COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO.
1884-cv-01808 (BLS2)

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE PHARMA INC., RICHARD SACKLER, THERESA SACKLER, KATHE SACKLER, JONATHAN SACKLER, MORTIMER D.A. SACKLER, BEVERLY SACKLER, DAVID SACKLER, ILENE SACKLER LEFCOURT, PETER BOER, PAULO COSTA, CECIL PICKETT, RALPH SNYDERMAN, JUDITH LEWENT, CRAIG LANDAU, JOHN STEWART, MARK TIMNEY, and RUSSELL J. GASDIA

Defendants

COMMONWEALTH'S APPENDIX TO ITS MEMORANDUM OF LAW IN OPPOSITION TO PURDUE'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

CASES

1. *State of Arkansas v. Purdue Pharma L.P.*, No. 60CV-18-2018 (Ark. Cir. Ct. Apr. 5, 2019)

2. *State of Vermont v. Purdue Pharma L.P.*, No. 757-9-18 (Ver. Super. Ct. Mar. 19, 2019)

3. *State of Tennessee v. Purdue Pharma L.P.*, No. 1-173-18 (Tenn. Cir. Ct. Feb. 22, 2019)

4. *State of Delaware v. Purdue Pharma L.P.*, No. N18C-01-223 MMJ CCLD, 2019 WL 446382 (Del. Super. Ct. Feb. 4, 2019)

5. *State of Minnesota v. Purdue Pharma L.P.*, No. 27-CV-18-10788 (Minn. Dist. Ct. Jan. 4, 2019)

6. *Grewal, Attorney General of New Jersey v. Purdue Pharma L.P.*, No. ESX-C-245-17, 2018 WL 4829660 (N.J. Super. Ct. Oct. 2, 2018)

7. *State of New Hampshire v. Purdue Pharma Inc*., No. 217-2017-CV-00402, 2018 WL 4566129 (N.H. Super. Ct. Sep. 18, 2018)

8. *State of Ohio v. Purdue Pharma L.P*., No. 17 CI 261, 2018 WL 4080052 (Ohio C.P. Aug. 22, 2018)

9. *State of Alaska v. Purdue Pharma L.P.*, No. 3AN-17-09966CI, 2018 WL 4468439 (Alaska Super. Ct. July 12, 2018)

10. *State of Oklahoma v. Purdue Pharma L.P*., No. CJ-2017-816, 2017 WL 10152334 (Okl. Dist. Ct. Dec. 6, 2017)

EXHIBIT 1

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SIXTEENTH DIVISION

STATE OF ARKANSAS, ex rel.
LESLIE RUTLEDGE, ATTORNEY GENERAL **PLAINTIFF**

V. **CASE NO. 60CV-18-2018**

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
AND DOES 1 THROUGH 100, INCLUSIVE **DEFENDANTS**

RULING ON MOTIONS TO DISMISS AND MOTION TO STRIKE

This case is brought by the Arkansas Attorney General on behalf of the public, seeking injunctive relief and disgorgement of profits from certain manufacturers of opioids. The complaint asserts violations of the Arkansas Deceptive Trade Practices Act (ADTPA), violations of the Medicaid Fraud False Claims Act (MFFCA), creation of a public nuisance by the Defendants, unjust enrichment of the Defendants, and civil conspiracy. Defendants seek dismissal, arguing that the claims fail because of federal preemption, because there is neither interference with a public right nor adequate causation alleged to support the nuisance claim, because the State neither plead any actionable conduct by the Defendants nor adequately alleged proximate causation, because there is not adequate causation alleged for the ADTPA claim, because there is neither adequate causation alleged for the MFFCA claim nor did the State adequately plead pursuant to Rule 9(b) of the Arkansas Rules of Civil Procedure the MFFCA claim, because the civil conspiracy claim is derivative and therefore inadequately plead,

and that the municipal cost recovery rule bars the claims. The Court requested argument on the pending Motions to Dismiss and Motion to Strike, which was heard on March 25, 2019.

Discussion

In deciding motions to dismiss such as those before this Court, our Supreme Court has stated that the court "must look only to the complaint." *Malone v. Trans–States Lines, Inc.*, 325 Ark. 383, 926 S.W.2d 659 (1996). Further, in testing the sufficiency of the complaint on a motion to dismiss, "all reasonable inferences must be resolved in favor of the complaint, and pleadings are to be liberally construed." *Fitzgiven v. Dorey*, 2013 Ark. 346, 429 S.W.3d 234.

Arkansas requires fact pleading: "a pleading which sets forth a claim for relief ... shall contain (1) a statement in ordinary and concise language of facts showing that the pleader is entitled to relief ..." ARCP 8(a)(1). ARCP 12(b)(6) provides for the dismissal of a complaint for "failure to state facts upon which relief can be granted." Our Supreme Court has stated that these two rules must be read together in testing the sufficiency of the complaint; facts, not mere conclusions, must be alleged. *Rabalaias v. Barnett*, 284 Ark. 527, 683 S.W.2d 919 (1985).

In order to properly dismiss the complaint, the court must find that the plaintiff either (1) failed to state general facts upon which relief could have been granted or (2) failed to include specific facts pertaining to one or more of the elements of one of the claims after accepting all facts contained in the complaint as true and in the light most favorable to the non-moving party. *Thomas v. Pierce*, 87 Ark. App. 26, 28, 184 S.W.3d 489, 490 (2004).

Oral Motion to Defer Ruling

1. At the outset of oral argument, Defendants Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively "Purdue Pharma") made an oral Motion to Defer Ruling in anticipation of a possible decision by the Supreme Court of the United States in the pending preemption issue case of *Merck v. Albrecht.* The oral Motion to Defer Ruling is DENIED. The Court has reviewed the opinion of the Court of Appeals below in *Merck, Sharpe & Dohme v. Albrecht*, 852 F.3d 268 (3d Cir. 2017). *Merchk* involves preemption as relates to the drug Fosamax. The Court has also reviewed the existing, settled standard in *Wyeth v. Levine*, 555 U.S. 555 (2009), as it pertains to the when and under what circumstances preemption applies to FDA labeling in a products case and is satisfied no delay is warranted.

Motion to Strike Reference to Endo Settlement in New York

2. The motion to strike Paragraphs 5, 61, 64, and 75 of the Complaint by Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. (collectively "Endo") is GRANTED without prejudice to the Plaintiff to move its admission for a limited purpose (e.g., to show notice or the date thereof) if the facts asserted in the above numbered portions of the Complaint are not otherwise established or stipulated.

3. The Court notes the information stricken from each respective Paragraph is limited to references to the settlement agreement and any portion remaining is not stricken. The Court further observes the striking of these portions of the Complaint do not affect the Plaintiff's claims against Endo at this stage of the proceeding.

Preemption

4. After preliminary motions, Purdue first argued the claim contained in the Defendants' Joint Motion to Dismiss, Purdue Pharma's Motion to Dismiss, and Johnson & Johnson (J&J) and

Janssen Pharmaceuticals, Inc.'s (Janssen) Motion to Dismiss: that the claims asserted by the Plaintiff are preempted by the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301, *et seq.*

5. In considering the issue of preemption, there are two main principles by which the Court is guided: first, that "the purpose of Congress is the ultimate touchstone in every preemption case," *Wyeth v. Levine*, 555 U.S. 555 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (internal quotation marks omitted)); and secondly, that "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated...in a field which the States have traditionally occupied,'...we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" U.S. CONST. art. 6, cl. 2; *id.* at 1194–95 (citing *Lohr*, 518 U.S. at 485, 116 S.Ct. 2240).

6. In arguing the issue of preemption, the Defendants assert "the federal [FDCA], 21 U.S.C. §§ 301, *et seq.*, impliedly preempts claims seeking to impose a duty to alter FDA-approved labeling or otherwise market FDA-approved prescription medications in a way that conflicts with federal law." Brief in Support of Defendants' Joint Motion to Dismiss at 5 (citing *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488–89 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–19 (2011)).

7. While the above recitation on the law of preemption is accurate, in the Plaintiff's Complaint, the State is not asserting the Defendants failed to comply with the FDA labeling requirements, nor that the FDA-approved labeling should be altered, but rather that in spite of the information contained within the FDA-approved labeling, each individual Defendant perpetrated fraud in marketing the prescription drugs in contravention to the FDA-approved labeling.

8. Thus, the claim asserted by the Plaintiff with any regard to FDA labeling is one of fraud. Fraud falls squarely within the realm of historic police powers of the state. *See, e.g., Reserve Vault Corp. v. Jones*, 234 Ark. 1011, 356 S.W.2d 225 (1962)("The enactment of statutes for the purpose of prevention of fraud is within the police power of the state."); *Stuart v. Elk Horn Bank & Trust Co.*, 123

Ark. 285, 185 S.W. 263 (1916)("[T]his legislation is a valid exercise of the police power, in that it is intended to protect...from fraud[]....").

9. Accordingly, the Defendants' contention that the claims are preempted by the FDCA, 21 U.S.C §§ 301, *et seq.*, is DENIED.

Public Nuisance

10. Plaintiff's public nuisance claim alleges that the "Defendants, individually and in concert with each other, have engaged in improper and unlawful conduct that is injurious to public health and safety and has caused material discomfort and annoyance to the public at large." Complaint at 131. Specifically, Plaintiff alleges the "Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used." *Id.* at 134. And that "[w]ithout Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted." *Id.*

11. The Defendants' rebuttal is four-fold: 1) that the State fails to plead unreasonable interference with a public right, 2) that the State fails to adequately plead causation, 3) that the State does not adequately plead facts as to each Defendant; and 4) that the municipal cost recovery rule bars the State's public nuisance claim.

12. Under Arkansas law, a public nuisance is any improper, indecent, or unlawful conduct that injures the public and produces material annoyance, inconvenience, and discomfort. *Lonoke v. Chicago, R.I. & P.R. Co.*, 92 Ark. 546, 123 S.W. 395, 398 (1909).

13. The first point of Defendants' rebuttal argument contends the Plaintiff has failed to allege facts sufficient to show the violation of "a public right held in common by the community as a whole." Defendants' Joint Brief at II.A. (citing *Ozark Poultry Prods., Inc. v. Garman*, 251 Ark. 389, 390–91 (1971). Defendants also cite to the Restatement of Torts for the proposition that public rights are "collective in nature and not like the individual right that everyone has not to be assaulted or defamed

or defrauded or negligently injured." *Id.* (citing Restatement (Second) of Torts § 821B cmt. g (1979)). The Restatement also notes as an example of a public nuisance "conduct [that] involves a significant interference with the public health," and offers as an example the spread of smallpox, risking an epidemic. Restatement (Second) of Torts § 821B cmt. g (1979). Defendants cannot seriously contend that the impacts of opiate addiction in Arkansas have not affected the general public.

14. The Defendants' second argument on public nuisance, that the State fails to adequately plead causation, relies on two similar cases: *Ashley County v. Pfizer, Inc.*, 552 F.3d 659 (2009) and *Independence Cty. v. Pfizer, Inc.*, 534 F. Supp. 2d 882 (E.D. Ark. 2008). Defendants' cite these cases for the proposition that the "remoteness doctrine" bars the Plaintiff's claims, such that Plaintiff failed to "plead a 'direct link' between the alleged malfeasance and the purported injury." Defendants' Joint Brief at II (citing *Independence Cty.*, 534 F. Supp. 2d at 888–89).

15. Both the *Ashley County* and *Independence County* cases are distinguishable from the present matter. The first and most obvious is the State's role in administering Medicaid claims for Defendants' products. Secondly, no third party intervening cause (criminal or otherwise) is alleged.

16. In each of the cases advanced by Defendants, the plaintiff counties' allegations that drug manufacturers knew its products would be used to create methamphetamines did not demonstrate proximate cause because "there is no direct link in between Defendants' products and Plaintiffs' damages." *Independence Cty.*, 534 F. Supp. 2d at 888–89. In each of those cases, however, the Defendant established an intervening cause that was the actual creation of the relevant injury independent of their conduct (i.e., the illegal actions in the manufacture and distribution of the methamphetamine).

17. The allegations by the Plaintiff herein are that Defendants not only knowingly put potentially harmful medication on the market (such as with *Ashley County*), but that the Defendants, individually and in concert with one another, intentionally spread false and deceptive statements

through direct marketing of their branded opioids, including such examples as patently misleading advertisements, sales representatives who visited individual doctors and promoted the use of opioids for chronic pain, and doctors who were hired by the Defendants to speak at programs in order to give the false impression that they were providing unbiased and medically accurate presentations.

18. While causation may prove to be an arguable obstacle to Plaintiff at trial, even there, Defendants have the burden of proving an intervening cause created the relevant injury independent of their conduct. *Belz-Burrows, L.P. v. Cameron Const. Co.*, 78 Ark. App. 84, 90, 78 S.W.3d 126, 130 (2002). Defendants have failed to adequately show an alleged intervening cause at this stage of the litigation.

19. Defendants' third point of rebuttal on the public nuisance claim, that the State does not adequately plead facts as to each Defendant, alleges the Plaintiff impermissibly engaged in "group pleading." This Court does not agree. There are ample specific allegations against each Defendant so as to allow each Defendant to meaningfully respond and defend themselves.

20. Defendants' last point of rebuttal with regard to public nuisance is that the Municipal Cost Recovery Rule, which provides the rule that governments cannot recover in tort for the costs of public services, bars the State's public nuisance claim. *See, e.g., United States v. Standard Oil Co. of Cal.*, 332 U.S. 301 (1947). While this Court is not convinced of the application of the Municipal Cost Recovery Rule in this situation, in either event, no court in Arkansas has recognized the Municipal Cost Recovery Rule and this Court is not inclined to do so now.

ADTPA

21. The sole basis on which the Defendants seek to dismiss Plaintiff's ADTPA claim is an assertion the Plaintiff insufficiently alleged causation.

22. At this stage of trial, Plaintiff has sufficiently alleged causation; thus Defendants' Motion to Dismiss Plaintiff's ADTPA claim is DENIED.

MFFCA

23. To state a claim under Arkansas's MFFCA a person must allege facts sufficient to show the Defendant: "1) Knowingly ma[de] or cause[d] to be made any false statement or representation of a material fact in any claim, request for payment, or application for any benefit or payment under the Arkansas Medicaid Program;" or "2) [k]nowingly ma[de] or cause[d] to be made any omission or false statement or representation of a material fact for use in determining rights to a benefit or payment under the Arkansas Medicaid Program." Ark. Code Ann. § 20-77-902(1)-(2).

24. Plaintiff's allegations contained in its Complaint are that the Defendants' alleged deceptive marketing practices made or caused to be made false statements, omissions or misrepresentations of material fact in the application for benefits or payments under the Arkansas Medicaid Program in that at the time of making or causing false or misleading statements or omissions in marketing that doctors would write prescriptions for opioids to treat chronic pain and that the Arkansas Medicaid Program would approve and pay such claims.

25. By comparison to pleading requirements for federal False Claims Act claims, the Defendants argue in their Joint Brief the Plaintiff fails to plead with the particularity required for asserting a claim of fraud pursuant to Arkansas Rules of Civil Procedure 9(b).

26. There is no authority in Arkansas to establish that claims made under the MFFCA require the stringent pleading requirements of Arkansas Rules of Civil Procedure 9(b).

27. This Court does not agree with the Defendants' assertion Arkansas was required to plead in its Complaint, on a claim-by-claim basis, to identify the false statement made, the person who made it, the doctor who wrote a prescription based on a false statement, the resulting medication prescribed, the person who filled the prescription, and when it was submitted.

28. Regardless, the Plaintiff's Complaint alleges sufficient facts to assert a claim under the MFFCA; the Defendant's motion to dismiss Plaintiff's MFFCA claim is therefore DENIED.

Unjust Enrichment

29. Defendants' Joint Motion to Dismiss alleges that Arkansas's claim for unjust enrichment should be dismissed because there was no implied contract between Arkansas and Defendants.

30. In support of their argument, they rely on *Ashley County*, but this matter is distinguishable from *Ashley County* with regard to unjust enrichment. In *Ashley County*, the Plaintiff counties sought to have the defendants, manufacturers and distributors of products containing pseudoephedrine, pay for "law enforcement, inmate housing, social services, and treatment." 552 F.3d at 666.

