hearing set 12-5-2017 1:00 p.m.

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

NOV 21 2017

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816

Honorable Thad Balkman

REPLY IN SUPPORT OF MOTION OF DEFENDANTS CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA INC. TO DISMISS PLAINTIFF'S PETITION FOR FAILURE TO STATE A CLAIM, OR, ALTERNATIVELY, FOR A MORE DEFINITE STATEMENT REQUIRING THE STATE TO PLEAD THE DETAILS OF ANY ALLEGED FRAUD

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Nowhere in its 100-page Opposition does the State attempt to dispute that the Petition fails to allege: a *single* statement that either Cephalon, Inc. or Teva Pharmaceuticals USA, Inc. ("Teva Defendants") made to anyone in Oklahoma; a *single* interaction between any Teva Defendant and any Oklahoma physician who wrote one of the opioid prescriptions at issue; a *single* prescription written because of a false statement or omission by the Teva Defendants; or a *single* Actiq or Fentora prescription that did not provide pain relief or that caused harm to a single Oklahoma resident. As numerous courts have held in dismissing nearly identical claims, this is fatal to all claims against the Teva Defendants.[1]

Nor does the State make any effort to dispute that the Teva Defendants are uniquely situated because they manufactured short-acting opioids. The stringent TIRF REMS Program applicable to those medicines (Actiq and Fentora) *precludes* all claims against them. Among other requirements, before writing any prescription of Actiq or Fentora, each physician was obligated to sign an agreement that she understood and had counseled her patient about the risks and approved uses of these medicines. Likewise, every patient that received a prescription also was required to sign an agreement attesting to the fact that he reviewed the FDA-approved risk disclosures with his doctor. (Teva Defendants and Acquired Actavis Entities' Motion to Dismiss ("MTD") at 6-7.) The State simply cannot plead that the Teva Defendants misled anyone.

Recognizing these fundamental failures, the State's Opposition attempts to introduce unpled assertions from unpled sources, including various internet articles. This, of course, is

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[1] *See Travelers Indem. Co. v. Cephalon, Inc.* ("*Travelers I*"), 32 F. Supp. 3d 538 (E.D. Pa. 2014), *aff'd*, 620 Fed. App'x 82 (3rd Cir. 2015) ("*Travelers II*"); *Indiana/Kentucky/Ohio/Reg'l Council of Carpenters Welfare Fund* v. *Cephalon, Inc.*, CIV.A. No. 13-7167, 2014 WL 2115498 (E.D. Pa. May 21, 2014); *Cen. Reg'l Employees Ben. Fund v. Cephalon, Inc.* ("*CREB II*"), No. 09-3418 MLC, 2010 WL 1257790 (D.N.J. Mar. 29, 2010); *Cen. Reg'l Employees. Ben. Fund v. Cephalon, Inc.* ("*CREB I*"), CIV. A. No. 09-3418 MLC, 2009 WL 3245485 (D.N.J. Oct. 7, 2009).

improper. But even if the Court were to consider these unpled allegations, they fail to state a claim. The State merely argues that the Teva Defendants engaged in entirely *lawful* activities by paying consultants, funding CMEs, and sponsoring nonprofit third-party organizations. (State's Omnibus Response to Motions to Dismiss ("Opp.") at 20-24, 27, 30, 36.) This is not fraud. Like the Petition, the State's Opposition still fails to identify a single false statement made to a single Oklahoma prescriber that it attempts to attribute to either Teva Defendant—much less the specific details of any such statement or how it supposedly misled an Oklahoma physician or patient, particularly given the TIRF REMS Program and the obligation of physicians under Oklahoma law to be aware of and advise their patients of the risks of any opioid medicines they prescribe. Okla. Admin. Code § 435:10-7-11(2)-(4).

Similarly, the State's Opposition fails to identify a single particularized allegation against the entities that recently became affiliated with the Teva Defendants—Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc. (the "Acquired Actavis Entities"). Nor can the State make any such allegations, given that the Acquired Actavis Entities sold generic medicines and did not promote them.

