

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;
- (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.

For Judge Balkman's

Consideration OF OKLAHOMA S.S.

FILED

APR 0 9 2019

In the office of the Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816 Honorable Thad Balkman

William C. Hetherington Special Discovery Master

REPLY IN SUPPORT OF MOTION OF DEFENDANTS WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., AND TEVA PHARMACEUTICALS USA, INC. FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

Despite attaching over 2000 pages of exhibits in its Response in Opposition ("Response"), the State has failed to provide a single piece of evidence that the Generic Manufacturers¹ engaged in any unlawful activity—an essential element of its public nuisance claim.² The State's public nuisance claim is predicated on alleged false representations or omissions regarding the risks and benefits of prescription opioids, but the State has not identified a single representation or omission made by the Generic Manufacturers about opioids in Oklahoma, much less one that provides the unlawful act necessary to bring a public nuisance claim. And for good reason: the Generic Manufacturers sold generic medicines and did not promote them.

To try to conceal this fundamental problem and invent a genuine issue of material fact where none exists, the State distorts the law. The State incorrectly argues that the Generic Manufacturers can be held liable for public nuisance based upon the acts of entirely separate entities (*i.e.*, Cephalon, Inc.) that did promote opioid medicines. This ignores black-letter Oklahoma law that each corporation is a separate and distinct entity. The State cannot simply attribute the representations and acts of Cephalon to any or all of the Generic Manufacturers,³ but must show that each and every Defendant engaged in false marketing in Oklahoma. Yet virtually all of the exhibits the State attaches to its Response relate to Cephalon, or Teva USA after October

All capitalized terms are used as defined in the Motion of Defendants Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., and Teva Pharmaceuticals USA, Inc. for Partial Summary Judgment ("Generic Manufacturers' Motion"). (See Generic Mfrs.' Mot. 1–2.)

On April 4, 2019, the State voluntarily dismissed all of its claims other than its claim for Public Nuisance. See 4/4/19, Notice of Voluntary Dismissal of Certain Claims Without Prejudice.

As noted in the Generic Manufacturers' Motion, Teva USA is moving for partial summary judgment only as to claims against it prior to October 2011—when it became affiliated with Cephalon. (Generic Mfrs.' Mot. 2 n.1.)

2011. As the uncontroverted evidence from the Generic Manufacturers' Motion shows, the Generic Manufacturers made no representations about the safety and efficacy of their generic medicines and did not fund third-party doctors or organizations.

In addition, when the State's unsupported rhetoric and irrelevant exhibits are cast aside, it is clear that the claims against the Generic Manufacturers rest upon a single premise: they sold generic opioids and benefited from the marketing of other companies. This theory, however, does not involve an unlawful act. And it is preempted as a matter of federal law for the very reasons explained in the Generic Manufacturers' Motion. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) ("Any state law-based holding that the generic manufacturers . . . should have ceased manufacturing these products because of insufficient warnings not only violates the duty of sameness but conflicts with FDA's exclusive authority to approve drugs and drug labels."); (Generic Mfrs.' Mot. 16).

Put simply, the State has failed to meet its burden to present evidence showing the existence of a material factual dispute that the Actavis Defendants or Teva USA (prior to October 2011) engaged in any marketing (much less false marketing) of opioid medicines. Accordingly, because the State cannot satisfy the unlawful element of its public nuisance claim, the Court should grant the Generic Manufacturers' motion for summary judgment. *See Abraham v. Trail Lanes, Inc.*, 2014 OK CIV APP 107, ¶¶ 7, 13, 352 P.3d 1256, 1260 (affirming grant of summary judgment on public nuisance claim where plaintiff presented no evidence that defendant acted unlawfully and there was no duty defendant failed to perform).

II. PUBLIC NUISANCE REQUIRES AN UNLAWFUL ACT

"For an act or omission to be a nuisance in Oklahoma, it must be unlawful." *Nuncio v. Rock Knoll Townhome Vill., Inc.*, 2016 OK CIV APP 83, ¶ 8, 389 P.3d 370, 374 (citing Okla. Stat. Ann. tit. 50, § 1). Doing something legal, like selling FDA-approved medicines, cannot form the

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basis of a public nuisance claim under Oklahoma law. Okla. Stat. Ann. tit. 50, § 4 ("Nothing which is done or maintained under the express authority of a statute can be deemed a nuisance."). The generic opioids sold by the Generic Manufacturers are FDA-approved medicines. And Oklahoma law expressly permits the use of controlled substances—like the Generic Manufacturers' FDA-approved medicines—for the treatment of chronic pain. Okla. Admin. Code § 435:10-7-11; see also id. § 475:30-1-2 (permitting physicians to prescribe controlled substances).