31. In contrast, Arkansas's claim for unjust enrichment alleges "the State has overpaid for opioid prescriptions and permitting Defendants to retain overpayments [they] fraudulently procured would be unjust and inequitable." Complaint at 139. Here the State provided services (Medicaid), which rendered services with the clear expectation of being reimbursed for any amounts overpaid, and Defendants clearly marketed and sold their opioids for chronic pain with "a reasonable expectation of their payment" by Arkansas Medicaid. *Ashley County*, 552 F.3d at 666; *Dews*, 288 Ark. at 536, 708 S.W.2d at 69 ("Courts . . . will only imply a promise to pay for services where they were rendered in such circumstances as authorized the party performing them to entertain a reasonable expectation of their payment by the party beneficiary.").

Conspiracy

32. Plaintiff alleges a civil conspiracy to deceive the State, physicians and consumers, in that the Defendants coordinated their efforts pursuant to a shared plan and common agreement to deceptively market opioids for chronic pain in Arkansas.

33. Specifically, Plaintiff alleges Defendants violated, "...at a minimum, the Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901, *et seq.*, the Arkansas Deceptive Trade Practices

Act, Ark. Code Ann. §§ 4-88-101, *et seq.*, and Arkansas common law..." Complaint at 144; *see also*, AMI 713, 714.

34. The Plaintiff further alleges that Defendants controlled the messages disseminated by Front Groups and KOLs by "funding, directing, reviewing, editing, and distributing" unbranded marketing, or advertising that does not name a specific opioid. Complaint at 34.

35. The State has sufficiently alleged facts to plead a conspiracy under Arkansas law, *i.e.* they have alleged facts sufficient to "show a combination of two or more persons to accomplish a purpose that is unlawful or oppressive...." *Dodson v. Allstate Ins. Co.*, 345 Ark. 430, 445 (2001).

Motion to Dismiss Johnson & Johnson

36. In its Motion to Dismiss, J&J alleges the State fails to state a claim against J&J, both in that the State does not allege any wrongdoing by J&J nor does the State allege any theory of vicarious liability under which J&J could be held liable for Janssen's conduct, and secondly that the State pleads no actionable conduct against Janssen.

37. With specific regard to the argument of vicarious liability, J&J alleges Arkansas's claim fails because Arkansas has failed to establish sufficient facts to pierce the corporate veil.

38. J&J's liability does not depend upon piercing the corporate veil, however, and is instead based on principles of vicarious liability, under which a parent corporation may be held responsible for a specific act that it ordered and authorized. *See* Restatement (Second) of Agency, Section 14M cmt. a (1958); Restatement (Third) of Agency, Section 1.01, cmt. f(2) (2006).

39. Plaintiff's Complaint alleges J&J is liable under agency principles because it is the only company that owns more than 10% of Janssen's stock, corresponds with the FDA regarding Janssen's products, controlled Janssen's marketing, and retained the benefits of Janssen's fraud. Complaint at 19.

40. Accordingly, at least for purposes of a motion to dismiss, the State has alleged enough for the Court to infer that J&J had an agency relationship with Janssen and can therefore be held liable for Janssen's actions as alleged in the Complaint. *See Rounds & Porter Lumber Co. v. Burns*, 216 Ark. 288, 225 S.W.2d 1 (1949)("Degree of parent company control is a fact question."); *Black v. Valley Behavioral Health System, LLC*, 2015 WL 13655174 (W.D. Ark.)("The Court recognizes that [corporate liability] principles could possibly preclude Acadia from being held liable for the acts of VBHS; however, a final decision on this status of the separate defendant entities' relationship would be premature at this juncture, as those circumstances have not yet been fully developed."); *see also Oliver v. Bluegrass*, 284 Ark. 1 (1984); *1st National Bank of Camden v. Tracor MBA*, 851 F.2d 212 (1988).

Punitive and Treble Damages

41. Defendants move to strike Arkansas's request for punitive and treble damages because the State does not allege (1) any egregious or malicious conduct by any Defendant that would support a claim for punitive damages or (2) any statutory basis for a claim for treble damages.

42. The Court does not agree. Under Arkansas law punitive damages are available if:

> (1) The defendant knew or ought to have known, in light of the surrounding circumstances, that his or her conduct would naturally and probably result in injury or damage and that he **or** she continued the conduct with malice or in reckless disregard of the consequences; or
>
> (2) The defendant intentionally pursued a course of conduct for the purpose of causing injury or damage.
>
> Ark. Code Ann. § 16-55-206.

43. Arkansas has pled sufficient allegations to meet this standard.

44. Further, treble damages are available to the State under the Medicaid Fraud False Claims Act. Under Arkansas Code Annotated § 20-77-902, "[a] person shall be liable to the State of

Arkansas, through the Attorney General, for a civil penalty of three (3) times the amount of damages if he or she [k]nowingly makes or causes to be made any false statement or representation of a material fact in any claim, request for payment, or application for any benefit or payment under the Arkansas Medicaid Program." *See* Complaint at 122.

45. While the fact questions regarding Defendants' alleged deceptive statements remain for trial, at this stage of the litigation, the Plaintiff has adequately pleaded a claim for both punitive and treble damages.

IT IS SO ORDERED.

HONORABLE MORGAN E. WELCH
Circuit Judge 4-5-19
DATE

EXHIBIT 2

VERMONT SUPERIOR COURT
CHITTENDEN UNIT
CIVIL DIVISION

STATE OF VERMONT, Plaintiff v. PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY, Defendants	VERMONT SUPERIOR COURT FILED Docket No. 757-9-18 Cncv MAR 19 2019 CHITTENDEN UNIT

RULING ON MOTION TO DISMISS

This case is brought by the Vermont Attorney General on behalf of the public, seeking injunctive relief and disgorgement of profits from a manufacturer of opioids. The complaint asserts violations of the Vermont Consumer Protection Act and creation of a public nuisance. Defendants seek dismissal, arguing that the claims fail because of federal preemption, because the remedies the State seeks are not available, and because there is neither interference with a public right nor adequate causation alleged to support the nuisance claim. At Purdue's request, the court heard oral argument on the motion on March 14.

Discussion

As Purdue's counsel acknowledged at oral argument, Purdue has an uphill battle here in seeking dismissal. The question on a motion such as this is whether "it is beyond doubt that there exist no facts or circumstances that would entitle the plaintiff to relief." Skaskiw v. Vermont Agency of Agric., 2014 VT 133, ¶ 6, 198 Vt. 187(citation omitted). A court must "assume as true all facts as pleaded in the complaint, accept as true all reasonable inferences that may be derived

from the plaintiff's pleadings, and assume as false all contravening assertions in the defendant's pleadings." Id. The question is "whether the bare allegations of the complaint are sufficient to state a claim." Id.

The gist of the complaint is that over a period of years Defendants (jointly Purdue) have aggressively and misleadingly marketed opioids such as Oxycontin in Vermont, leading to massive addiction and the resulting societal costs. The State alleges that even after a 2007 consent judgment these acts have continued, and that they have included marketing not just to medical professionals but also to consumers. The complaint seeks injunctive relief to require the termination of such marketing efforts, and disgorgement of profits associated with sales of opioids in Vermont.

The Statute of Limitations Argument

This case was filed in 2018. The parties agree that the statute of limitations is six years, and that the claims were subject to a two-year tolling agreement. The applicable time frame therefore begins in 2010. 12 V.S.A. § 511. Purdue argues that the claims are based on events that occurred prior to 2010 and are therefore barred. Purdue is correct that much of the complaint recites historical information that predates 2010. Nonetheless, it does allege that Purdue has continued to act wrongfully since 2010. *See, e.g.*, Complaint ¶¶ 119-26, 132, 135. It is not time-barred.[1]

Consumer Protection Claims

The complaint asserts, in sum, that Purdue has made material misrepresentations and omissions, engaged in deceptive marketing, and targeted vulnerable patients in the face of

[1] Purdue asks that the court order Plaintiff to amend the complaint to drop the pre-2010 allegations. The court sees no need to do so. Recovery at trial will, of course, be limited to 2010 and later, and the evidence at trial can be limited in scope. At least some of the pre-2010 allegations are necessary background to understanding the later claims.

heightened risks to those patients, in violation of the Vermont Consumer Protection Act (CPA), 9 V.S.A. §2453(a). Complaint, Counts I and II.

Preemption

Purdue argues first that these claims are preempted by the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* That argument is based upon the claim that what the State is asserting here is a violation of federal law regarding advertising of medications. Motion at 6. There is a provision in the CPA providing for state law claims based upon violations of the FDCA. *See* 9 V.S.A. § 2466a(c)(1)(It is a violation of the law to advertise in Vermont "if that advertisement does not comply with the requirements concerning . . . prescription drug advertising in federal law and regulations"). Advertisement is broadly defined to include conveying "commercial messages" to health care providers through mail or at conferences or meetings. Id. § 2466a(c)(2)((B). However, a violation of federal law is not what is alleged here: the State does not assert a claim under section 2466a of the CPA. Nor has Purdue presented anything to suggest that by regulating advertising of medications Congress intended to restrict states from enforcing consumer fraud statutes.[2]

The primary case upon which Purdue relies here is Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), and cases following it. However, that case involved a tort claim that a medical device manufacturer's consultant had made false statements to the Federal Food and Drug Administration, and that but for that fraud upon the federal agency the plaintiffs would not have been injured by the device. The Court noted that "the fraud claims exist solely by virtue of

[2] Purdue suggests that the general provisions of the CPA cannot apply because they apply only when the deceptive acts are directed at consumers. The court does not read the provisions allowing suit by the Attorney General, as opposed to private parties, to be so narrow. *See* 9 V.S.A. § 2458 and 2453(a)(allowing Attorney General to sue to restrain "unfair or deceptive acts or practices in commerce" when such suit is in the public interest). Moreover, there are allegations that Purdue took acts directed at consumers, such as offering "savings cards" to sell more OxyContin. Complaint ¶¶ 119-126.

the FDCA disclosure requirements," and that "the existence of these federal enactments is a critical element in [Plaintiffs'] case." Id. at 353. That is entirely distinguishable from the claims in this case, which do not rely upon violations of federal law.

Purdue also cites 21 U.S.C. § 337, a section of the FDCA, as a basis for preemption. However, that section says that "all such proceedings for the enforcement, or to restrain violations, of this chapter" must be filed by the United States. This case does not seek enforcement of federal law, or restraint of violations of federal law.

What Purdue argues is that the claims here are really ones under § 2466a(c)(1) of the CPA, even though that is not what the complaint alleges. However, on a motion to dismiss it is what the complaint alleges that matters. The fact that the federal government imposes restrictions on drug advertising does not necessarily mean that the states may not regulate deceptive acts by drug manufacturers and distributors. At least at this stage of the proceedings, the court is not persuaded that federal preemption applies here.

CPA Remedies

Purdue next argues that the CPA does not provide for the remedies the State seeks here: disgorgement and injunctive relief. To the contrary, the statute grants broad power to fashion relief in consumer protection cases. The statute provides that "the Attorney General . . . may request and the court is authorized to render any . . . temporary or permanent relief . . . as may be in the public interest . . . " 9 V.S.A. § 2458(b). While the statute lists several specific modes of relief, the list is expressly non-exclusive. Id.

Public Nuisance Claims

The public nuisance claim alleges that Purdue has created, or was a substantial factor in creating, a public nuisance by harming "the health, safety, peace, comfort, or convenience of the

general community." Complaint Count III, ¶ 248. For example, the complaint cites a distortion of the medical standard of care for treatment of chronic pain, high rates of opioid abuse and overdoses, the impact of those events upon Vermont families and communities, and increased costs for health care, emergency services and law enforcement across the state. Id. ¶ 252. It further alleges that these impacts were foreseeable, and could be abated by steps such as education, honest marketing, and addiction treatment. Id. ¶¶ 254-55. Purdue contends that the claim fails because it does not allege interference with any public right, and fails to plead causation.

As to the "public right" argument, Purdue describes the complaint as merely alleging "private injuries to some individuals and subsequent costs to the State." Motion at 14. It points to a recent trial court opinion in which Judge Teachout rejected a public nuisance claim brought in connection with contaminated groundwater. State v. Atlantic Richfield Co., No. 340-6-14 Wncv (July 31, 2018). That decision, says Purdue, stands for the widely-accepted proposition that products liability claims cannot be brought against manufacturers in the guise of public nuisance claims. It may, but this is not a products liability case, and no damages are sought for injuries to individual patients from Purdue's products. More to the point, what the court was concerned with in Atlantic Richfield was the expansion of the statute of limitations, as the State sought to raise claims dating back to 1985 by relying upon the continuing nuisance doctrine. Id. 14-16. It was also concerned that the relief sought by the State would require entry onto private lands of non-parties. Id. at 16-17. Those are not concerns in this case. The court does not find that case to be useful here.

Purdue also argues that nuisance claims should be limited to those relating to land use issues. Some courts have so limited nuisance claims. *See, e.g.*, State ex rel. Jennings v. Purdue Pharma L.P., No. CVN18C01223MMJCCLD, 2019 WL 446382, at *12 (Del. Super. Ct. Feb. 4, 2019) ("There is a clear national trend to limit public nuisance to land use."). Vermont, however,

has not done so, and the Restatement expressly says that "a public nuisance does not necessarily involve interference with use and enjoyment of land." Restatement (Second) of Torts § 821B cmt. h (Westlaw, Oct. 2018 update). Because it is an open issue in Vermont, dismissal on this basis is not appropriate. The court cannot say that "there exist no facts or circumstances that would entitle the plaintiff to relief." Skaskiw, 2014 VT 133, ¶ 6.

A public nuisance is one that affects the general public, rather than solely private parties. State v. Howe Cleaners, 2010 VT 70, ¶¶ 48-52, 188 Vt. 303. The Restatement notes as an example of a public nuisance "conduct [that] involves a significant interference with the public health," and offers as an example the spread of smallpox, risking an epidemic. Restatement (Second) of Torts § 821B and cmt. g. It cannot seriously be argued that the impacts of opiate addiction in Vermont have not affected the general public. If the State can ultimately prove its allegations as to Purdue's responsibility for the widespread nature of this scourge, it will meet the "public" aspect of such a nuisance claim.

As to the issue of causation, Purdue argues that there are too many other factors that contribute to a person becoming addicted to establish that Purdue is responsible for the widespread addiction in Vermont. That may well present a challenge as to the proof at trial, but the only question before the court today is whether the complaint sufficiently alleges causation. It does. It alleges, for example, that Purdue's misrepresentations resulted in a dramatic increase in prescriptions, that those led to increased addiction, that the majority of opioid deaths in Vermont are causally linked to opioid prescriptions, that Purdue created or was a substantial factor in creating the alleged public nuisance, and that all of this was foreseeable to Purdue. Complaint ¶¶ 12-13, 15, 18, 34, 251, 252, 254.

Order

The motion to dismiss is denied. Defendants are directed to file their answers within 14 days, and the parties are directed to submit a discovery schedule within thirty days thereafter or, if agreement cannot be reached, to request a discovery conference.

Dated at Burlington this 18th day of March, 2019.

Helen M. Toor
Superior Court Judge

EXHIBIT 3

IN THE CIRCUIT COURT FOR KNOX COUNTY, TENNESSEE

STATE OF TENNESSEE, *ex rel.* HERBERT H. SLATERY III, ATTORNEY GENERAL and REPORTER,	)	
Plaintiff,	)	
v.	)	Case No. 1-173-18
PURDUE PHARMA L.P., a foreign limited partnership,	)	
Defendant.	)	

ORDER

In this case, the State of Tennessee makes various allegations against Purdue Pharma L.P. ("Purdue") related to Purdue's marketing of opioid medications, including OxyContin, Butrane, and Hysingla ER. The State alleges that Purdue's marketing is in violation of the Tennessee Consumer Protection Act, Tenn. Code Ann. §47-18-104(a), (b); is in violation of a 2007 Agreed Final Judgment between the parties; and constitutes a common law public nuisance. Purdue has filed a motion to dismiss, contending that it cannot be liable for its proper promotion of FDA-approved medication and that the State's Complaint does not adequately plead causation or public nuisance. For the reasons set forth herein, Purdue's motion is denied.