The State tries to conceal these defects by grouping the Teva Defendants and the Acquired Actavis Entities with other entirely distinct corporations and repeatedly blaming all Defendants for opioid addiction in Oklahoma. (Opp. at 1, 51). But this group pleading tactic is improper. There is a significant difference between pleading that Oklahoma is suffering harm and pleading facts to support a claim that the Teva Defendants or the Acquired Actavis Entities caused it. The State must plead sufficient facts linking each independent company it has chosen to sue to some wrongdoing and harm. It fails to do so. Thus, all claims should be dismissed.

I. THE STATE'S PETITION IMPROPERLY GROUPS CEPHALON AND TEVA USA IN WITH ALL DEFENDANTS.

Oklahoma law is clear that a petition sounding in fraud must "plead facts from which fraud may be reasonably inferred ***as to each defendant***." *Gay v. Akin*, 1988 OK 150, 766 P.2d 985, 990 (1988) (emphasis added). The State's Petition falls far short of this requirement. Of the 134 paragraphs in the Petition, ***only five*** reference the Teva Defendants, while nearly 90 improperly lump both Cephalon and Teva USA (and the Acquired Actavis Entities) with each other and every other Defendant, without differentiating between companies, individuals, drugs, labels, or time period. (*See* MTD at 10-11.)

The State insists that this group pleading is somehow appropriate because some of its claims do not sound in fraud. (Opp. at 11.) But as the State's Opposition makes abundantly clear (*id.* at 1-10, 51), ***all*** of the State's allegations rise or fall on the theory that the Teva Defendants knowingly disseminated misrepresentations regarding the safety and efficacy of their products. (Petition ("Pet.") ¶¶ 5, 21, 31, 34, 45-46, 51, 75, 82-83, 89-90, 94, 99, 105, 107-08, 110-12, 118-19, 121-29, 131; *see also* MTD at 11.)[2] The State cannot avoid *Gay*'s prohibition on group pleading by ignoring its allegations; *Gay*'s binding holding "extends to *all* averments of fraud, regardless of the theory of legal duty." 766 P.2d at 990; *see also Estrada v. Kriz*, 2015 OK CIV APP 19, 345 P.3d 403, 407-08 (averment of fraud exists whenever "there is some 'false suggestion or suppression of the truth'—some false representation—by which 'one can get advantage over another.'").

[2] For example, the State characterizes its claims as resting upon "Defendants' false and deceptive marketing campaigns." (Pet. ¶ 5; *see also id.* ¶¶ 31, 34, 45-46, 51.) It further asserts that Defendants profited "through their deceptive and misleading opioid marketing campaign." (*Id.* ¶ 21.) These fundamental allegations are incorporated by reference into every single one of the State's causes of action. (*Id.* ¶¶ 73, 92, 102, 116, 121, 130.) Thus, each one of the State's claims is an averment of fraud.

The State's group pleading strategy is particularly flawed given the unique nature of the Teva Defendants' products. The Teva Defendants manufacture and sell short-acting, immediate-release opioids which, as the State concedes, are always accompanied by labels bearing FDA-approved warnings about their risks. (Pet. ¶ 70.) These opioids are subject to the rigorous and stringent TIRF REMS Program, which ensures that physicians and patients are aware of the risks of Actiq and Fentora and agree that the medicines are appropriate before a prescription is written. (MTD at 6-7; Ex. C to MTD.) Further, as the State's allegations make readily apparent (Pet. ¶¶ 35, 37), Actiq and Fentora represent a miniscule share of the opioid market. (MTD at 7.) Because the Teva Defendants and the other named Defendants are not similarly situated, they cannot be grouped together.

II. THE STATE HAS NOT PLED ANY MISREPRESENTATION OR OMISSION MADE IN OKLAHOMA BY EITHER TEVA DEFENDANT.

Even though all of its claims sound in fraud, the State does not dispute that its Petition makes only ***two*** conclusory assertions (Pet. ¶¶ 53, 64) in particular against Cephalon (and none against Teva USA). (MTD at 11-14.) The State fails to identify a single statement that either Teva Defendant made about its products in Oklahoma—much less a false one. It does not describe the content of any publication purportedly sponsored or influenced by either Teva Defendant—much less describe the extent to which any such publication was disseminated in Oklahoma. And it does not identify any Oklahoma prescriber who was exposed to any allegedly false statement by either Teva Defendant—much less a single instance in which a prescriber was influenced by any such statement to write a prescription for which the State paid.