The State asserts that "Defendants engaged in a widespread marketing campaign and made false representations to healthcare providers and/or omitted material facts regarding the risks, efficacy, and medical necessity of opioids." (Resp. 8–11 (quoting Statement of Additional Facts ("SAF") ¶ 1.)) Yet, in support of this so-called "fact," the State does not cite a single statement, let alone a false misrepresentation, made by any Generic Manufacturer, and instead cites thousands of pages related to other entities. (*Id.* (citing Exs. 5–8 (all pre-2011 Cephalon, Inc. documents); Ex. 4 (document identified as copyright Actavis Inc., not Actavis LLC or Actavis Pharma, Inc.); Exs. 16–57 (Mar. 7–8, 2019, Kolodny Dep. and accompanying Exhibits, none of which identify false misrepresentations by the Generic Manufacturers)).) This "throw everything against the wall" approach, without identifying any false statement made by the Actavis Defendants or Teva USA (prior to October 2011), does not and cannot defeat summary judgment.⁴

Similarly, the State's additional so-called "facts"—that "Defendants falsely marketed their opioids through the use of 'Key Opinion Leaders'" (SAF \P 2); "promoted the false concept of 'pseudoaddiction'" (SAF \P 3); and "were active collaborators in the Pain Care Forum . . . and also used seemingly unaffiliated organizations like The American Pain Foundation . . . to spread their

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The State attaches the Kolodny transcript and accompanying exhibits in their entirety, rather than excerpting the relevant portions. Even more egregiously, the State fails to provide any pin cite directing the Court to the supposedly relevant material.

misrepresentations" (SAF ¶ 4)—have nothing to do with the Generic Manufacturers. The cited documents and testimony show only that other distinct legal entities funded these doctors and organizations. (Id.) The Generic Manufacturers' uncontroverted evidence shows that they did not fund third-party doctors or organizations, or otherwise engage in marketing of their generic opioid medicines. (See Generic Mfrs.' Mot. \P 2–8.) Not surprisingly, the State does not identify a single false marketing statement attributable to any Generic Manufacturer in Oklahoma.

The remainder of the State's "facts" likewise do not point to any false marketing or other unlawful act by the Generic Manufacturers, and, thus, cannot form the basis of its public nuisance claim. (See SAF ¶ 5 (correlation between marketing strategy and sale of branded medicines); ¶ 6 (correlation between sales of branded medication and generic medications)⁵; ¶ 7 (Teva is the largest manufacturer of generic opioids); ¶ 8 ("Teva," "Actavis," and "Watson" had distribution agreements with Purdue to sell generic OxyContin or MS Contin).) Indeed, when all the rhetoric is cast aside, these "facts" make clear that the State seeks to hold the Generic Manufacturers liable merely because they sold generic opioid medicines in Oklahoma. This is not an unlawful act, and, in fact, this novel theory of liability is preempted as a matter of law. See, e.g., Morris, 713 F.3d at 778 ("Any state law-based holding that the generic manufacturers . . . should have ceased manufacturing these products" is preempted).

This is a misrepresentation of Hassler's deposition testimony, but, even if it were not, it still does not present an unlawful act on which public nuisance liability could be imposed. (See Ex. 1 to Resp., Hassler Dep. at 271:4–16 (Q: At that time, what unbranded marketing was Teva specifically doing related to chronic pain or opioids? A: I – I don't recall seeing specific initiatives, in that it really isn't part of what the generic companies do. There may be specific small grants in different areas, but generics usually ride in the wake of what a branded company has done to build a market for an innovative product, and then the generic simply announce availability of generic versions of that product and there isn't – there isn't much, if any, disease education that generics typically engage in that come to mind.); see also id. at 271:21–272:9 (testifying that prior to 2011 Teva did not use unbranded marketing materials.)

Put simply, because the State fails to provide evidence of any misrepresentation by the Generic Manufacturers to support its public nuisance claim, the Court should grant the Generic Manufacturers' Motion. *Abraham*, 2014 OK CIV APP 107, ¶ 13, 352 P.3d at 1262.