I. STANDARD OF REVIEW

When considering a motion to dismiss for failure to state a claim upon which relief can be granted, the Court is limited to an examination of the complaint alone. *See Walcotts Fin. Serv., Inc. v. McReynolds*, 807 S.W. 708, 710 (Tenn. Ct. App. 1990). Such a motion avers that the allegations in the complaint, when considered alone and taken as true, are insufficient to state a claim as a matter of law. *See Cornpropst v. Sloan*, 528 S.W.2d 188 (Tenn. 1975). In other words,

such a motion tests the legal sufficiency of the complaint, not the strength of the plaintiff's proof. *See Bell ex rel. Snyder v. Icard*, 986 S.W.2d 550, 554 (Tenn. 1999). The Court is required to construe the complaint liberally in favor of the plaintiff, taking all the allegations of fact therein as true. *See Cook ex rel. Uithoven v. Spinnaker's of Rivergate, Inc.*, 878 S.W.2d 934, 938 (Tenn. 1994).

II. PREEMPTION

Purdue first contends that the Complaint should be dismissed because federal law preempts the State's claims. It is well-established that states possess sovereignty "concurrent with that of the Federal Government, subject only to the limitations imposed by the Supremacy Clause" of the United States Constitution. *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). The Supremacy Clause provides that federal law "shall be the supreme Law of the Land." (U.S. Const. art. VI, cl. 2). Thus, when state law and federal law conflict, federal law controls, and Purdue's argument is based on this conflict preemption. Conflict preemption only occurs "where it is impossible for a private party to comply with both state and federal requirements" or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quotations and citations omitted). A motion to dismiss based on preemption should only be granted when "the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Galper v. LP Morgan Chase Bank, NA*, 802 F.3d 437, 444 (2d Cir. 2015).

Importantly, the United States Supreme Court has held that "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Those police powers include protecting consumers against deceptive business practices. *See California*

v. ARC Am. Corp., 490 U.S. 93, 101 (1989). When the issue is one that is traditionally the subject of state control, courts must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.*

Synthesized, Purdue's argument is that the Food and Drug Administration ("FDA"), via the Federal Food, Drug, and Cosmetic Act ("FDCA"), controls prescription medication warning labels; that Purdue's labels complied with FDCA requirements; and that the State is seeking to impose state law liability on Purdue when federal law controls. The Court finds that Purdue's argument is based upon a mischaracterization of the State's Complaint, which is not grounded in the content of the medication labels but rather the conduct of Purdue and its pharmaceutical sales representatives.

For example, Purdue contends that the State's Complaint regarding dosing limitations conflicts with the FDA's decision not to recommend a maximum duration of use for the medications. However, the Complaint alleges that Purdue's sales representatives incorrectly asserted that OxyContin had no dose ceiling at all:

> 58. Purdue represented without qualification that OxyContin did not have a dose ceiling when those claims were false, deceptive, and/or unsubstantiated at the time they were made.
> 59, OxyContin has a dose ceiling that is imposed by adverse reactions to patients taking increased doses of the drug, including overdose, respiratory depression, somnolence, addiction, and other serious adverse effects.
> 60. While the FDA approved a limited statement on OxyContin's Full Prescribing Information making clear that OxyContin's dose ceiling *was* imposed by adverse reactions, Purdue's Tennessee sales representatives routinely asserted that OxyContin had no dose ceiling *at all*. Further, Purdue failed to discipline or correct sales representatives who made such claims.

(Complaint) (emphasis original). Similarly, regarding the State's claim that Purdue pushed the concept of "pseudoaddiction" in order to increase prescriptions, Purdue contends that its FDA-

approved label addresses these concerns. However, the State's allegation is that Purdue invented and pushed the concept of pseudoaddiction (which Purdue described as "the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors")[1] for the purpose of getting around the FDA-required language regarding red flags for drug-seeking behaviors.

Purdue further takes issue with the State's allegations regarding Purdue's use of screening tools and failure to disclose the efficacy of OxyContin use beyond twelve weeks. Again, the State has not alleged liability for Purdue's use of the FDA-mandated Risk Evaluation and Mitigation Strategy Program; rather, the State alleges that "[i]n order to make health care providers more willing to prescribe its addictive opioid products, Purdue overstated the efficacy of abuse and diversion mitigation tools like patient contracts, urine drug testing, pill counts, and similar strategies" and that a 2016 CDC Guideline "confirms the lack of adequate substantiation to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk." (Complaint, ¶¶93, 96). The Complaint then gives specific examples of ways in which Purdue allegedly overstated the efficacy of abuse prevention programs, including the use of a "General Objection Handler" to address provider concerns, as well as specific notes from sales representatives documenting their touting of the various screening tools. In addition, the Complaint alleges that Purdue "downplayed the increased risk of addiction from higher doses of its opioid products through material omissions" and "failed to disclose the material fact that there is an increased risk of addiction at higher doses of its opioid products." (Complaint, ¶¶ 139, 140).

---

[1] Complaint, ¶79.

In sum, Purdue's argument with respect to preemption is based upon its erroneous assertion that the Complaint seek to hold it liable for actions that were approved or required by the FDA and the FDCA. In reality, the Complaint seeks to hold Purdue liable for alleged misleading and deceptive practices in violation of Tennessee's Consumer Protection Act and actions that constitute Tennessee's common law tort of public nuisance. Thus, the Court concludes that the State's claims do not conflict with FDA and FDCA requirements, and preemption does not apply.

III. THE 2007 AGREED FINAL JUDGMENT

Purdue also seeks dismissal of the State's claim that Purdue violated portions of a 2007 Agreed Final Judgment between the parties. The Judgment required Purdue to stop promoting and marketing off-label uses for OxyContin and to establish and implement an abuse and diversion detection program to identify providers who were over-prescribing OxyContin. Upon discovery of these "red-flag" providers, Purdue was obligated to "take further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." (Agreed Final Judgment, ¶13). Purdue characterizes the State's Complaint as alleging that "the 2007 Agreed Judgment requires Purdue to stop promoting opioid medication for long-term treatment of chronic pain." Purdue contends that the State is judicially estopped from making claims of misrepresentation based on statements that were permitted or required by the Agreed Judgment.

The Court again disagrees with Purdue's characterization of the Complaint. The State has not alleged that Purdue is liable for promoting opioids in a manner consistent with FDA requirements, nor has the State alleged liability for promotion of Purdue's products in accordance

with the 2007 Agreed Final Judgment. Rather, the State has alleged that Purdue was required but failed to stop promoting its products to specific health care providers or otherwise failed to take any appropriate action once Purdue had knowledge of behaviors indicative of over-prescribing. The Complaint describes in great detail the specific factual bases for these allegations- in fact, these allegations comprise the bulk of the 273-page complaint. The State describes and names specific red-flag providers and explains when, how, and why Purdue continued to market to these providers, as well as Purdue's alleged failure to take the steps required in paragraph 13 of the Agreed Final Judgment. The Complaint adequately states a claim for relief for violation of the 2007 Agreed Final Judgment.

IV. TENNESSEE CONSUMER PROTECTION ACT

Purdue seeks dismissal of the Tennessee Consumer Protection Act ("TCPA") claim, contending that the State has failed to adequately plead causation. The Tennessee Supreme Court explained the purpose and construction of the TCPA in *Faye v. Vincent*, 301 S.W.3d 162, 177-78 (Tenn. 2009):

> The Tennessee Consumer Protection Act, enacted in 1977, was passed, in part, to protect consumers from unfair and deceptive acts and practices occurring "in the conduct of any trade or commerce" in the state and to provide a means "for maintaining ethical standards of dealing between persons engaged in business and the consuming public." Tenn. Code Ann. §47-18-102(2),-102(4). The Act is to be liberally construed in order to enable it to protect the consumer and to promote the other policies which motivated its passage. Tenn. Code Ann. § 47-18-102; *Myint v. Allstate Ins. Co.*, 970 S.W.2d at 926; *Morris v. Mack's Used Cars*, 824 S.W.2d 538, 540 (Tenn. 1992); *see also* Tenn. Code Ann. § 47-18-115 (noting that the Act is "remedial legislation" which would be construed to effectuate its purposes). It is also to be construed consistently with the Federal Trade Commission and federal courts' interpretations of the Federal Trade Commission Act. Tenn. Code Ann. § 47-18-115. The Tennessee Consumer Protection Act forbids "unfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. § 47-18-104(b).... The Act defines "trade," "commerce," or "consumer transaction" as "the advertising, offering for sale, lease or rental, or distribution of any goods, services, or property, tangible or intangible, real, personal, or mixed,

> and other articles, commodities, or things of value wherever situated." Tenn. Code Ann. § 47-18-103(11).

A "deceptive act or practice" under the TCPA is "one that causes or tends to cause a consumer to believe what is false or that misleads or tends to mislead a consumer as to a matter of fact." *Tucker v. Sierra Builders*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005).

Purdue first contends that that the State failed to plead an ascertainable loss of money or property. In response, the State contends that at least part of its claim is based on the TCPA's enforcement provision, not its private right of action. The State is correct that the TCPA's enforcement provision, Tenn. Code Ann. § 47-18-108, does not require that a person suffer an ascertainable loss. The enforcement provision provides as follows: "Whenever the division has reason to believe that any person has engaged in, is engaging in, or, based upon information received from another law enforcement agency, is about to engage in any act or practice declared unlawful by this part and that proceedings would be in the public interest, the attorney general and reporter, at the request of the division, may bring an action in the name of the state against such person to restrain by temporary restraining order, temporary injunction, or permanent injunction the use of such act or practice." Tenn. Code Ann. § 47-18-108(a)(1). Thus, to the extent the State's Complaint seeks injunctive relief, civil penalties, and other remedies contemplated by the enforcement provision of the TCPA, the State correctly asserts that pleading an ascertainable loss of money or property is not required.

In addition to the enforcement provision, however, the State acknowledges that it also seeks recovery of ascertainable losses as a remedy under Tenn. Code Ann. § 47-18-108(b)(1). An "ascertainable loss" is broadly defined in the TCPA as "[a]n identifiable deprivation, detriment, or injury arising from ... any unfair, misleading, or deceptive act or practice even when the precise amount of the loss is not known. Whenever a violation of this part has occurred, an ascertainable

loss shall be presumed to exist." Tenn. Code Ann. § 47-18-2102(1). Purdue's objection to the Complaint is that the State has failed to adequately causally link the alleged deceptive behavior to any such ascertainable loss. The Court disagrees. As set forth in the State's response to Purdue's motion, "the Complaint alleges Purdue made widely-disseminated, deceptive, and express health and safety claims, material omissions of health and safety information, and material omissions of Purdue's financial connections to third-party groups it substantially funded," and that, as a result, persons purchased Purdue's opioid products. The State then alleges that Purdue's conduct "led to addiction, abuse, diversion, and other negative outcomes that have caused the State and its political subdivisions to spend substantial resources to attempt to address." (Complaint, ¶ 874). The State further alleges that it and its political subdivisions "have spent significant public resources on treatment, toxicology reports and autopsies, law enforcement, corrections, intervention programs, drug courts, prosecution, probation, and child welfare related to opioids, OxyContin, and heroin and more funds are needed to address this public health crisis." (Complaint, ¶ 909). At this juncture, the Court does not inquire into whether the State can actually prove its assertions. It must assume the State's assertions are true and determine whether the assertions state a claim for relief. The Court finds that the State has properly pleaded a claim for violation of the Tennessee Consumer Protection Act.

V. PUBLIC NUISANCE

Finally, Purdue seeks dismissal of the State's public nuisance claim and contends that the States seeks to hold Purdue liable for a sweeping array of societal harms that have occurred as a result of the opioid crisis. Purdue contends that the Complaint fails to adequately plead causation, that the derivative injury rule applies, and that the State does not allege an interference with any right common to the public.

A public nuisance is an act or omission that unreasonably interferes with or obstructs rights common to the public. *See Metropolitan Gov't of Nashville v. Counts*, 541 S.W.2d 133, 138 (Tenn. 1976); Restatement (Second) of Torts §821B (1977). In *Sherrod v. Dutton*, 635 S.W.2d 117, 119 (Tenn. Ct. App. 1982), the Tennessee Court of Appeals explained that a nuisance "extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable and comfortable use of property." (Citations omitted); *see also State ex rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975) (defining a public nuisance as "a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law.") (Citations omitted).

With respect to causation, the Court finds that the complaint is adequately pleaded. As has been set forth previously, the Complaint describes with great specificity the actions of Purdue with respect to its marketing of opioid products, including alleged misrepresentations regarding the safety, efficacy, and benefits of its products and an alleged practice of marketing its products to known "pill mills." The Court will not rehash the allegations, but the Complaint is replete with specific examples of behavior on the part of Purdue that, if proven, would establish interference with the health, comfort, and safety of the citizens of the State of Tennessee. Furthermore, the Complaint alleges resulting damages, including but not limited to "increased opioid use, abuse, addiction, and overdose deaths" and "[t]he greater demand for emergency services, law enforcement, addiction treatment, and other social services," which place "an unreasonable burden on governmental resources including the State and its political subdivisions." (Complaint, ¶ 960, 961).

Purdue further argues that intervening and superseding acts prohibit a finding of causation. Specifically, Purdue contends that any alleged nuisance was caused not by Purdue's sale of its medications but rather by doctors who wrote "improper prescriptions" and/or by third parties who allowed persons without prescriptions to obtain opioid medications illegally. However, the State's Complaint alleges that the foregoing acts were foreseeable and made possible by Purdue's acts. In addition, "[t]here is no requirement that a cause, to be regarded as the proximate cause of an injury, be the sole cause, the last act, or the one nearest to the injury, provided it is a substantial factor in producing the end result.... An intervening act will not exculpate the original wrongdoer unless it appears that the negligent intervening act could not have been reasonably anticipated." *McClenahan v. Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991).

Purdue contends that the Complaint should be dismissed because "where a plaintiff's injuries are wholly derivative of harm to a third party, the injuries are generally deemed indirect and consequently, too remote as a matter of law to support recovery." *Steamfitters Local Union No. 614 Health & Welfare Fund v. Philip Morris, Inc.*, 2000 WL 1390171 (Tenn. Ct. App. Sept. 26, 2000). However, the Complaint seeks damages for injuries to the State, not for the injuries of those who have become addicted to opioids. Purdue's reliance on the *Steamfitters* case is misplaced. In that case, the union's Health and Welfare Fund sued tobacco companies to recover money spent by the Fund to treat its members' smoking-related illnesses. The premise of the Fund's claim was that the tobacco companies' activities prevented the Fund from implementing programs to educate its participants on the addictive qualities of tobacco. Ultimately, the Court of appeals held that "it would be 'virtually impossible' for the Funds to prove with reasonable certainty the effect education or smoking cessation programs would have had on the physical injuries suffered by plan participants since the damages stem from individual smokers' decisions

whether to continue smoking and, if so, how frequently to smoke." *Id.* at *6. The Court noted that "'it would be the sheerest sort of speculation to determine how these damages might have been lessened had the Funds adopted the measures defendants allegedly induced them not to adopt.'" *Id.* (citing *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 238-39 (2d Cir. 1999)).

The allegations in the present case are wholly different in that they are not based upon the State being fraudulently induced to inaction, nor does the State seek damages for the physical injuries of the individual opioid users. Rather, the State seeks damages sustained by it and its political subdivisions as a direct result of Purdue's alleged marketing activities designed to increase prescriptions. The claims are simply different.

Lastly, Purdue contends that the Complaint must be dismissed because the State does not allege interference with any right common to the public, "such as clean air or water." Purdue's argument takes too narrow a view of public nuisance. As set forth above, a public nuisance can encompass virtually anything that endangers life or health. In fact, the Tennessee Supreme Court has deemed a church's handling of snakes to be a public nuisance:

> Under this record, showing as it does, the handling of snakes in a crowded church sanctuary, with virtually no safeguards, with children roaming about unattended, with the handlers so enraptured and entranced that they are in a virtual state of hysteria and acting under the compulsion of "anointment", we would be derelict in our duty if we did not hold that respondents and their confederates have combined and conspired to commit a public nuisance and plan to continue to do so. The human misery and loss of life at their 'Homecoming' of April 7, 1970 is proof positive.
>
> Our research confirms the general pattern. Tennessee has the right to guard against the unnecessary creation of widows and orphans. Our state and nation have an interest in having a strong, healthy, robust, taxpaying citizenry capable of self-support and of bearing arms and adding to the resources and reserves of manpower. We, therefore, have a substantial and compelling state interest in the face of a clear and present danger so grave as to endanger paramount public interests.