In its Opposition, the State makes numerous new assertions against the Defendants based upon external non-governmental documents found on the internet that were not referenced in its Complaint. This is improper as a matter of law. *See, e.g., State ex rel. Wright v. Okla. Corp.*

Comm'n, 2007 OK 73, ¶51, 170 P.3d 1024, 1040 (recognizing that a plaintiff cannot "unilaterally change a movant's motion [to dismiss for failure to state a claim] into one for summary judgment" by asserting new facts in its opposition to the motion); *see also Choate v. Lawyers Title Ins. Corp.*, 2016 OK CIV APP 60, ¶18, 385 P.3d 670, 676 (upholding dismissal of complaint and declining to consider "separate affidavits and extraneous materials" attached to plaintiff's response to motion to dismiss).

Nonetheless, only a handful of new assertions are raised against the Teva Defendants, and these unpled allegations still fail to describe any fraud. They assert nothing more than lawful behavior, including utilizing consultants, sponsoring CMEs, and funding two trade organizations and a third-party publication about opioids from more than a decade ago (titled *Responsible Opioid Prescribing*). (Opp. at 20, 22-24, 29-30.) The State does not allege any facts to show that the Teva Defendants controlled, wrote, or edited any third-party statement or publication; that any particular third-party statements were false; or that any Oklahoma prescriber ever saw any supposedly false third-party statement, much less wrote a prescription because of it. This is insufficient to plead their claims. *See, e.g., City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *11 (N.D. Ill. May 8, 2015) (dismissing claims based upon similar but more detailed allegations because "[t]he City does not [ ] explain what editorial control, if any, is entailed in 'sponsoring' or 'facilitating' materials or events" and "alleges no facts that connect the alleged misrepresentations specifically to Chicago doctors or consumers").

The State's Opposition also argues that, nearly ten years ago, Cephalon entered into a plea agreement with the federal government to resolve a charge that it promoted certain products off-label. (Opp. at 50.) But apart from failing to plead this assertion in its Petition, the State

does not allege that any such off-label promotion was done in Oklahoma.[3] More fundamentally, because it is well-settled that "the promotion of off-label drug use is ***not in and of itself false or misleading***," *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012) (emphasis added), courts have rejected nearly identical claims against the Teva Defendants based upon nearly identical allegations. *CREB I*, 2009 WL 3245485, at *4 (dismissing nearly identical fraud-based claims and noting that "[r]eferring to a plea agreement and civil settlement in another action . . . does not satisfy plaintiffs' burden of pleading fraud with specificity under Rule 9(b) in this case, nor does such a reference 'raise a right to relief about the speculative level'"); *see also In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at *10 (D.N.J. July 10, 2009) (dismissing fraud-based claims because although plaintiff violated FDA regulations and pled guilty, "the off-label promotion of a pharmaceutical product in violation of the FDCA simply does not give rise to fraud-based rights of action").

The State also ignores that numerous courts have dismissed complaints against the Teva Defendants for failure to allege any misrepresentation, omission, or other fraudulent conduct—complaints that contained ***more*** detail than the Petition at issue here. (*See* MTD at 12-13 (discussing cases).) In its Opposition, the State sheds no light on why this case is any different, particularly given that the Oklahoma Supreme Court has relied upon federal case law to apply and interpret § 2009(B). *Gay*, 766 P.2d at 990 (citing *Natowitz v. Mehlman*, 542 F. Supp. 674, 676 (S.D.N.Y. 1982) and other federal decisions). Instead, it insists that it has adequately alleged fraud because Defendants' misrepresentations were "undoubtedly" material. (Opp. at 84.) But the State identifies no such misrepresentations made by the Teva Defendants in

[3] In addition, the conduct described in Cephalon's plea agreement pertaining to Actiq and two other non-opioid medicines took place during a ten-month period more than sixteen years ago in 2001. Guilty Plea Agreement, *United States v. Cephalon, Inc.*, No. 2:08-cr-00598 (E.D. Pa. Oct. 10, 2008), ECF No. 7, at 5.

