Tablet Label at 1; Nucynta Solution Label at 1.

[17] Nucynta Tablet Label at 1; Nucynta Solution Label at 1.

[18] *Available at* https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.

[19] *See also Davis v. G.N. Mortg. Corp.*, 396 F.3d 869, 884 (7th Cir. 2005) (finding that purportedly deceptive statements should be reviewed "in light of the totality of the information made available to the plaintiff"); *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 300 (S.D.N.Y. 1998) (noting that "challenged statements" must be "read in their entirety and in context").

### C. The State Fails to State a Claim Against J&J.

Finally, the Petition fails to allege even a single instance of wrongdoing by J&J. Rather, it suggests that J&J should be held liable because J&J and Janssen "acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein." Pet. ¶ 19. Even if the Petition alleged a colorable claim against Janssen (which it does not), this skeletal allegation would be insufficient to support a claim against J&J.

"The fundamental reason for the corporate form is to allow for limited liability; the corporate veil should only be pierced reluctantly and cautiously." *Lewis v. Am. Gen. Assur. Co.*, 2001 WL 36160929, at *2 (W.D. Okla. Feb. 26, 2001). The corporate form may be disregarded if a corporation "is merely an instrumentality or agent of [an]other." *Gilbert v. Sec. Fin. Corp. of Okla., Inc.*, 2006 OK 58 ¶ 22, 152 P.3d 165, 175. But a mere boilerplate assertion of agency will not establish the exception. The Oklahoma Supreme Court has listed ten non-exclusive factors to be considered when deciding whether to disregard the corporate form, which "hinge[] primarily on control":

> (1) whether the dominant corporation owns or subscribes to all the subservient corporation's stock, (2) whether the dominant and subservient corporations have common directors and officers, (3) whether the dominant corporation provides financing to the subservient corporation, (4) whether the subservient corporation is grossly undercapitalized, (5) whether the dominant corporation pays the salaries, expenses or losses of the subservient corporation, (6) whether most of the subservient corporation's business is with the dominant corporation or the subservient corporation's assets were conveyed from the dominant corporation, (7) whether the dominant corporation refers to the subservient corporation as a division or department, (8) whether the subservient corporation's officers or directors follow the dominant corporation's directions, and (9) whether the corporations observe the legal formalities for keeping the entities separate.

*Frazier v. Bryan Mem. Hosp. Auth.*, 1989 OK 73, ¶ 17, 775 P.2d 281, 288. Two corporations' "act[ions] in concert," Pet. ¶ 19, are irrelevant.

The barebones agency allegations here do not support a claim against J&J. *See Tanner v. W. Pub. Co.*, 1984 OK CIV APP 22, ¶ 11, 682 P.2d 239, 241 (holding that "conclusions are to be ignored" when evaluating the sufficiency of a petition). "When analyzing the sufficiency of the

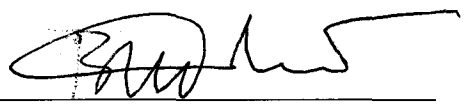
facts pled to pierce the corporate veil, [a c]ourt will analyze [a petition] with respect to each factor of the *Frazier* test." *Lewis*, 2001 WL 36160929, at *3. But here, the Petition provides no allegations about any *Frazier* factor. The State's claims against J&J must therefore be dismissed. *See Med. Supply Chain, Inc. v. Gen. Elec. Co.*, 144 Fed. App'x 708, 713, 2005 WL 1745590, at *4 (10th Cir. 2005) (dismissing claim premised on alter-ego theory where plaintiff provided "no well-pleaded factual allegations that would support its conclusory legal allegation that [one corporation] was [the other corporation's] alter ego and should be held responsible for [the other corporation's] actions"); *Lewis*, 2001 WL 36160929, at *3 (dismissing complaint where plaintiff failed to "come forward with the showing of actual domination required to pierce the corporate veil").

## III. CONCLUSION

For the foregoing reasons and the reasons described in Defendants' Joint Motion to Dismiss, the Court should dismiss the State's Petition in its entirety as to both Janssen and J&J.

Dated: September 22, 2017

Respectfully submitted,

By: 

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## CERTIFICATE OF SERVICE

Pursuant to Okla. Stat. tit. 12, § 2005(D), this is to certify on September 22, 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:

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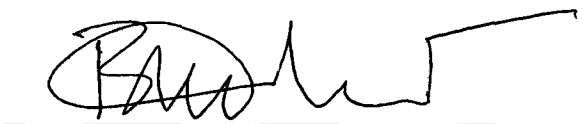

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