Pack, 99 S.W.2d at 113-14.

In the present case, the State's Complaint alleges that Purdue engaged in misleading and deceptive marketing practices for the purpose of increasing opioid prescriptions and that, as a result, Purdue created an opioid epidemic that has endangered the health and safety of the citizens of Tennessee and has resulted in financial loss to the State. The Complaint adequately states a claim for public nuisance.

V. CONCLUSION

Having carefully considered the arguments set forth in Purdue's motion to dismiss, the Court finds that the State's Complaint sets forth a cause of action for violation of the Tennessee Consumer Protection Act, violation of the 2007 Agreed Final Judgment, and public nuisance. Accordingly, Purdue's motion to dismiss is respectfully **DENIED.**

Entered this 22 day of February, 2019.

JUDGE KRISTI M. DAVIS

CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify pursuant to Rule 58, Tenn. R. Civ. P., that a copy of this ORDER has been served on all parties or their counsel of record by mail.

This 22 day of Feb., 2019.

Charles D. Susano, III
Knox County Circuit Court Clerk

By: K. Keen
Deputy Clerk

EXHIBIT 4

2019 WL 446382
Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of Delaware.

STATE of Delaware, EX REL. Kathleen JENNINGS, Attorney General of the State of Delaware, Plaintiff,
v.
PURDUE PHARMA L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; McKesson Corporation; Cardinal Health Inc.; AmerisourceBergen Corporation; Anda Pharmaceuticals, Inc.; H.D. Smith, LLC; CVS Health Corporation; and Walgreens Boots Alliance, Inc., Defendants.

C.A. No. N18C-01-223 MMJ CCLD
|
Submitted: November 15, 2018
|
Decided: February 4, 2019

Upon Defendants' Motions to Dismiss and Motion to Strike

Attorneys and Law Firms

Ryan P. Newell, Esq., Shaun Michael Kelly, Esq., Kyle Evans Gay, Esq., Connolly Gallagher, LLP, Wilmington, Delaware; Richard W. Fields, Esq., Fields PLLC, Washington, District of Columbia; Scott W. Gilbert, Esq., Richard Shore, Esq. (Argued), Mark A. Packman, Esq., Jenna A. Hudson, Esq. (Argued), Michael B. Rush, Esq. (Argued), Monique T. Abrishami, Esq., Richard J. Leveridge, Esq., Gilbert LLP, Washington, District of Columbia; Kathleen Jennings, Attorney General, Michael Vild, Esq., Michelle Whalen, Esq., Delaware Department of Justice, Attorneys for the State of Delaware.

Brian D. Tome, Esq., Kelly E. Rowe, Esq., Reilly, McDevitt, & Henrich, PC, Wilmington, Delaware; Mark S. Cheffo, Esq., Hayden A. Coleman, Esq. (Argued), Debra D. O'Gorman, Esq., Dechert LLP, New York, New York; Judy L. Leone, Esq., Dechert LLP, Philadelphia, Pennsylvania, Attorneys for Defendant Purdue Pharma L.P. & The Purdue Frederick Company ("Purdue Pharma").

Michael P. Kelly, Esq., Steven P. Wood, Esq., Daniel J. Brown, Esq., Hayley J. Reese, Esq., McCarter & English, Wilmington Delaware; John A. Freedman, Esq. (Argued), Arnold & Porter Kay Scholer LLP, Washington, District of Columbia; Sean O. Morris, Esq., Arnold & Porter Kay Scholer LLP, Los Angeles, California, Attorneys for Defendant Endo Pharmaceuticals, Inc. & Endo Health Solutions, Inc. ("Endo").

Kevin B. Collins, Esq., Katherine B. Shaffer, Esq., Covington & Burling, Washington, District of Columbia; Neil K. Roman, Esq., Covington & Burling, New York, New York; A. Thompson Bayliss, Esq., Michael A. Barlow, Esq. (Argued), Sarah E. Delia, Esq., David A. Seal, Esq., Daniel J. McBride, Esq., Abrams & Bayliss, Wilmington, Delaware, Attorneys for Defendant McKesson Corporation.

David A. Felice, Esq., Bailey & Glasser LLP, Wilmington, Delaware; Steven Pyser, Esq., Ashley W. Hardin, Esq. (Argued), Joshua D. Tully, Williams & Connolly, Washington, District of Columbia, Attorneys for Defendant Cardinal Health, Inc.

Jennifer C. Wasson, Esq. (Argued), Jesse L. Noa, Esq., Carla M. Jones, Esq., Potter, Anderson, & Corroon LLP, Wilmington, Delaware; Louis W. Schack, Esq., Shannon E. McClure, Esq., Neil A. Hlawatsch, Esq., Reed Smith LLP, Philadelphia, Pennsylvania, Attorneys for Defendant AmerisourceBergen Corporation.

Jami B. Nimeroff, Esq., Brown, Garry, Nimeroff, Wilmington, Delaware; James W. Matthews, Esq. (Argued), Katy E. Koski, Esq., Jaclyn V. Piltch, Esq., Redi Kasollja, Esq., Foley & Lardner, Boston, Massachusetts, Attorneys for Defendant Anda Pharmaceuticals, Inc.

Thomas E. Hanson, Esq., Barnes & Thornburg LLP, Wilmington, Delaware; Oni N. Harton, Esq., Barnes & Thornburg LLP, Indianapolis, Indiana, Attorneys for Defendant H.D. Smith LLC.

Daniel B. Rath, Esq., Rebecca L. Butcher, Esq., Jennifer L. Cree, Esq., Landis, Rath, & Cobb LLP, Wilmington, Delaware; Eric R. Delinsky, Esq., Alexandra W. Miller, Esq., R. Miles Clark, Esq. (Argued), Zuckerman Spaeder

LLP, Washington, District of Columbia, Attorneys for Defendant CVS Health Corporation.

Beth Moskow-Schnoll, Esq., William Burton, Esq., Elizabeth A. Sloan, Esq., Ballard Spahr LLP, Wilmington, Delaware; Kaspar J. Stoffelmayr, Esq., Katherine M. Swift, Esq., Bartlit, Beck, Herman, Palenchar, & Scott LLP, Chicago, Illinois; Alex J. Harris, Esq., Bartlit, Beck, Herman, Palenchar, & Scott LLP, Denver, Colorado, Attorneys for Defendant Walgreens Boots Alliance, Inc.

JOHNSTON, J.

PROCEDURAL CONTEXT

***1** The State of Delaware ("State"), ex rel. Kathleen Jennings, [1] Attorney General of the State of Delaware, brought this suit seeking compensatory, punitive, and other damages, as well as restitution, disgorgement, and civil penalties. Defendants are: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively, "Manufacturers"); McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda Pharmaceuticals, Inc., and H.D. Smith, LLC (collectively, "Distributors"); and CVS Health Corporation and Walgreens Boots Alliance, Inc. (collectively, "Pharmacies").

As to the Manufacturers, the State argues that Manufacturers have duties to disclose accurately the risks associated with opioid medications, specifically, the high risk of addiction and subsequent misuse. The State contends that Manufacturers misrepresented those risks through multi-million-dollar advertising campaigns, and inaccurately claimed that those who were showing signs of addiction were not actually addicted. The State argues that these misstatements were targeted for maximum effect and to a specific audience. The State contends that Manufacturers knew or should have known that their statements were false and misleading. Because they knew the statements were misleading, Manufacturers violated their duties to disclose accurately the risks of using purportedly highly dangerous opioid medications.

As to Distributors, the State argues that Distributors have duties to actively prevent opioid diversion. [2] The State asserts that both Delaware and federal law have established the duties of care that Distributors must follow. The State argues that, as evidenced by prior regulatory actions against Distributors for failing to prevent diversion, Distributors have violated their duties.

Similarly, as to Pharmacies, the State argues that Pharmacies have duties to prevent opioid diversion and to report any suspicious orders. The State alleges that Pharmacies repeatedly have failed to report suspicious orders made obvious to them by certain "red flags," such as unusually large orders, repetitive orders, and improperly filled orders. The State argues that Pharmacies have violated their duties owed to the State, as evidenced by prior regulatory actions against Pharmacies.

The State argues that Defendants' collective misconduct has harmed and continues to harm the State of Delaware and its citizens. [3] The State alleges the following:

> Count I: Consumer Fraud (Against Manufacturer Defendants)
>
> Count II: Nuisance (Against Manufacturer Defendants)
>
> Count III: Negligence (Against Manufacturer Defendants)
>
> Count IV: Unjust Enrichment (Against Manufacturer Defendants)
>
> ***2** Count V: Consumer Fraud (Against Distributor Defendants and Pharmacy Defendants)
>
> Count VI: Nuisance (Against Distributor Defendants and Pharmacy Defendants)
>
> Count VII: Negligence (Against Distributor Defendants and Pharmacy Defendants)
>
> Count VIII: Unjust Enrichment (Against Distributor Defendants and Pharmacy Defendants)
>
> Count IX: Civil Conspiracy (Against Manufacturer Defendants, Distributor Defendants, Pharmacy Defendants).

Defendants have filed Motions to Dismiss. Manufacturers joined together to file one Motion to Dismiss. Four of the five Distributors filed Motions to Dismiss:

McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation have jointly filed one motion. Anda Pharmaceuticals, Inc. has separately filed its own motion. The remaining distributor, H.D. Smith, LLC, has not joined in or filed its own motion to dismiss, but did answer the complaint. The Pharmacies jointly filed one motion to dismiss. Oral Argument was heard over two days: October 24, 2018 and November 15, 2018.

MOTION TO DISMISS STANDARD

In a Rule 12(b)(6) Motion to Dismiss, the Court must determine whether the claimant "may recover under any reasonably conceivable set of circumstances susceptible of proof." [4] The Court must accept as true all well-pleaded allegations. [5] Every reasonable factual inference will be drawn in the non-moving party's favor. [6] If the claimant may recover under that standard of review, the Court must deny the Motion to Dismiss. [7]

ANALYSIS

NEGLIGENCE AND CONSUMER FRAUD

The State contends that all Defendants violated statutory and common law duties, which caused injury to the State. The State's claims vary slightly as to each class of Defendant.

Manufacturers

State's Allegations

The State argues that each Manufacturer Defendant has a legal obligation under Delaware statutory and common law to exercise reasonable care in the marketing, promotion, and sale of opioids. The State argues that Manufacturers' duties are established by 16 *Del. C.* § 3302, which states: "No person shall manufacturer, sell or trade in, within this State, any article of food or drugs which is ... misbranded ... within the meaning of this chapter." [8]

***3** The State argues that Manufacturers have breached their duties by misstating facts and by failing to disclose accurately the risks associated with the use of opioids. The State claims that Manufacturers have done this via a multi-million-dollar advertising campaign that is run through websites, promotional materials, live conferences, publications for doctors, and other vehicles. The State asserts that Manufacturers trained pharmaceutical salesmen to tell doctors that the risk of opioid addiction is less than 1%, which is contrary to Center for Disease Control ("CDC") findings that suggest that there are significant risks of serious opioid addiction and abuse. The CDC reports that about 26% of long term users experience problems with addiction or dependence. [9] The State claims although there are warning labels approved by the Food and Drug Administration ("FDA") on the bottles of medication, the content in the advertising campaign is inconsistent with those warning labels in that the advertising scheme significantly minimizes the risks.

Further, the State argues that Manufacturers stated that patients who showed signs of addiction were not actually addicted to opioids. The State claims that Manufacturers published a physician education pamphlet which suggested that patients who showed signs of addiction were actually in need of more medication, a phenomenon Manufacturers refer to as "pseudoaddiction." The State argues that "pseudoaddiction," a term coined by a Manufacturer, is a concept rejected by the CDC because it lacks scientific evidence. The State claims that Manufacturers advocate for increasing dosages regardless of a patient's actual prescribed dosage. The State contends that, through their web content, Manufacturers actually encourage patients, who believe they have not been prescribed an adequate dose, to seek a different doctor who will prescribe them the dose they feel they require. The State asserts that Manufacturers claim there is no risk of addiction when the dosage is increased.

The State argues that Manufacturers' conduct amounts to a breach of duty owed to the State.

Manufacturers' Response

Manufacturers argue first that the State's claims are preempted because the FDA has approved opioid medications for the treatment of pain. Manufacturers maintain that they have complied with the FDA's warning label requirements. Manufacturers argue that the State

cannot impose a duty to alter FDA-approved medicine. Further, Manufacturers assert that courts repeatedly have held that state law claims are preempted where they would require a manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required.

Manufacturers also argue that the State has failed to allege causation. Manufacturers argue that the State has failed to identify any physician who heard the alleged misrepresentations and subsequently prescribed opioid medications in reliance on Manufacturers' statements. Manufacturers cite *Teamsters Local 237 Welfare Fund, et al., v. AstraZeneca Pharmaceuticals LP and Zeneca, Inc.*[10] in support of their argument that simply pleading deceptive advertising to the public generally is insufficient.[11] Manufacturers assert that ultimately there is no connection between the alleged misstatements and the harm to the State. Any misstatement is simply too attenuated to establish causation. Manufacturers argue that there is no fraud on the market. Further, as third-party payors, Manufacturers cannot be forced to cover costs incurred by the State because the State is not an insurer.

Manufacturers offer for support *State of Sao Paulo of Federative Republic of Brazil v. American Tobacco Co.*,[12] a case in which a municipality sought to recover medical expenses supposedly incurred as a result of its citizens' increased use of tobacco products.[13] Manufacturers ask the Court to adopt the reasoning in *Sao Paulo*, specifically that it would be "both unfair and unsound policy"[14] to allow a government to sue in its capacity as health care insurer or provider, and to pursue claims on which its injured citizens, had they sued directly, might not be entitled to recover. Manufacturers assert that this type of claim is something that the legislature should address and that the government should not be able to circumvent the burden of proving individual claims.

***4** This Court finds *Sao Paulo* distinguishable. The plaintiffs in *Sao Paulo* were foreign governments, not United States municipalities. As such, the plaintiffs lacked standing to sue as *parens patriae*.[15] The Court finds this distinction crucial in determining whether or not the State has standing in this case to sue in its capacity as *parens patriae*.

In support of the lack of causation argument, Manufacturers cite *Ashley County, Arkansas v. Pfizer Incorporated.*[16] In *Ashley*, Arkansas counties brought an action against manufacturers and distributors of over-the-counter cold and allergy medications containing ephedrine or pseudoephedrine.[17] The counties sought damages under the Arkansas Deceptive Trade Practices Act and the Arkansas crime victims civil liability statute, and under theories of public nuisance and unjust enrichment.[18] The court found that the defendants did not proximately cause plaintiffs' damages and dismissed the claim because "the Counties cite[d] no case, federal or state, that recognizes a cause of action available to a government entity to recover against pharmaceutical manufacturers for the legal sale of products containing pseudoephedrine based on the subsequent use of the product in the manufacture of methamphetamine."[19]

Manufacturers also argue that the State has failed to allege injury. Manufacturers contend that the State has failed to identify any prescription received by a patient that ultimately caused injury to the State. Further, Manufacturers argue that the State is only able to make broad allegations as to all Manufacturers, and cannot single out any wrongdoing by any individual Manufacturer. Manufacturers also argue that the State's claims are barred by the derivative-injury rule, municipal cost recovery rule, and economic loss doctrine.

The State Has Stated Prima Facie *Claims Against Manufacturers*

The Court finds that the State has met the notice pleading requirements as to its claims against Manufacturers. Under Delaware's notice pleading requirements, a plaintiff need only "state a short and plain statement of the claims showing that the pleader is entitled to relief."[20] The State has met this burden by putting the Manufacturers on notice of its claims of misrepresentations ("low risk" of addiction and understated risk) made in literature and during training. The State plead its claims with sufficient particularity to allow the case to move forward. The State's allegations of labeling inconsistent with FDA approvals ("pseudoaddiction," softening and minimization) are sufficient to survive dismissal on the grounds of

federal preemption. Therefore, Manufacturers' Motion to Dismiss must be denied.