Oklahoma. Because the State has failed to plead "the time, place, and content of [the] alleged false representation," as required by § 2009(B), its claims should be dismissed. *See Gay*, 766 P.2d at 990; *Gianfillippo v. Northland Cas. Co.*, 1993 OK 125, 861 P.2d 308, 310-11.

III. THE STATE HAS FAILED TO ALLEGE CAUSATION AS TO THE TEVA DEFENDANTS.

The State concedes that causation is a required element of each one of its claims as a matter of Oklahoma law (Opp. at 95), that the risks for opioid medicines were spelled out in their FDA-approved labels (*id.* at 3), and that Oklahoma physicians have an independent medical duty to know "the qualities and characteristics of those products which he administers or prescribes for use of his patients." *McKee v. Moore*, 1982 OK 71, 648 P.2d 21, 24. Yet the State fails to identify a single Oklahoma doctor who nevertheless supposedly relied upon some false statement by the Teva Defendants in prescribing a harmful or inappropriate prescription of Actiq or Fentora (or any other opioid medicine).

The State tries to gloss over its failure to plead causation by urging that Oklahoma doctors ***must*** have been impacted by Defendants' statements because the Petition "plainly alleges that Defendants conducted their marketing campaign in Oklahoma." (Opp. at 96.) This is beside the point. The Petition is devoid of allegations linking ***any*** (unidentified) fraudulent statement by either Teva Defendant to ***any*** prescription written in Oklahoma. Without this causal nexus, all claims against the Teva Defendants fail even under the most minimal of pleading standards.

The State's failure to allege facts to show that the Teva Defendants caused any medically-unnecessary prescription is not surprising; it cannot. The State does not dispute that, before prescribing opioids for pain management, physicians must familiarize themselves with the risks of opioids, advise patients of these risks, devise a treatment plan for each patient, monitor each patient, and consider entering into a risk-management plan with each high-risk patient.

(MTD at 3-4, 16); Okla. Admin. Code § 435:10-7-11(2)-(4). Oklahoma prescribers also must comply with the TIRF REMS Program before prescribing Actiq or Fentora, including signing an agreement with the patient that expressly acknowledges the risks and appropriate use of each medicine. (MTD at 4, 6-7.)

The State argues that it would be premature to dismiss the Petition for lack of causation. (Opp. at 96.) But this assumes the Petition has at least ***alleged*** a nexus between the actions of the Teva Defendants and the resulting injury (here, repayment for individual medically-unnecessary opioid prescriptions). The State has not even satisfied this threshold requirement. Perhaps recognizing this deficiency, the State's 100-page Opposition accuses Defendants of "try[ing] to overcomplicate and confuse" its allegations and attempting to impose a "heightened level of pleading prior to any discovery." (Opp. at 98, 99.) But even if § 2009(B) did not apply (and it does), requiring the State to put the Teva Defendants on notice of the basis for the claims against it by pleading causation is not a "heightened level of pleading." *Gens v. Casady Sch.*, 2008 OK 5, 177 P.3d 565, 570. It is a basic requirement—and one that the State simply cannot satisfy.

IV. THE STATE HAS FAILED TO ALLEGE ANY INJURY CAUSED BY THE TEVA DEFENDANTS.

The State does not dispute that injury is a required element of its claims and that, under Oklahoma law, merely paying for a product (even if prescribed off-label) is not a cognizable injury in the absence of facts that the prescription medicines were ineffective for or caused harm to the patients who received them. (MTD at 17-19); *see, e.g.*, *Walls v. Am. Tobacco Co.*, 2000 OK 66 ¶ 13, 11 P.3d 626, 630 (individual does not suffer "actual injury or damage" under OCPA "solely as a result of his or her payment of the purchase price for that product"); *Sisemore v. Dolgencorp, LLC*, 212 F. Supp. 3d 1106, 1110 (N.D. Okla. 2016) (applying rule to dismiss

claim under Oklahoma law).[4] Nonetheless, the State's Opposition makes no effort to show that it paid for a single prescription of Actiq or Fentora for an off-label condition—much less that any Actiq or Fentora prescription was ineffective or caused harm to a single Oklahoma consumer. For this very reason, numerous courts have dismissed nearly identical claims against the Teva Defendants—decisions that the State simply ignores. *See, e.g.*, *Travelers I*, 32 F. Supp. 3d at 555-56; *CREB II*, 2010 WL 1257790 at *3.