III. JOINT AND SEVERAL LIABILITY DOES NOT RELIEVE THE STATE OF ITS BURDEN TO SHOW LIABILITY ON THE PART OF EACH SEPARATE DEFENDANT

A prerequisite to the State's joint and several liability theory is a showing of liability. (See Resp. 2–3 ("Once proven"; "at fault"; "a cause").) As discussed above, the State has failed to show any unlawful act by the Generic Manufacturers, a necessary element of its public nuisance claim. If the Generic Manufacturers are not individually liable for the State's public nuisance claim, they cannot be jointly liable for that claim either.

The State's reliance on *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 227 Cal. Rptr. 3d 499 (2017), is misplaced. Unlike here, the defendants in *ConAgra* conceded that they marketed their lead paint for interior residential use. *Id.* at 108. As the State identifies, the *ConAgra* defendants instead argued that "their promotions could not have caused the presence of interior lead paint in homes without proof that paint made by each of them was currently present in those homes[.]" (Resp. 3.) This is wholly distinguishable from the Generic Manufacturers argument, which is not that their promotion did not cause the alleged public nuisance, but that there was *no promotion*—and therefore no unlawful act—to form the basis of the State's public nuisance claim against the Generic Manufacturers. *Abraham*, 2014 OK CIV APP 107, ¶ 13, 352 P.3d at 1262.

IV. THE GENERIC MANUFACTURERS ARE DISTINCT LEGAL ENTITIES AND THE STATE CANNOT SIMPLY DISREGARD THE CORPORATE FORM

It is black-letter law that "[c]orporations are distinct legal entities, and generally one corporation will not be held responsible for the acts of another." Hitch Enterprises, Inc. v.

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Cimarex Energy Co., 859 F. Supp. 2d 1249, 1265 (W.D. Okla. 2012) (quoting Gilbert v. Security Finance Corporation of Oklahoma, Inc., 152 P.3d 165, 175 (Okla. 2006).) Thus, to hold the Generic Manufacturers liable for its public nuisance claim, the State must identify and provide evidence of an unlawful act constituting the public nuisance for each Generic Manufacturer. As discussed above, the State has failed to do so. Instead, the State has provided evidence (and insufficient evidence at that) related only to Cephalon, a branded manufacturer that did not join the Generic Manufacturers' Motion. The Court cannot disregard the separate corporate existence of these entities. See McCall v. Chesapeake Energy Corp., 2007 OK CIV APP 59, ¶ 28, 164 P.3d 1120, 1127.

Likewise, the State's argument that the "Teva Defendants" are responsible for the acts of Cephalon fails. The evidence cited by the State (Ex. 2 to Resp.) shows only that the Generic Manufacturers' parent corporation (who is not a Defendant in this case) acquired Cephalon⁶—not that any Generic Manufacturer did so. As a result, the State's incorrect argument that a "purchasing corporation is a mere continuation of the selling company," even if true, is simply irrelevant.⁷ (Resp. 6, 14 (citing *Pulis v. United States Elec. Tool Co.*, 1977 OK 36 ¶ 5, 561 P.2d 68, 69).) The Generic Manufacturers did not purchase Cephalon; thus, their "[s]eparate corporate

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Although the State has dismissed its other claims, mooting Cephalon's Motion for Partial Summary Judgment, the State concedes that it settled a subset of these claims with Cephalon. (See Resp. 14.) Cephalon intends to separately move for summary judgment on the remaining claim in accordance with the Court's scheduling order.

The State's evidence shows that defendant Teva USA was not the purchasing corporation. (Ex. 2 to Resp., at 1–2 ("Jerusalem, Israel, and Frazer, PA, May 2, 2011 – Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Cephalon, Inc. (NASDAQ: CEPH) today announced that their Boards of Directors have unanimously approved a definitive agreement under which Teva will acquire all of the outstanding shares of Cephalon . . . expected to be completed in the third quarter of 2011."); see also Ex. 2 to Generic Mfrs' Mot., J. Hassler Decl. ¶ 11 (showing generic business of Actavis Defendants was acquired by the parent company of Teva USA in 2016).)

existence will not be disregarded" *McCall v. Chesapeake Energy Corp.*, 2007 OK CIV APP 59, ¶ 28, 164 P.3d 1120, 1127.