Distributors

State's Allegations

The State argues that Distributors have common law, statutory, and regulatory duties to act reasonably as distributors of opioids. Specifically, the State claims that Distributors have a duty to prevent opioid diversion. The State cites several statutes and regulations which, it claims, establish relevant duties.[21] The State claims that the Delaware Controlled Substances Act ("CSA") "requires distributors of controlled substances to take precautions to ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels."[22] The State claims that Delaware law has certain registration requirements for Distributors, and that in order to distribute in Delaware, the Distributors must "establish, maintain, and adhere to written policies and procedures for: identifying, records, and reporting losses or thefts" and have written policies for "reporting criminal or suspected criminal activities involving the inventory of a drug or drugs."[23] The State makes clear that it is not asserting a cause of action under these laws, but rather, is using the laws to argue that there are established, industry-wide duties.

***5** The State alleges that Distributors have the knowledge and expertise to identify issues relating to diversion and know how to minimize the risk of diversion. The State claims that Distributors have acknowledged these duties by making "statements assuring the public they recognize their duty to curb the opioid epidemic."[24] The State claims that despite acknowledging and understanding their duties to prevent diversion, Distributors have violated those duties. The State asserts that Distributors have failed to identify suspicious orders,[25] which could have led to the discovery and prevention of diversion.

The Drug Enforcement Agency ("DEA") supposedly has provided guidance on how to deal with suspicious orders. Since 2006, the DEA has briefed pharmaceutical distributors regarding "legal, regulatory, and due diligence responsibilities."[26] The DEA has pointed out the "red flags distributors should look for to identify potential diversion."[27] The DEA provided further information at conferences and in subsequent publications. The State claims that because Distributors have been educated on drug diversion, they have been put on notice of the problem of opioid diversion and the solution. Despite being put on notice, Distributors allegedly failed to prevent or address this issue.

The State argues that Distributors have negligently or recklessly allowed diversion. The State, as a basis for this allegation, points out that Distributors' conduct has resulted "numerous civil fines and other penalties recovered by government agencies - including actions by the DEA related to violations of the [Federal Controlled Substances Act]."[28] The State claims that Distributors have engaged in a consistent nationwide pattern and practice of illegally distributing opioids by allowing diversion to occur.

In sum, the State claims that the Distributors had duties to prevent opioid diversion, acknowledged and understood those duties, and violated those duties, resulting in injury to the State.

Distributors' Response

Distributors argue that the State has failed to plead a cognizable injury under Delaware law. Distributors assert that the State cannot recover damages belonging to individuals who allegedly have been personally injured by opioid addiction. Distributors argue that the State cannot recover on the basis of these indirect injuries.[29] Distributors further argue that the State may not recover the costs of normal public services. In support of this position, Distributors cite *Baker v. Smith & Wesson Corporation*,[30] in which the Court stated: "[P]ublic expenditures made in the performance of governmental functions are not recoverable from a tortfeasor in the absence of a specific statute."[31]

Distributors argue that the State has failed to allege a negligence claim. Specifically, Distributors argue that they do not owe a duty to the State to report or halt shipment of "suspicious" orders. Distributors maintain that there is

no common law or statutory duty to report these orders. Distributors also contend that there is no duty to the State because the State is not the customer. Distributors claim that their duties are solely to their customer, the pharmacies. Distributors assert that they act merely as middlemen between manufacturers and pharmacies, and that their responsibility is to take and fill orders. Distributors claim that the State has failed to allege that Distributors made any specific misrepresentations to pharmacies.

The State Has Stated Claims Against Distributors

***6** The Court finds that Distributors' duties are not limited to pharmacies. Pursuant to 6 *Del. C.* § 2513:

> (a) The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent *that others rely upon* such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice... (*emphasis added*).

Because the language of the statute contemplates general reliance, the Court finds that the State need not limit its claims to misrepresentations made directly to pharmacies.

Drug diversion is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use. The State claims that a purpose of the Delaware Consumer Fraud Act is to prevent diversion, and under this statute, Distributors have a duty to prevent diversion. Distributors maintain that the State's claims are barred by the safe harbor provided in 6 *Del C.* § 2513 which states:

> (b) This section shall not apply:
>
> (2) To any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission...

The Court finds that whether or not Distributors complied with "rules and regulations" cannot be determined without further discovery. The Court cannot find, as a matter of law, that Distributors fall within in this safe harbor provision at this stage in the litigation.

Distributors rely on *Baker*[32] to support the proposition that a municipality may not recover for its citizens' injuries. In *Baker*, the Mayor of Wilmington, on behalf of the City, sued several handgun manufacturers.[33] The lawsuit was part of a nationwide effort to force the handgun industry to make its products safer and to reduce gun violence. The plaintiffs in *Baker* were not the direct victims of injuries caused by firearms. The Court in *Baker* considered whether the City of Wilmington could recover the costs of municipal services, including police work and emergency response, in the absence of claims brought by direct victims. The issue was "whether the common law prohibition on municipalities recovering costs from tortfeasors...is the law in Delaware."[34] The Court granted the defendant's motion to dismiss, stating that "the court will not twist a jury trial involving municipal costs into a wildly expensive referendum on handgun control. The Mayor and the City must find another means to their ends."[35]

The Court finds that the municipal cost recovery rule does not apply in this case. In five separate courts, and in the multi-district federal litigation based in Ohio, judges have rejected the notion that the municipal cost recovery rule bars recovery for public costs. These courts reasoned that when the alleged conduct is ongoing and persistent (as opposed to a one-time event), the rule may be suspended. The Court finds that the conduct in this case is continuous. Thus, the municipal cost recovery rule does not apply.

***7** Under 16 *Del. C.* § 4733, manufacturers, distributors, and pharmacies must register and be licensed in order to dispense opioid medications. The applicant must have an underlying professional license in the State. The Secretary of State may deny registration to an

applicant if the Secretary "determines that the issuance of that registration would be inconsistent with the public interest." [36] The statute lists eight factors that the Secretary shall consider when determining whether an issuance of a registration would be inconsistent with the public interest:

> (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;
>
> (2) Compliance with applicable federal, state and local law, including but not limited to such requirements as having a license to practice as a practitioner or having documented training and continuing education as a drug detection animal trainer;
>
> (3) Any convictions of the applicant under any federal and state laws relating to any controlled substance;
>
> (4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
>
> (5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
>
> (6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, prescribe, dispense or research controlled substances as authorized by federal law;
>
> (7) Any professional license disciplined in any jurisdiction; and
>
> (8) Any other factors relevant to the public interest. [37]

The State argues that this statute imposes on Distributors (and Pharmacies) a duty to report, and that a breach of that duty could result in a revocation of license and registration. The State has not alleged any claims under this statute, but argues that Section 4733 creates a well-established duty to report in the opioid industry.

The Court finds that Section 4733 does not create a cause of action. However, the statute may be evidence of a standard of care.

Delaware recognizes the traditional "but for" definition of proximate causation. [38] "Most simply stated, proximate cause is [defined in Delaware as] that direct cause without which the accident would not have occurred." [39] To show proximate cause, there must be known and intentional consequences.

The State alleges that Distributors had actual or constructive knowledge that they were breaching common law duties and violating the Delaware Controlled Substances Act and Federal Controlled Substances Act. Distributors counter that any diversion and subsequent harm are intervening, superseding causes that extinguish their liability. A superseding cause is a new and independent act that breaks the causal connection between the original tortious conduct and the injury. [40] However, if the intervening negligence of a third party was reasonably foreseeable, the original tortfeasor is liable for negligence because the causal connection between the original tortious act and the resulting injury remains unbroken. [41]

In *Ashley County, Arkansas v. Pfizer Incorporated*, [42] the court determined that "criminal actions of the methamphetamine cooks and those further down the illegal line of manufacturing and distributing methamphetamine are 'sufficient to stand as the cause of the injury'...and they are 'totally independent' of the Defendants' actions of selling cold medicine to retail stores." [43] Distributors ask this Court to apply the reasoning in *Ashley County*.

***8** The Court finds *Ashley County* distinguishable. The State's allegations regarding proximate cause establish a *prima facie* case of reasonable foreseeability. The intervening causes that aid diversion and subsequent illegal activities are not "totally independent" from Distributors' conduct. The *Ashley County* court's finding that defendants' conduct was too attenuated to establish liability does not apply in this case.

The Court finds that the State has met its pleading requirements. Distributors' duties are not limited to pharmacy customers. The Court cannot determine, without discovery, whether Distributors are protected by the safe harbor provision in 6 *Del. C.* § 2513. The State has set forth a *prima facie* case of reasonable foreseeability and proximate cause. Therefore, Distributors' Motion to Dismiss the negligence and consumer fraud claims must be denied.

The State Has Stated Claims Against Anda

Distributor Defendant Anda Pharmaceuticals, Inc. ("Anda") has moved separately from other Distributors. Anda argues that the Complaint improperly lumps all of the Distributors together in group allegations, and that these allegations are conclusory. Anda echoes the arguments presented by other Distributors, but adds that the Complaint is not specific enough to put Anda on notice.

Superior Court Rule 9(b) requires that certain types of claims be plead with a heightened particularity. "The purpose of this Rule is to '(1) provide defendants with enough notice to prepare a defense; (2) prevent plaintiffs from using complaints as fishing expeditions to unearth wrongs to which they had no prior knowledge; and (3) preserve a defendant's reputation and goodwill against baseless claims.' " [44]

In order to plead negligence with the requisite particularity, "a defendant must be apprised of: (1) what duty, if any, was breached; (2) who breached it, (3) what act or failure to act breached the duty, and (4) the party upon whom the act was performed." [45] In its Complaint, the State repeatedly refers to specific statutory and common law duties, identifies defendant groups, points out the actions or inactions Defendants allegedly committed or omitted, and claims that Defendants' conduct caused injury to the State of Delaware.

At the pleading stage, a defendant in a group of similar defendants may attempt to distinguish its behavior from other defendants. [46] When given the opportunity at oral argument to distinguish itself from other Distributors, Anda only highlighted two differences: (1) that there were no enforcement actions against Anda initiated by the DEA; and (2) that there were no allegations of specific misrepresentations, unlike those in the Complaint against Cardinal and McKesson. Anda emphasized that the State only referenced Anda specifically a few times in its Complaint.

The Court finds that there is no meaningful or substantive distinction between Anda and other Distributor defendants at this stage of the proceedings. The Court's rulings apply to Anda in the same manner as to Distributors. Anda has failed to distinguish itself from other Distributor defendants. Therefore, Anda's Motion to Dismiss must be denied.

Pharmacies

State's Allegations

***9** The State argues that Pharmacies also have a duty to prevent diversion, and that Pharmacies have breached that duty by failing to address certain "red flags" when filling prescriptions. The State claims that at "the pharmacy level, diversion occurs whenever a pharmacist fills a prescription despite having reason to believe it was not being filled for a legitimate medical purpose." [47] The State claims:

> A prescription may lack a legitimate medical purpose when a patient is either a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different doctors, travels great distances between a doctor and a pharmacy to fill a prescription, presents multiple prescriptions for the largest dose of more than one controlled substance such as opioids and benzodiazepines, or when there are other red flags surrounding the transaction. [48]

The State alleges that "[o]n information and belief, Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably-prudent pharmacy." [49] The State argues that Pharmacies have a duty under the Delaware CSA to take precautions to "ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels." [50]

The State also argues that Delaware's Prescription Monitoring Program ("PMP") imposes certain duties on Pharmacies. Delaware's PMP is a reporting system that aims to monitor the sale and distribution of controlled substances in the State of Delaware. [51] The State claims that the PMP imposes a duty on Pharmacies to submit information related to dispensing prescription opioids. The State argues that "under Delaware law ' [w]hen a [pharmacy] has a reasonable belief that a patient may be seeking a controlled substance [including opioids] for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the [PMP] before dispensing the prescription.' " [52] The State argues that Delaware law requires that "[i]f a pharmacist believes he or she has discovered a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted." [53]

The State argues that despite industry-specific knowledge of the risks of opioid abuse, [54] Pharmacies breached their duties by failing to identify "red flags" and report those issues to the proper authorities. [55] The State contends that this breach caused injury to the State of Delaware and its citizens.

Prescription Monitoring Program

Delaware has promulgated comprehensive regulation of dispensing controlled substances. [56] Section 4735(b) of Title 16 sets forth an express purpose to prevent diversion in Delaware's PMP:

> (b) The Secretary, after due notice and hearing may limit, suspend, fine or revoke the registration of any registrant who:
>
> ***10** (1) Has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.... [57]

Regulation of prescription drug distribution also is contained in Delaware's Uniform Controlled Substances Act (16 *Del. C.* §§ 4701, *et seq.*), Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0 *et seq.*), code sections regarding branding of drugs (*e.g.*, 16 *Del. C.* §§ 3302, *et seq.*), and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances. These provisions provide strict controls and requirements throughout the opioid distribution chain. Delaware law also incorporates and references Federal law regarding the marketing, distribution, and sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 321 *et seq.*

Delaware's Uniform Controlled Substances act is administered by the Secretary of State:

> The Secretary shall administer this chapter. Except as otherwise provided in this chapter, the Secretary may delete or reschedule substances enumerated in the schedules of controlled substances only if:
>
> (1) Such substances have been deleted from or rescheduled within the federal schedules of controlled substances by the Attorney General of the United States pursuant to 21 USC § 811, *et seq.*; and
>
> (2) The findings required by this chapter for placement of substances in the schedules of controlled substances have been made. [58]

Pharmacies' Response

Pharmacies argue that the PMP administration by Delaware's Secretary of State has exclusive jurisdiction over the regulation of prescription sales. Thus, no negligence claims may be brought by the State. However, Pharmacies concede: that the State has authority to prosecute criminal conduct; that the PMP does not prohibit medical negligence claims; and that common law negligence claims are possible. If negligence results in injury to a patient receiving a prescription, all "red flags" are coextensive with statutory and regulatory reporting obligations.

Pharmacies proffer *Doe v. Bradley* [59] in support of their argument that statutory duties to report misconduct do not give rise to common law negligence claims. In *Doe v. Bradley*, the Court considered "the scope of a physician's duty to report to appropriate authorities that another physician might be engaged in conduct that could

endanger the health, welfare or safety of that physician's patients or the public at large." [60] The Court found that the "[p]laintiffs' complaint did not allege facts that would allow the court to impose a common law duty upon the medical society defendants to prevent Dr. Bradley from causing harm to the [p]laintiffs." [61] Pharmacies argue that under *Doe v. Bradley*, the regulatory scheme and enforcement procedures under Delaware law prohibit a private cause of action.

The State Has Not Stated a Claim Against Pharmacies

***11** Delaware law requires that a medical negligence claim be accompanied by an Affidavit of Merit:

> (a) No health-care negligence lawsuit shall be filed in this State unless the complaint is accompanied by:
>
> (1) An affidavit of merit as to each defendant signed by an expert witness, as defined in § 6854 of this title, and accompanied by a current curriculum vitae of the witness, stating that there are reasonable grounds to believe that there has been health-care medical negligence committed by each defendant.... [62]

To the extent that the State's claims fall within the definition of medical negligence, the Complaint against Pharmacies must be dismissed without prejudice to provide the State an opportunity to obtain an Affidavit of Merit.

The Court finds that the remaining allegations against Pharmacies - breaches of duties to prevent diversion - are entirely speculative and conclusory. Additionally, Delaware's comprehensive pharmacy regulatory scheme and enforcement procedures, as well as federal regulations, preempt the claims alleged in the Complaint. Therefore, Pharmacies' Motion to Dismiss must be granted. The dismissal is without prejudice as to claims sounding in medical negligence, to allow the State an opportunity to submit an Affidavit of Merit.

NUISANCE

Under Delaware law, a public nuisance is "activity which produces some tangible injury to neighboring property or persons coming into contact with it and which a court considers to be objectionable under the circumstances." [63]

Distributors argue that the State's public nuisance claim is not cognizable under Delaware law. Distributors assert that Delaware Courts do not recognize products-based public nuisance claims, only property-based nuisance claims. Distributors rely on *Sills v. Smith & Wesson Corporation* [64] to support this position. [65] Distributors argue that the State has not identified or alleged a public right with which Distributors have interfered, claiming this as an essential element to a nuisance claim.