Recognizing that it has not pled a cognizable injury linked to the Teva Defendants, the State argues that it must have been injured because "Defendants intended to change prescribers' habits" and "intended the State's Medicaid program to pay for the additional prescriptions that resulted." (Opp. at 99.) But this resorts to improper group pleading, and "inten[t]" alone is insufficient to state a claim. The Petition says nothing about any particular prescriptions of Actiq or Fentora that were written. Because the State cannot identify any prescriptions linked to the Teva Defendants that were inappropriate or that harmed an Oklahoma patient, it cannot bring a claim against them.

V. THE PETITION FAILS TO ALLEGE ANY MISCONDUCT BY TEVA USA OR THE ACQUIRED ACTAVIS ENTITIES.

The State's Petition makes clear that its entire theory of liability against Teva USA rests upon the conclusory assertion that Teva USA "acted in concert" with Cephalon. (Pet. ¶ 17; *see also* Opp. at 88.) But this allegation says nothing about what role, if any, Teva USA had with respect to Actiq or Fentora; what marketing, if any, it supposedly did; or how it can be held responsible for statements it did not make. Recognizing this deficiency, the State argues that it should be allowed to conduct discovery on the relationship between Cephalon and Teva USA.

[4] *See also Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 634 F.3d 1352, 1360 (11th Cir. 2011); *Travelers I*, 32 F. Supp. 3d at 546-48; *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2010 WL 2346624, at *7-8 (D.N.J. June 9, 2010); *CREB II*, 2010 WL 1257790, at *3.

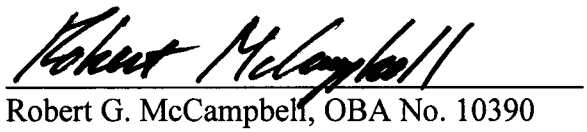
(Opp. at 90.) But this would negate the State's pleading burden. Moreover, the State already knows that Teva USA's corporate relationship with Cephalon commenced in 2011—it pleaded as much in its Petition. (Pet. ¶ 17.) Yet the Petition does not identify any particular conduct by Cephalon ***after 2011***. Clearly, Teva USA could not have "acted in concert" with Cephalon ***before*** the two (by the State's own admission) became affiliated, and there are no allegations of unlawful conduct by either entity after that affiliation commenced.

Similarly, in its Opposition, the State does not even bother to identify—much less address—any separate conduct by any of the Acquired Actavis Entities (Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc.). (Opp. at 88-90). In fact, it continues to inaccurately group these companies as part of a completely distinct corporate family. (*Id.* at 43, 88). The State's failure to attribute any purportedly fraudulent marketing to the Acquired Actavis Entities is unsurprising: the Acquired Actavis Entities sold only generic medications and ***did not promote their products***. Because the State fails to plead any wrongdoing by the Acquired Actavis Entities, much less with the specificity required by § 2009(B), all claims against them fail.

VI. CONCLUSION

For the foregoing reasons, as well as those set forth in their opening brief and in the Joint Reply, the Teva Defendants (Teva Pharmaceuticals USA, Inc. and Cephalon, Inc.) and the Acquired Actavis Entities (Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc.) respectfully request that the Court enter an Order dismissing all claims against them, or, alternatively, requiring the State to plead the necessary particulars of the alleged fraud against each company (to the extent it can).

Dated: November 21, 2017

By: 

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CERTIFICATE OF MAILING

I certify that a true and correct copy of the foregoing was mailed this 21st day of November, 2017, by depositing it in the U.S. Mail, postage prepaid to:

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