V. THE STATE CANNOT AVOID PREEMPTION

The Generic Manufacturers have demonstrated that, based upon the unique statutory and regulatory requirements applicable to them, any claim based on a failure to warn or communicate the risks of generic opioid medicines is preempted under *PLIVA*, *Inc. v. Mensing*, 564 U.S. 604 (2011) and other controlling United States Supreme Court precedent. (*See* Generic Mfrs.' Mot. 10–16.) The State does not dispute this point. Indeed, at bottom, the State's argument appears to be that the Generic Manufacturers should not have sold generic opioids or somehow should not have benefited from the alleged fraud of others—a theory that is also preempted as a matter of law by *Mensing* and its progeny. (*See* Generic Mfrs.' Mot. 16); *see also Morris*, 713 F.3d at 778 (recognizing rule).

Tellingly, the State tries to avoid preemption by conceding that it does not make any failure to warn claim and is basing its public nuisance claim upon affirmative marketing. (See Resp. 16.) But on summary judgment, the State can no longer rely on broad, unsupported assertions. Rather, it must present actual *evidence* that the Generic Manufacturers engaged in an unlawful act to support its public nuisance claim. *Abraham*, 2014 OK CIV APP 107, ¶ 13, 352 P.3d at 1262. The State has failed to do so.

VI. <u>CONCLUSION</u>

The undisputed facts show that the Generic Manufacturers made no representations about the therapeutic value of their products other than those required by the FDA. Partial summary judgment should be granted to the Generic Manufacturers on the State's public nuisance claim.

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Dated: April 9, 2019

Dit Telley

Robert G. McCampbell, OBA No. 10390

Nicholas ("Nick") V. Merkley, OBA No. 20284

Leasa M. Stewart, OBA No. 18515

Jeffrey A. Curran, OBA No. 12255

Ashley E. Quinn, OBA No. 33251

GABLEGOTWALS

One Leadership Square, 15th Fl.

211 North Robinson

Oklahoma City, OK 73102-7255

T: +1.405.235.3314

E-mail: RMcCampbell@Gablelaw.com
E-mail: NMerkley@Gablelaw.com
E-mail: LStewart@gablelaw.com
E-mail: JCurran@Gablelaw.com

E-mail: AQuinn@Gablelaw.com

OF COUNSEL:

Steven A. Reed

Harvey Bartle IV

Mark A. Fiore

Rebecca Hillver

Redecta Hillyel

Evan K. Jacobs

MORGAN, LEWIS & BOCKIUS LLP

1701 Market Street

Philadelphia, PA 19103-2921

T: +1.215.963.5000

E-mail: steven.reed@morganlewis.com
E-mail: harvey.bartle@morganlewis.com
E-mail: mark.fiore@morganlewis.com
E-mail: rebecca.hillyer@morganlewis.com
E-mail: evan.jacobs@morganlewis.com

Nancy L. Patterson

MORGAN, LEWIS & BOCKIUS LLP

1000 Louisiana St., Suite 4000 Houston, TX 77002-5006

T: +1.713.890.5195

E-mail: nancy.patterson@morganlewis.com

Brian M. Ercole

Melissa M. Coates

Martha A. Leibell

MORGAN, LEWIS & BOCKIUS LLP

200 S. Biscayne Blvd., Suite 5300

Miami, FL 33131

T: +1.305.415.3000

E-mail: <u>brian.ercole@morganlewis.com</u>
E-mail: <u>melissa.coates@morganlewis.com</u>

E-mail: martha.leibell@morganlewis.com

Collie T. James, IV

MORGAN, LEWIS & BOCKIUS LLP

600 Anton, Blvd., Suite 1800

Costa Mesa, CA 92626

T: +1.714.830.0600

E-mail: collie.james@morganlewis.com

Tinos Diamantatos

MORGAN, LEWIS & BOCKIUS LLP

77 W. Wacker Dr. Chicago, IL 60601

T: +1.312.324.1000

E-mail: tinos.diamantatos@morganlewis.com

Steven A. Luxton

MORGAN, LEWIS & BOCKIUS LLP

1111 Pennsylvania Ave., NW

Washington, DC 20004

T: +1.202.739.3000

E-mail: steven.luxton@morganlewis.com

Attorneys for Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was emailed this 9th day of April, 2019, to the following:

Attorneys for	Mike Hunter, Attorney General	Michael Burrage	
Plaintiff	Abby Dillsaver, General Counsel	Reggie Whitten	
	Ethan Shaner, Dep. Gen. Counsel	J. Revell Parrish	
	ATTORNEY GENERAL'S	WHITTEN BURRAGE	
	OFFICE	512 N. Broadway Ave., Ste. 300	
	313 N.E. 21st Street	Oklahoma City, OK 73102	
	Oklahoma City, OK 73105		
	Bradley Beckworth	Robert Winn Cutler	
	Jeffrey Angelovich	Ross E Leonoudakis	
	Lloyd Nolan Duck, III	NIX PATTERSON & ROACH	
	Andrew G. Pate	3600 N. Capital of Texas Hwy.	
	Lisa Baldwin	Suite B350	
	Brooke A. Churchman	Austin, TX 78746	
	Nathan B. Hall		
	NIX, PATTERSON & ROACH		
	512 N. Broadway Ave., Ste. 200		
	Oklahoma City, OK 73102		
	Glenn Coffee		
	GLENN COFFEE & ASSOCIATES, PLLC		
	915 N. Robinson Ave.		
	Oklahoma City, OK 73102		

Attorneys for	John H. Sparks	Charles C. Lifland
Johnson & Johnson,	Benjamin H. Odom	Jennifer D. Cardelus
Janssen	Michael W. Ridgeway	Wallace M. Allan
Pharmaceutica, Inc.,	David L. Kinney	Sabrina H. Strong
N/K/A Janssen	ODOM SPARKS & JONES	Houman Ehsan
Pharmaceuticals,	2500 McGee Drive, Suite 140	Esteban Rodriguez
Inc., and Ortho-	Norman, OK 73072	Justine M. Daniels
McNeil-Janssen		O'MELVENY & MEYERS
Pharmaceuticals,		400 S. Hope Street, 18th Floor
Inc. N/K/A Janssen		Los Angeles, CA 90071
Pharmaceuticals,	Stephen D. Brody	Daniel J. Franklin
Inc.	David Roberts	Ross B Galin
	Emilie K. Winckel	Desirae Krislie Cubero Tongco
	O'MELVENY & MEYERS	Vincent S. Weisband
	1625 Eye Street NW	O'MELVENY & MEYERS
	Washington, DC 20006	7 Times Square
		New York, NY 10036
	Amy R. Lucas	Jeffrey A. Barker
	Lauren S. Rakow	Amy J. Laurendeau
	Jessica L. Waddle	Michael Yoder
	O'MELVENY & MEYERS	O'MELVENY & MEYERS
	1999 Ave. of the Stars, 8 th Fl.	610 Newport Center Drive
	Los Angeles, CA 90067	Newport Beach, CA 92660
	Larry D. Ottaway	
	Amy Sherry Fischer	
	Andrew Bowman	
	Steven J. Johnson	
	Kaitlyn Dunn	
	Jordyn L. Cartmell	
	FOLIART, HUFF, OTTAWAY & BOTTOM	
	201 Robert S. Kerr Ave., 12th Fl.	
	Oklahoma City, OK 73102	

Attorneys for Purdue Pharma, LP, Purdue Pharma, Inc. and The Purdue Frederick Company

Sheila L. Birnbaum Mark S. Cheffo Hayden Adam Coleman

Paul LaFata Jonathan S. Tam Lindsay N. Zanello Bert L. Wolff

Mara C. Cusker Gonzalez

DECHERT, LLP
Three Bryant Park

1095 Avenue of the Americas

New York, NY 10036

William W. Oxley **DECHERT LLP** U.S. Bank Tower

633 West 5th Street, Suite 4900 Los Angeles, CA 90071

Britta E. Stanton
John D. Volney
John T. Cox, III
Eric W. Pinker
Jared D. Eisenberg
Jervonne D. Newsome
Ruben A. Garcia

Russell Guy Herman Samuel Butler Hardy, IV

Alan Dabdoub David S. Coale

LYNN PINKER COX & HURST 2100 Ross Avenue, Suite 2700

Dallas, TX 75201

Erik W. Snapp **DECHERT, LLP**

35 W. Wacker Drive, Ste. 3400

Chicago, IL 60601

Meghan R. Kelly

Benjamin F. McAnaney

Hope S. Freiwald Will W. Sachse DECHERT, LLP 2929 Arch Street

Philadelphia, PA 19104

Jonathan S. Tam
Jae Hong Lee
DECHERT, LLP

One Bush Street, 16th Floor San Francisco, CA 94104

Robert S. Hoff

WIGGIN & DANA, LLP

265 Church Street New Haven, CT 06510

Sanford C. Coats Joshua Burns

CROWE & DUNLEVY 324 N. Robinson Ave., Ste. 100

Oklahoma City, OK 73102

Nick Merkley

Diet Zehley