In *Sills v. Smith & Wesson Corporation*, [66] the Mayor of Wilmington sued twelve handgun manufacturers and three trade associations to recover money damages incurred by the City in connection with the design, marketing, and advertising of handguns. One of the nine counts alleged was a nuisance claim. The complaint alleged that "governmental entities may recover direct costs associated with protecting their citizens in the 'abatement of a public nuisance.' " [67] The Court stated that "Delaware has yet to recognize a cause of action for public nuisance based upon products. Delaware public nuisance claims have been limited to situations involving land use. While no express authority exists requiring public nuisance claims be restricted to those based on land use, Delaware courts remain hesitant to expand public nuisance." [68] The Court held that there was "no independent claim for public nuisance" and refused to recognize a public nuisance claim for products. [69]

***12** Other jurisdictions also have refused to allow products-based public nuisance claims. There is a clear national trend to limit public nuisance to land use. [70]

On December 28, 2018, the State submitted to the Court supplemental authority related to briefing on Defendants' Motions to Dismiss, attaching an opinion issued by MDL Judge Dan Aaron Polster of the United States District Court for the Northern District of Ohio. This Court concurs with Judge Polster as to the vast majority of his conclusions. However, the Court finds this supplemental authority distinguishable from the State's case regarding the public nuisance claim.

Judge Polster's Opinion discusses in great detail Ohio legislative history relating to product liability and nuisance claims. The Opinion determined that "in light of the legislative history, the Court finds it at least plausible, if not likely, that the 2005 and 2007 Amendments to the OPLA intended to clarify the definition of 'product liability claim' to mean 'a claim or cause of action [including any common law negligence or public nuisance theory of product liability...] that is asserted in a civil action...that seeks to recover compensatory damages...for [harm]....' " [71]

There is no comparable legislative history in Delaware.

The State only has alleged a public nuisance claim. The State has not alleged a product liability claim, nor has it asked the Court to determine whether Delaware product liability law contemplates a public nuisance claim. In Delaware, public nuisance claims have not been recognized for products. [72]

***13** The State has failed to allege a public right with which Defendants have interfered. A defendant is not liable for public nuisance unless it exercises control over the instrumentality that caused the nuisance at the time of the nuisance. [73] The State has failed to allege control by Defendants over the instrumentality of the nuisance at the time of the nuisance. Thus, all Defendants' Motions to Dismiss the nuisance claims must be granted.

CIVIL CONSPIRACY

To establish a valid claim for civil conspiracy, a plaintiff must prove: "(1) A confederation or combination of two or more persons; (2) An unlawful act done in furtherance of the conspiracy; and (3) Actual damage." [74] "In Delaware, 'civil conspiracy is not an independent cause of action...it must arise from some underlying wrong.' " [75]

The State argues that Manufacturers "have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids." [76] The State argues that "[w]ithout Manufacturer Defendants' misrepresentations, which created demand, Distributor Defendants would not have been able to sell to Pharmacy Defendants the increasing number of orders of prescription opioids for non-medical purposes throughout Delaware." [77] The State asserts that "[w]ithout Distributor Defendants' supply of prescription opioids, Pharmacy Defendants would not have been able to fill and dispense the increasing number of orders of prescription opioids for non-medical purposes throughout Delaware." [78] The State alleges that this chain of conduct lead to damages suffered by the State of Delaware and its citizens.

"There is no such thing as a conspiracy to commit negligence or, more precisely, to fail to exercise due care." [79] However, in *Nicolet, Inc. v. Nutt*, [80] the Delaware Supreme Court found allegations of intentional misrepresentation of fraudulent concealment sufficient to support the plaintiffs' claim that a manufacturer participated in an industry-wide conspiracy to conceal the health hazards of asbestos. [81]

In order to allege a *prima facie* case of fraudulent concealment, a plaintiff must show: "(1) deliberate concealment of a material fact or silence in the face of a duty to speak; (2) scienter; (3) intent to induce reliance upon the concealment; (4) causation; and (5) resulting damage." [82] In *Nicolet*, the Delaware Supreme Court found that the plaintiffs met these elements, reasoning:

> [P]laintiffs claim ... the conspiracy, which allegedly included [defendant], caused "to be positively asserted to plaintiffs in a manner not warranted by the information possessed by said defendants, ... that it was safe ... to work in close proximity to [the] [asbestos] materials" and ... suppressed "medical and scientific data and other knowledge, causing plaintiffs to be and remain ignorant thereof." The complaint clearly alleges scienter in that the participants "knowingly and willfully conspired" in the scheme ... [and] alleges an intent ... to induce ... reliance on false or incomplete material facts. In our opinion these allegations are sufficient to state a tort claim based on a theory of fraudulent concealment. [83]

***14** In this case, the Court finds that the State has not adequately alleged in its Complaint that Defendants engaged in a civil conspiracy similar to the allegations in *Nicolet*. The State has merely alleged parallel conduct by Defendants, making no claims that "the participants 'knowingly and willfully conspired' in the scheme" [84]

in order to induce reliance. The State has not alleged that the Defendants intended to conspire, but merely stated at oral argument that Defendants attended the same conferences. There are no allegations of a concerted action, an agreement to commit an underlying wrong, awareness of an agreement, or action in accordance with that agreement. The State argues that "Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants need not have expressly agreed to this course of action; concerted conduct itself is sufficient." This argument is not supported by Delaware law.

The Civil Conspiracy claims are hereby dismissed without prejudice. The claims may be added if evidence supporting a conspiracy surfaces during discovery.

UNJUST ENRICHMENT

Delaware law defines unjust enrichment as "the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience." [85] Unjust enrichment requires the following: (1) an enrichment; (2) an impoverishment; (3) a relation between the enrichment and the impoverishment; (4) the absence of justification; and (5) the absence of a remedy provided by law. [86]

Under Delaware law, unjust enrichment is not a stand-alone claim in Superior Court. The claim must be brought in the Court of Chancery. In this Court, unjust enrichment may be asserted as a possible measure of damages. Therefore, the unjust enrichment claim must be dismissed.

ENDO PHARMACEUTICALS INC.'S MOTION TO STRIKE

Endo argues that to the extent that the State relies on references to a 2016 Assurance of Discontinuance (AOD) between the New York Attorney General and Endo, those allegations should be stricken or, at a minimum, cannot form the basis of the State's claims. Endo also argues that the AOD was made without Endo admitting to any of the findings of the New York Attorney General's investigation. The parties allegedly agreed that the AOD was not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission by Endo of any liability or finding set forth hererin." [87] Endo argues that the State is trying to use the settlement against Endo. Endo claims that many courts have stricken as immaterial and impertinent allegations that refer to or are derived from settlements and other preliminary or non-adjudicated proceedings, including governmental investigations.

The State claims that it is only using two findings from the New York Attorney General's investigation, which Endo did not admit. Further, the settlement is not an admission by Endo, but the statements quoted by the State in its Complaint are the New York Attorney General's findings, and the State has a right to use them. The State contends that it is not using the findings to establish Endo's liability, but to help refute Endo's contention that the State has not stated a claim. The State argues that pleadings are not evidence of liability and are more properly a subject of a motion *in limine*. [88]

***15** When ruling on a motion to strike, the Court considers: (1) whether the challenged averments are relevant to an issue in the case; and (2) whether they are unduly prejudicial. [89] "Motions to strike are not favored and are granted sparingly, and then only if clearly warranted, with doubt being resolved in favor of the pleading, and objectionable matter will be stricken only if it is clearly shown to be unduly prejudicial." [90]

The Court finds that the matters objected to in Endo's motion are relevant and have not been shown to be unduly prejudicial. Therefore, Endo's Motion to Strike Paragraph 83 of the Complaint must be denied.

CONCLUSION

The Court finds that the State of Delaware has established a *prima facie* case for Negligence and Consumer Fraud against the Manufacturer Defendants, Anda Pharmaceuticals, and the Distributor Defendants. However, the State of Delaware has not demonstrated a *prima facie* case for Negligence and Consumer Fraud claims against the Pharmacy Defendants. **Therefore, Manufacturer Defendants', Distributor Defendants', and Anda Pharmaceuticals' Motions to Dismiss the Negligence and Consumer Fraud claims are hereby DENIED.**

Pharmacy Defendants' Motion to Dismiss the Negligence and Consumer Fraud claims is hereby GRANTED.

The Court finds that the State of Delaware's nuisance claims fail as a matter of law. **Therefore, all Motions to Dismiss the Nuisance claims are hereby GRANTED.**

The Court finds that the State of Delaware has failed to adequately plead its civil conspiracy claim because the State only asserts parallel conduct by Defendants and has failed to establish a *prima facie* case involving concerted action, agreement, awareness of the agreement, and action in accordance with that agreement. **Therefore, all Motions to Dismiss the Civil Conspiracy claims are hereby GRANTED, without prejudice. Claims for Civil Conspiracy may be added if such evidence surfaces during discovery.**

The Court finds that the State of Delaware's unjust enrichment claim is not a stand-alone claim at law. This claim must be brought in the Court of Chancery. Unjust enrichment may be asserted as a possible measure of damages. **Therefore, all Motions to Dismiss the Unjust Enrichment claims are hereby GRANTED.**

The Court finds that the matter objected to in Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint has not been shown to be unduly prejudicial. **Therefore, Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint is hereby DENIED.**

IT IS SO ORDERED.

All Citations

Not Reported in Atl. Rptr., 2019 WL 446382

Footnotes

1 At the time the pending motions were heard, Matthew P. Denn was Attorney General.

2 Drug diversion refers to the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

3 In recent years, the frequency of opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of prescription opioid abuse. According to the Centers for Disease Control and Prevention ("CDC"), Delaware lost 669 people to drug overdose deaths between 2014 and 2016. The alleged "main driver" of such deaths was prescription and illicit opioids.

4 *Spence v. Funk*, 396 A.2d 967, 968 (Del. 1978).

5 *Id.*

6 *Wilmington Sav. Fund. Soc'v, F.S.B. v. Anderson*, 2009 WL 597268, at *2 (Del. Super.) (citing *Doe v. Cahill*, 884 A.2d 451, 458 (Del. 2005)).

7 *Spence*, 396 A.2d at 968.

8 *See* 16 *Del. C.* § 3308 ("For the purposes of this chapter, a drug is deemed to be misbranded: (1) If it is an imitation of or offered for sale under the name of another drug; (2) If the contents of the package as originally put up were removed, in whole or in part, and other contents were placed in such package or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilide, or any derivative or preparation of any such substances contained therein; (3) If its package or label bears any statement, design or device regarding such article, or the ingredients or substances contained therein which is false or misleading in any particular way; (4) If it is included in the definition of misbranding in the Federal Food, Drug and Cosmetic Act.").

9 Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016,* 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

10 2015 WL 4111826 (Del. Super.).

11 *Id.* at *8.

12 919 A.2d 1116 (D. Del. 2007).

13 *Id.*

14 *Id.* at 1123.

15 *Id.* at 1122.

16 552 F.3d 659 (8th Cir. 2009).

17 *Id.* at 670.
18 *Id.*
19 *Id.* at 673.
20 Super. Ct. Civ. R. 8(a).
21 Delaware's Uniform Controlled Substances Act (16 *Del. C.* § 4701); Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0); and "numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances." Compl. ¶ 95.
22 Compl. ¶ 103.
23 Compl. ¶ 104-05 (quoting 24 *Del. Admin. C.* § 2500-8).
24 Compl. ¶ 141.
25 The State describes these orders as unusually large or frequent orders.
26 Compl. ¶ 134.
27 Compl. ¶ 134.
28 Compl. ¶ 145.
29 *See State of Sao Paulo of Federative Rep. of Braz. v. Am. Tobacco Co.*, 919 A.2d 1116, 1123 (Del. 2007)("State may not bring a direct action to seek damages for others' injuries without standing in their shoes as a subrogee").
30 2002 WL 31741522 (Del. Super.).
31 *Id.* at *4.
32 2002 WL 31741522 (Del. Super.).
33 *Id.* at *1.
34 *Id.*
35 *Id.* at *7.
36 16 *Del. C.* § 4733(a).
37 *Id.*
38 *See Duphily v. Delaware Electric Cooperative, Inc.*, 662 A.2d 821, 828 (Del. 1995)(citing *Laws v. Webb*, 658 A.2d 1000 (Del. 1995)); *Moffitt v. Carroll*, 640 A.2d 169, 174 (Del. 1994); *Culver v. Bennett,* 588 A.2d 1094 (Del. 1991).
39 *Culver v. Bennett*, 588 A.2d 1094 (Del. 1991)(quoting *Chudnofsky v. Edwards*, 208 A.2d 516 (Del. 1965)).
40 *Duphily*, 662 A. 2d at 829.
41 *Id.*
42 552 F.3d 659 (8th Cir. 2009).
43 *Id.* at 670.
44 *Greenfield for Ford v. Budget of Delaware, Inc.*, 2017 WL 729769, at *2 (Del. Super.)(quoting *In re Benzene Litigation*, 2007 WL 625054, at *6 (Del. Super.)(citing *Stuchen v. Duty Free Int'l, Inc.*, 1996 WL 33167249, at *5 (Del. Super.))).
45 *Myer v. Dyer*, 542 A.2d 802, 805 (Del. Super.).
46 *In re Benzene Litigation*, 2007 WL 625054, at *1 (Del. Super.)(In a mass tort case, the Court allowed defendants to isolate claims among a group of defendants. The defendants moved separately to distinguish behavior, and the court treated defendants as individual movants.).
47 Compl. ¶ 11.
48 Compl. ¶ 11.
49 Compl. ¶ 189.
50 Compl. ¶ 114.
51 16 *Del. C.* § 4798.
52 Compl. ¶ 120 (citing 16 *Del. C.* § 4798(e)).
53 Compl. ¶ 131.
54 The State argues that Pharmacies (along with other Defendants) have received extensive guidance on how to identify signs of illegal opioid use and how to prevent that use. The State claims that Pharmacies have received training from the DEA, "state pharmacy boards," and "national industry associations." Compl. ¶ 170.
55 Compl. ¶ 186.
56 16 *Del. C.* §§ 4701 *et seq.*
57 16 *Del. C.* § 4735(b)(1).

58 16 *Del. C.* § 4711.
59 2011 WL 290829 (Del. Super.).
60 2011 WL 290829, at *1.
61 *Id.* at *4.
62 16 *Del. C.* § 6853(a).
63 *Patton v. Simone*, 1992 WL 398478, at *9 (Del. Super.)(citing *State v. Hill*, 167 A.2d 738, 741 (Del. Ch. 1961)).
64 2000 WL 33113806 (Del. Super.).
65 *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806 (Del. Super.)(holding that Delaware law does not recognize products-based nuisance claims).
66 2000 WL 33113806 (Del. Super.).
67 *Id.* at *2 (citing *City of Evansville v. Kentucky Liquid Recycling, Inc.*, 604 F.2d 1008, 1017 (7th Cir. 1979), *cert. denied*, 444 U.S. 1025 (1980)(costs of abating toxic waste public nuisance are recoverable); *U.S. v. Occidental Chem. Corp.*, 965 F.Supp. 408, 412—413 (W.D.N.Y. 1997) (exercise of police power to protect public health in abating toxic waste public nuisance are recoverable)).
68 *Id.* at *7.
69 *Id.*
70 *See, e.g.*, *Tioga Public School Dist. No. 15 of Williams County, State of N.D. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993)("to interpret the nuisance statute in the manner espoused by Tioga would in effect totally rewrite North Dakota tort law"); *State v. Lead Industries, Ass'n, Inc.*, 951 A.2d 428, 456 (R.I. 2008)("[t]he law of public nuisance never before has been applied to products, however harmful"); *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007) ("were we to permit these complaints to proceed, we would stretch the concept of public nuisance far beyond recognition and would create a new and entirely unbounded tort antithetical to the meaning and inherent theoretical limitations to the tort of public nuisance"); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (111. 2004)("there is no authority for the unprecedented expansion of the concept of public rights to encompass the right asserted by plaintiffs...the plaintiff's claim does not meet all of the required elements of a public nuisance action"); *People ex re. Spitzer v. Sturm, Ruger & Co., Inc.*, 761 N.Y.S. 2d 192, 196 (N.Y. App. Div. 2003)("giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities").
71 *In re National Prescription Opiate Litigation*, No. 1:17-md-2804 (6th Cir. 2018), http://courtweb.pamd.uscourts.gov/courtwebsearch/ndoh/BOTExQ3LV4.pdf.
72 *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806, at *7 (Del. Super.).
73 *Patton v. Simone*, 1992 WL 183064, at *13 (Del. Super.).
74 *Johnson v. Preferred Professional Ins. Co.*, 91 A. 3d 994, 1014 (Del. Super.)(citing *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149-50 (Del. 1987)(citing *McLaughlin v. Copeland*, 455 F.Supp. 749, 752 (D.Del. 1978), *aff'd*, 595 F.2d 1213 (3d Cir. 1979))).
75 *Id.* at 1014 (citing *Ramunno v. Cawley*, 705 A.2d 1029, 1030 (Del. 1998)).
76 Compl. ¶ 303.
77 Compl. ¶ 305.
78 Compl. ¶ 306.
79 *Szczerba v. American Cigarette Outlet, Inc.*, 2016 WL 1424561, at *3 (Del. Super.)(citing *Anderson v. Airco, Inc.*, 2004 WL 2827887 (Del. Super.)(citing *Ryan v. Eli Lilly & Co.*, 514 F.Supp. 1004, 1012 (D.S.C.1981))).
80 525 A.2d 146 (Del. 1987).
81 *Id.* at 149.
82 *Szczerba*, 2016 WL 1424561, at *3 (citing *Nicolet*, 525 A.2d at 149-50).
83 *Nicolet*, 525 A.2d at 149.
84 *Id.*
85 *Incyte Corporation v. Flexus Biosciences, Inc.*, 2017 WL 7803923, at *4 (Del. Super.)(citing *Nemec v. Shrader*, 991 A.2d 1120, 1130 (Del. 2010)).
86 *See Nemec v. Shrader*, 991 A.2d 110, 1130 (Del. 2010).

87 Assurance of Discontinuance ¶¶ 54, 67 (Endo requested in its Motion to Dismiss that the Court take judicial notice of the AOD, an executed copy of which is available on the NYAG's website.); *See* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

88 The State proffers *Johnson v. M & M*, 242 F.R.D. 187, 190 (D. Conn. 2007)("a complaint is not submitted to the jury" and "whether evidence of the prior investigations will be admissible at trial is an issue to be resolved at a later stage").

89 *See Shaffer v. Davis*, 1990 WL 81892, at *4 (Del. Super.)(citing *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1990)).

90 *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1985).

EXHIBIT 5

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

STATE OF MINNESOTA DISTRICT COURT

COUNTY OF HENNEPIN FOURTH JUDICIAL DISTRICT

Court File No. 27-CV-18-10788

State of Minnesota by its Attorney General Lori Swanson,
Plaintiff,

v.

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

ORDER DENYING MOTION TO DISMISS

This case came on for hearing before Judge Kevin S. Burke on October 17, 2018.

Eric Maloney and Evan Romanoff, Assistant Minnesota Attorney Generals, appeared on behalf of Plaintiff State of Minnesota by its Attorney General Lori Swanson.

Erik Snapp and Peter Gregory, Esqs., appeared on behalf of Defendants Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc.

Based upon the record and arguments,

IT IS HEREBY ORDERED that:

1. Defendants Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc.'s Motion to Dismiss is **DENIED**.
2. The attached Memorandum is incorporated.

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

BY THE COURT:

Date: January 4, 2019

Kevin S. Burke
District Court Judge

MEMORANDUM

It is common knowledge there is an opioid epidemic in this nation. News reports regularly showcase the devastating impact opioid overdoses have on families and communities across the country. Opioids alone cause more deaths than drunk driving. While there are many causes for this tragedy, the forum to address this crisis is not merely a courtroom and this lawsuit. The decision to deny the motions to dismiss should not be misconstrued. There is no presumption of innocence in civil actions but there is also no presumption of guilt. Purdue vigorously denies liability in this matter. Purdue may or may not have done something wrong. This decision is driven by the Minnesota Rules of Civil Procedure and no one should read anything deeper into this decision.

Minnesota state courts have a vastly different approach to civil justice than the federal courts. Over the past decade, the U.S. Supreme Court has made it much harder for plaintiffs to proceed with lawsuits in our federal courts. How much detail should be required in a complaint is not any easy analysis. Notice pleading for decades was the standard in the Federal Rules of Civil Procedure.

In *Conley v. Gibson*, the U.S. Supreme Court held that a complaint should not be dismissed unless there were no set of facts upon which relief could be

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

granted. 355 U.S. 41 (1957). *Bell Atlantic Corp. v. Twombly*, changed that. 550 U.S. 544 (2007). The U.S. Supreme Court abandoned the "no set of facts" language from *Conley v. Gibson*. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly* at 570).

The catch phrase of federal pleading is "plausibility." Federal law requires a plaintiff to allege enough facts that a court can find it plausible for the plaintiff to recover. Justice Kennedy's majority opinion in *Ashcroft v. Iqbal* said that courts should decide what is plausible based on the context. "Determining whether a complaint states a plausible claim for relief will … be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." 556 U.S. at 679.

In a dissent joined by Justice Ginsburg, Justice Stevens objected to the Court's overruling of the *Conley v. Gibson* test.

> Consistent with the design of the Federal Rules, *Conley's* "no set of facts" formulation permits outright dismissal only when proceeding to discovery or beyond would be futile. Once it is clear that a plaintiff has stated a claim that, if true, would entitle him to relief, matters of proof are appropriately relegated to other stages of the trial process. Today, however, in its explanation of a decision to dismiss a complaint that it regards as a fishing expedition, the Court scraps *Conley's* "no set of facts" language.… That exact language . . . has been cited as authority in a dozen opinions of this Court and four separate writings. In not one of those 16 opinions was the language "questioned," "criticized," or "explained away." Indeed, today's opinion is the first by any Member of this Court to express *any* doubt as to the adequacy of the *Conley* formulation. Taking their cues from the federal courts, 26 States and the District of Columbia utilize as their standard for dismissal of a complaint the very language the

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

> majority repudiates: whether it appears "beyond doubt" that "no set of facts" in support of the claim would entitle the plaintiff to relief. Petitioners have not requested that the *Conley* formulation be retired, nor have any of the six *amici* who filed briefs in support of petitioners.

Bell Atl. Corp. v. Twombly, at 577–79 (internal citations omitted).

Reasonable minds may differ about which approach is better, but the current state of the law in Minnesota state courts is clear. A motion to dismiss pursuant to Rule 12.02(e) of the Minnesota Rules of Civil Procedure requires the Court to determine whether the complaint sets forth a legally sufficient claim for relief. *Bahr v. Cappella University*, 788 N.W.2d 76, 80 (Minn. 2010). "A pleading must 'contain a short plain statement of the claim showing that the pleader is entitled to relief and a demand for judgment for the relief sought.'" *Id.* (citing Minn. R. Civ. P. 8.01). The Court must "consider only the facts alleged in the complaint, accepting those facts as true and must construe all reasonable inferences in favor of the nonmoving party." *Id.* (citation omitted).

A pleading will be dismissed only if it appears to a certainty that no facts exist which could be introduced, consistent with the pleading, which would support granting the relief demanded. *Id.* The law in Minnesota dictates that this Court view the evidence in the light most favorable to the State for purposes of deciding the motion to dismiss. This case contains a very detailed Complaint put forth by the State.

Purdue argues that this case is an attempt to impose liability for Purdue's "lawful promotion of FDA approved medications for an FDA approved us." The Supremacy Clause of the United States Constitution states that the laws of the

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

United States "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby." U.S. Const. art. VI, cl. 2. "The Supremacy Clause enables Congress, in the exercise of its legislative authority, to preempt state law." *All. Ins. Co. v. Wilson*, 384 F.3d 547, 551 (8th Cir. 2004) (citation omitted); *Angell v. Angell*, 791 N.W.2d 530, 534 (Minn. 2010) (stating that "a federal law prevails over a conflicting state law"). The Supremacy Clause applies with equal force to federal regulations promulgated pursuant to an agency's statutory authority. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 139, 153, (1982).

Federal law supersedes state law where (1) Congress is empowered to preempt state law pursuant to express language (express preemption); (2) "the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" (field preemption); or (3) state law actually conflicts with federal law (conflict preemption). *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280-81 (1987) (citations omitted); *Hous. & Redevelopment Auth. of Duluth v. Lee*, 852 N.W.2d 683, 687 (Minn. 2014). Although vigorously and effectively argued by the defendants this case – particularly at this procedural stage – is not preempted by federal law.

Federal preemption of state law begins with an "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine,* 555 U.S. 555, 565 (2009). The State has alleged Purdue Pharma L.P., Purdue

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively "Purdue") engaged in conduct both governed, at least in part, by the FDCA and conduct outside of the purview of the FDCA. While Purdue correctly states that state law is preempted when it "stands as an obstacle," viewing the evidence in the light most favorable to the plaintiff no such obstacle between federal and state law is established here to satisfy a motion to dismiss. The State's claims are not preempted by federal law.

Causation

The State alleges that Purdue engaged in deceptive marketing schemes that "contributed to a rising tide of widespread opioid prescribing in Minnesota." Compl. ¶ 5. Further, the State alleges those deceptive practices engaged in by Purdue injured Minnesotans. Compl. ¶¶ 245, 257, 265, 273, 280. The State further alleges injury, including overdose deaths, resulted from Purdue's conduct. Compl. ¶¶ 212-13, 218. By denying this motion, Purdue will incur far more significant legal fees and costs then the firm has thus far incurred. If Purdue prevails that will be unfortunate. But even though this may not be an easy case for the State to prove causation, at this procedural stage, dismissing the State's claims would be improper.

The recent decisions by the Minnesota Supreme Court illustrate that the trend in Minnesota law is to be conservative in deciding cases on summary judgment when there are disputed facts. *Fenrich v. The Blake School*, No. A17-0063, 2018 WL 6072429, at *1 (Minn. Nov. 21, 2018); *Montemayor v. Sebright Products, Inc. v. VZ Hogs, LLP*, 898 N.W.2d 623 (Minn. 2017); *Senogles v. Carlson*,

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

902 N.W.2d 38 (Minn. 2017). This is not a summary judgment, but if the trend in Minnesota law is to be conservative with respect to summary judgment, it would be illogical for a court to apply the heightened standard that Purdue asks for at this procedural stage.

Requisite Particularity for Claim

(Consumer Protection Claims, False Claim Act, Essential Elements)

The Minnesota Supreme Court has applied Rule 8.01 when reviewing Consumer Protection Claims. *See Welfare Fund A v. CVS Caremark Corp.,* 850 N.W.2d 682, 692-93 (Minn. 2014). Rule 8.01 states, in part, that a claim requires "a short and plain statement of the claim." Minn. R. Civ. P. 8.01. In applying Rule 8.01 to Consumer Protection cases, courts have not applied the heightened pleading standard of "particularity" required under Rule 9.02. Minn. R. Civ. P. 9.02. Even if a heightened pleading standard, as required under Rule 9.02, was applicable in this case, the State's lengthy complaint sufficiently alleges violations to survive a Motion to Dismiss. For example, the State alleges Purdue made misrepresentations of the Unlawful Trade Practices Act and details the who, what, when, where, and how. *See* Compl. ¶¶ 242-43, 251-56, 263-64, 278-279).

Standing

The State contends that the plain language of the Deceptive Trade Practices Act does not require, as Purdue alleges, that a plaintiff be a business competitor for a Deceptive Trade Practices Act claim. Authority is given to the Attorney General to "investigate violations of the law of this state respecting

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

unfair, discriminatory, and other unlawful practices in business, commerce, or trade." Minn. Stat. § 8.31. Purdue has misconstrued the Deceptive Trade Practices Act. There is a history of the Minnesota Attorney General's Office bringing cases like this. While there are no doubt other alternatives, such as allowing parties bring a "private attorney general" action cases *Ly v. Nystrom*, 615 N.W.2d 302 (Minn. 2000) discourages – if not destroys – that option. Minnesota law gives the Minnesota Attorney General's Office wide birth in enforcing our state's consumer protection statutes. A plain language reading of the statute does not prohibit the State's standing as Purdue alleges.

Unjust Enrichment

Unjust Enrichment is established when a party "knowingly receive[s] something of value, not being entitled to the benefit, and under circumstances that would make it unjust to permit its retention. *Southtown Plumbing, Inc. v. Har-Ned Lumber Co., Inc.,* 493 N.W.2d. 137, 140 (Minn. Ct. App. 1992). The State claims that Purdue accepted value, through payment for its opioid products, for which Purdue was not entitled to because the payments were a result of misleading and deceptive marketing practices. (Compl. ¶¶ 283-84). Again, this may be a case where there are so "many intervening actions and events that break the causal chain" as Purdue argues, but this is unquestionably a case where proceeding through the discovery process is appropriate.

Special Duty

The State has plead a special-duty claim and alleges Purdue violated that duty. The State claims Purdue had "(1) the existence of a duty of care, (2) a

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

breach of that duty, (3) an injury, and (4) the breach of the duty being the proximate cause of the injury." *Gradjelick v. Hance,* 646 N.W.2d 225, 230 (Minn. 2002). The State contends that Purdue undertook a duty of care to health care providers, the public, and the State. The State alleges Purdue breached that duty by misrepresenting the danger of opioids causing harm to both the State and the public at large. *See* Compl. ¶¶ 21, 212-37, 242-43, 251-56, 263-64, 278-79.

Public Nuisance

The State alleges that Purdue created a public nuisance by an "act or failure to perform a legal duty" has resulted in the "maint[enance] or [permission of] a condition which unreasonably annoys, injures or endangers the safety, health, morals, comfort, or repose of any considerable number of members of the public." Minn. Stat. § 609.74. The State alleges Purdue's marketing deceived health care providers and patients about the dangers associated with opiods and was a "substantial factor in opioids becoming widely available and widely used in Minnesota." (Compl. ¶ 301). The State alleges in detail throughout the Complaint that Purdue's marketing "misconduct" impacted opioid overdose deaths, increases in hospitalization, substance abuse treatment rates, money spent by government health care programs as a result of opioids, and criminal justice and societal costs related to opioids. (Compl. ¶¶ 5-6, 212, 219-21, 228, 233-37).

Purdue cites *State v. Red Owl Stores, Inc.*, 115 N.W.2d 643 (Minn. 1962). While many trial judges may view a public nuisance theory of recovery with a jaundice eye, *Red Owl* does not preclude this claim. The opinion states:

Filed in District Court
State of Minnesota
1/4/2019 1:44 PM

> We think the record as a whole supports the conclusion of the trial court that the state and the association have failed to establish that there is any greater danger to the public when these drugs are sold at self-service counters in supermarkets than when sold by a clerk in a drugstore. The public receives no greater protection in one case than in the other. Moreover, the record supports the trial court's conclusion that there is no causal relationship between injuries sustained by the excessive use of these drugs and the place where they are purchased. The injury may result as well from the excessive use when purchased at a licensed pharmacy. The trial court found that all control over the usage or dosage of the medicines ceased with completion of the purchase and delivery to the customer. We must also agree with the findings of the trial court on the record before us that the sale of these drugs in nonlicensed outlets did not constitute a nuisance nor did such sales affect or endanger the public health to the point where injunctive relief is required.

Id. at 651. The State's theory in this case, unlike *Red Owl*, is the drugs Purdue sold were the problem, not whether they had a license to sell drugs.

EXHIBIT 6

2018 WL 4829660 (N.J.Super.Ch.) (Trial Order)
Superior Court of New Jersey, Chancery Division.
Essex County

GREWAL, et al.,
v.
PURDUE PHARMA L.P., et al.

No. ESX-C-245-17.
October 2, 2018.

Letter Opinion

Patricia Schiripo, Esq., Jesse Sierant, Esq., Office of the Attorney General of the State of New Jersey, Patricia.schiripo@law.njoag.gov, Jesse.sierant@law.njoag.gov.

Stephen Matthews, Esq., DLA Piper LLP, Stephen.matthews@dlapiper.com.

Thomas M. Moore, Judge.

***1** Dear Counsel:

Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, **"Purdue"**), have moved to dismiss the Complaint for failure to state a claim upon which relief can be granted under *Rule* 4:6-2(e). The Court heard oral argument on July 9, 2018. This letter opinion shall be the Court's order and opinion on this motion.

1. FACTS AND PROCEDURAL HISTORY

Plaintiffs Gurbir Grewal, the Attorney General of New Jersey, and Paul Rodriguez, the Acting Director of the New Jersey Division of Consumer Affairs, (collectively, **"the State"**) filed this action on October 31, 2017. [1] The Complaint alleges that Purdue's marketing violated the New Jersey Consumer Fraud Act (**"the CFA"**), the New Jersey False Claims Act (**"the FCA**"), and created a public nuisance. Purdue filed a motion to dismiss in lieu of an answer on February 2, 2018. The Court heard oral argument on July 9.

A. PURDUE'S ALLEGED MARKETING SCHEME

Purdue "manufactures, promotes, sells, and distributes" opioid prescription drugs, including OxyContin, *Compl.* ¶ 28. The State alleges that Purdue's marketing contributed to the current opioid crisis. The State seeks "to hold Purdue accountable for its key role in the opioid epidemic and demand the company's contribution to the expensive solutions, including addiction treatment and prescriber education, that are necessary to abate the crisis." *Id.* at ¶ 1. The State contends that Purdue, starting in the late 1990s, tried "to change the perception of opioids to permit and encourage the use of these drugs not just for acute and palliative [end of life] care, but also long-term, for chronic conditions like back pain, migraines, and arthritis." *Id.* at ¶ 5 (brackets added). The State defines chronic pain as "non-cancer pain lasting three months or longer." *Id.* The State claims that before Purdue's marketing push, opioids were ordinarily used only to treat short-term acute pain and palliative care "because they were considered too addictive and debilitating for long-term use." *Id.* at ¶ 4.

The State alleges that Purdue's marketing campaign changed the medical consensus about the use of opioids. *Id.* at ¶ 7. It asserts that, now, more than ninety percent of prescription opioids are for chronic pain conditions. Id The State claims that Purdue's marketing affects doctors that it has not targeted because it successfully established "opioids as a first-line treatment for chronic pain." *Id.* at ¶ 180. Purdue's opioids allegedly account for more than sixty percent of the brand-name opioid prescriptions that the State reimbursed through its Medicaid and workers' compensation programs and employee and retiree health plans. *Id.* at ¶ 12: *see id.* at ¶ 176.

The State alleges that Purdue's marketing consisted of: (1) direct marketing to prescribers by advertising and in-person sales calls, (2) "generating a biased and methodologically defective body of scientific research, the purpose of which was to support, rather than objectively investigate, the use of opioids for chronic pain," and (3) marketing opioids to physicians and consumers through unbranded websites, third-party "front" groups, and opinion leaders. *Id.* at ¶ 6. Such gro*ups and opinion leaders included pain advocacy groups, professional societies, and* physicians. *Id.* Purdue allegedly financed these websites, groups, and individuals. *Id.*

***2** The State alleges that, beginning in 1996, Purdue marketed OxyContin "as the solution to the problem of chronic pain." *Id.* at ¶ 35. It convinced prescribers that "the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven." *Id.* The State asserts that "Purdue knew its claims about long-term opioid use lacked scientific support." *Id.* at ¶ 36. The State claims that the Food and Drug Administration ("FDA") approved labeling of Purdue's opioids does not address long-term use, which the State defines as more than twelve weeks. *Id.* The State asserts that the clinical study for OxyContin's efficacy was a two-week study. *Id.* However, Purdue allegedly "marketed OxyContin with the understanding and expectation that health care providers—believing the drug to be appropriate fof long-term use—would prescribe it to their chronic pain patients over periods of months and even years." *Id.* The State asserts that Purdue targeted general practitioners, who were the most likely to treat patients with chronic pain and the "least likely to have the training and experience to evaluate Purdue's marketing and patients' pain conditions." *Id.* at ¶ 37. The State contends that this targeting "laid the groundwork for today's epidemic of opioid abuse, injury, and death." Id.

Purdue allegedly made deceptive statements in its marketing that understated the risk of addiction. *Id.* at ¶¶ 39-40. Additionally, Purdue claimed that OxyContin was effective for a full twelve hours and "less likely than other opioids to create a cycle of crash and cravings that fuel addiction." *Id.* at ¶¶ 41-42. Its competitors sold less expensive opioids which were prescribed in four or six hour doses. *Id.* at ¶ 41.

In 2007, Purdue and three of its then-executives "pleaded guilty to federal criminal charges for certain deceptive conduct in the sale and marketing of opioids." *Id.* at ¶ 8. The State alleges that after the guilty pleas, Purdue did not correct its prior misrepresentations and instead "echoed the deceptions for which it was cited in 2007 and made diverse other misrepresentations." *Id.* at ¶ 74. The State asserts that Purdue
has falsely and misleadingly presented the risks of opioids by (a) continuing to downplay the serious risk of addiction, including by claiming that signs of addiction merely reflect undertreated pain; (b) overstating the effectiveness of screening tools in preventing addiction, giving prescribers unwarranted confidence that they can safely prescribe opioids; (c) denying or failing to disclose the dangers of opioids at higher doses, which increase the risk of addiction, overdose, and death; and (d) exaggerating the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Purdue also has misrepresented the benefits of opioids, falsely claiming that long-term opioid therapy is appropriate and effective—and, in particular, will improve patients' function and quality of life—without disclosing that there is no good evidence to support these claims. Purdue further has misleadingly promoted OxyContin as providing a full 12 hours of pain relief, when in fact the effect wears off well before 12 hours in many patients—causing patients to experience a "crash" and fueling a cycle of higher-dose prescribing (which Purdue expressly encouraged) and addiction.

[*Id.* at ¶ 10; *see id.* at ¶¶ 11, 79-158.]

B. PURDUE'S ALLEGED TARGETING OF THE ELDERLY

The State alleges that Purdue targeted the elderly and opioid-naive patients to expand its market share and increase its profits. *Id.* at ¶¶ 159-72. The State asserts that Purdue's training materials and sales goals for its sales representatives, its sales representatives' notes, and its sales managers' reports reference "Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients." *Id.* at ¶ 160. Purdue instructed its sales representatives to persuade doctors to convert elderly patients from non-steroidal anti-inflammatory drugs, such as Tylenol, or other opioids to Purdue's opioid products. *Id.* at ¶ 161. Part of the persuasion strategy was to suggest starting the patient at a low dosage, which, according to the State, implies that a low dose was safe. *Id.* at ¶¶ 162, 167-68. Additionally, Purdue knew that it was likely the dosage would need to be increased as the patient developed a tolerance for the opioid. *Id.* at ¶ 168. Purdue also allegedly targeted nursing homes and focused its marketing on educating physicians about Medicare Part D coverage for opioids. *Id.* at ¶¶ 163-64.

C. ALLEGED INJURIES TO THE PUBLIC AND THE STATE

***3** The State claims that Purdue's marketing has caused "an epidemic of addiction, abuse, overdose, and other injuries, with their attendant societal costs." *Id.* at ¶ 173. The State asserts that Purdue's marketing has caused increase in opioid use, which "has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Jersey." *Id.* at ¶ 182; *see id.* at ¶ 184. The State claims that "[p]atients receiving opioid prescriptions for chronic pain account for the majority of overdoses." *Id.* at ¶ 185 (citing a 2016 report by the Centers for Disease Control and Prevention). Further, up to eighty percent of heroin addicts used prescription opioids before using heroin. *Id.* at ¶ 196.

Through its health programs, the State has paid hundreds of millions of dollars for opioid prescriptions, many of which, it asserts, "were not medically necessary and would not have been written but for Purdue's fraudulent scheme." *Id.* at ¶ 173; *see id.* at ¶ 237. Moreover, the State has paid for additional medical treatment and prescription drugs for conditions and injuries caused by chronic opioid use. Id. at ¶ 202. The State funds the New Jersey Medicaid program, the State employee and retiree health plans, and the State employee workers' compensation program. *Id.* at ¶¶ 202, 204-16, 223-25. The State argues that most long-term use of opioids to treat chronic pain is not medically necessary as defined by the State's health programs. *Id.* at ¶¶ 217, 219, 228, 234-35. Alternatively, if the prescriptions were medically necessary because of accepted professional and community standards, the State argues that Purdue's deceptive marketing caused the change in these standards. *Id.* at ¶¶ 218, 229. The State alleges that it has incurred additional and consequential costs to pay for additional medical care and drugs for patients who used opioids long-term for chronic pain, such as the costs of rehabilitation. *Id.* at ¶¶ 222, 231-32.

The State asserts that its payment for the prescriptions and medical services was the "foreseeable and intended consequence of Purdue's fraudulent marketing scheme." *Id.* at ¶ 236. Moreover, the State alleges that Purdue intended physicians to prescribe and the government to pay for long-term prescriptions to treat chronic pain. Id The State contends that, but for the deceptive marketing campaign, "the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain." *Id.* at ¶ 237. The State asserts that "prescribers would have more accurately understood the risks and benefits of long-term opioid use and would not have prescribed opioids as medically necessary or reasonably required to treat chronic pain." *Id.* at ¶ 238. Additionally, the State claims that it and its municipalities has suffered increased costs for law enforcement because of the rise in the criminal market for opioids. *Id.* at ¶ 199.

D. PURDUE'S ALLEGED KNOWLEDGE AND CONCEALMENT

The State alleges that Purdue knew its marketing was false and misleading. *Id.* at ¶ 245. It claims that Purdue had access to studies, prescription data, and incident reports, "which made clear the harms from the long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers." *Id.* The State accuses Purdue of taking "steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct, and also to conceal or minimize questions or concerns raised by prescribers about addiction." *Id.* at ¶ 246. Purdue allegedly disguised its role in the marketing by "funding and working through biased science, unbranded marketing, third party advocates, and professional associations." *Id.* at ¶ 253. The State contends that it "purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain." *Id.*

***4** The 2007 settlement with the federal government included a Corporate Integrity Agreement. *Id.* at ¶ 247. The Agreement "requires Purdue to establish written procedures governing the response to requests for information about … withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products." Id (internal quotation marks omitted). The State alleges that Purdue has violated the Agreement by "deflecting questions from prescribers about the risk of addiction." *Id.* at ¶ 248. Moreover, the State accuses Purdue of fraudulently concealing or underrepresenting prescriber questions about addiction in its sales representatives' meeting notes or instructing its representatives not to raise to topic of addiction. *Id.* at ¶¶ 249-51. Additionally, Purdue did not start noting addiction materials that it gave to prescribers prior to October 3, 2016. *Id.* at ¶ 252.

Finally, the State asserts that "Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids." *Id.* at ¶ 259. Contrary to Purdue's public statements, the State accuses Purdue of continuing to supply these providers with its products. *Id.* at ¶¶ 259-60.

The State argues that it "did not know the existence or scope of Purdue's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence." *Id.* at ¶ 261.

E. COUNTS OF THE COMPLAINT

The Complaint has five counts. The first three counts allege violations of the CFA, *N.J.S.A.* 56:8-1 *et seq.* Count One asserts that Purdue's marketing violated the CFA because of making false or misleading statements, causing false or misleading statements to be made or disseminated, omitting or concealing material facts, and failing to correct prior misrepresentations and omissions. *Id.* at ¶ 269; *see id.* at ¶¶ 270-71. The State seeks a permanent injunction prohibiting Purdue from engaging in these acts and practices, disgorgement "of any money acquired or retained as a result of these practices," restitution of money acquired from these practices, civil penalties for each CFA violation, and attorneys' fees and costs. *Id.* at p. 93

Count Two alleges that Purdue's marketing constitutes an unconscionable commercial practice under the CFA. *Id.* at ¶¶ 276-77. The State contends that Purdue's marketing "unethically deprived prescribers of the information they needed to appropriately prescribe, or not prescribe, these dangerous drugs." *Id.* at ¶ 278. The State seeks a permanent injunction prohibiting Purdue from engaging in these acts and practices, disgorgement "of any money acquired or retained as a result of these practices," restitution of money acquired from these practices, civil penalties for each practice, and attorneys' fees and costs. *Id.* at p. 95.

Count Three alleges that Purdue's targeting of the elderly is an unconscionable commercial practice under the CFA. *Id.* at ¶¶ 283-85. The State seeks restitution of money acquired from this practice, enhanced civil penalties under *N.J.S.A.* 56:8-14.3 for each deceptive and unconscionable commercial practice directed at the elderly, and attorneys' fees and costs. *Id.* at p. 96.

Count Four asserts a claim under the FCA, *N.J.S.A.* 2A:32C-1 *et seq.* The State accuses Purdue of, "through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State." *Id.* at ¶ 291. The State alleges that Purdue's deceptive statements to prescribers caused the prescribers to write medically unnecessary prescriptions, which the State paid for. *Id.* at ¶¶ 292-95. Additionally, the State has paid consequential health care costs that were caused by the unnecessary prescriptions. *Id.* at ¶ 296. The State seeks an injunction prohibiting Purdue from engaging in conduct that violates the FCA, maximum penalties for each false or fraudulent claim that Purdue caused to be presented to the State for payment, treble damages, and attorneys' fees and costs. *Id.* at p. 99.

***5** Count Five asserts a public nuisance claim. The State alleges that Purdue's marketing caused "a public nuisance by unreasonably interfering with a right common to the general public that harms the health, safety, peace, comfort, or convenience of the general community." Id. at 1! 298; *see* ¶ 302. Specifically, the State contends that Purdue's conduct has caused

(a) widespread dissemination of false and misleading information about the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

[*Id.* at ¶ 300.]

The State argues that the nuisance was foreseeable to Purdue because it knew of the lack of evidence behind its marketing claims, it could foresee "a vastly expanded market for chronic opioid therapy" as a result of its conduct, and it was on notice and aware that broader use of opioids was causing the injuries that the State has described. *Id.* at ¶ 304. The State seeks an order requiring Purdue to provide for the abatement of the nuisance, enjoining Purdue from further contributing to the nuisance, and "awarding damages to redress the consequential damages resulting from" the nuisance. *Id.* at pp. 101-02.

II. ARGUMENTS

A. PURDUE'S MOTION TO DISMISS

Purdue moves to dismiss the Complaint for six reasons:

1. Federal law preempts the State's claims because the claims conflict with the FDA's decisions regarding what Purdue should tell doctors and patients about its products;

2. New Jersey law forecloses the State's public nuisance claim;

3. Portions of all claims are time-barred;

4. The State does not plead the alleged fraud with particularity;

5. The State does not allege that Purdue controlled third-party publications and statements; and

6. The State has not pleaded and cannot plead causation.

Purdue's Br. 3-4.

1. Preemption

Purdue argues that the federal law preempts the State's claims because "any claim arising from Purdue's promotion of opioid medications as safe and effective for its FDA-approved indications necessarily conflicts with the FDA's jurisdiction over drug labeling, and specifically its approval of those indications." *Purdue's Br.* 12 (internal quotation marks and citation omitted). Purdue claims that it has marketed its medications for their FDA-approved uses and consistent with FDA's policies. *Id.* at 16. Purdue asserts that the FDA has approved Purdue's medications for long-term use to treat chronic pain. Id at 10. Further, Purdue contends that the FDA-approved labels on the medications expressly address the misrepresentations alleged by the State. *Id.*

Purdue applies its preemption analysis to each category of the State's allegations. First, the FDA has approved Purdue's medications for long-term use to treat chronic pain. Id. at 12-13. Additionally, in 2012, it denied a petition from the Physicians for Responsible Opioid Prescriptions (**"PROP"**), which sought to limit the use of opioids in non-cancer patients to ninety days. *Id.* at 13; *see id.* at 2.

***6** Second, the State alleges that Purdue promoted the concept of pseudoaddiction and implied there was scientific evidence to support it. *Id.* at 14 (citing *Compl.* ¶¶ 10, 86, 97). Purdue characterizes pseudoaddiction as drug-seeking behavior that mimics addiction from patients receiving inadequate pain relief. Id. at 14. Purdue contends that the FDA-approved label embodies the concept of pseudoaddiction. *Id.*

Third, the State alleges that "Purdue misrepresented that addiction risk screening tools allow doctors to identify and safely prescribe opioid medications to patients predisposed to addiction. *Id.* (citing *Compl.* ¶¶ 10, 101-06). Purdue argues that federal law preempts this claim because the FDA-mandated Risk Evaluation and Mitigation Strategy (**"REMS"**) requires Purdue to provide risk-benefit information to physicians. *Id.* at 7-8. REMS directs physicians "to understand and appropriately use screening tools for addiction or abuse to help assess potential risks associated with chronic opioid therapy and to help manage patients using ER/LA opioid analgesics." *Id.* at 14 (internal quotation marks and citation omitted).

Fourth, "[t]he State alleges that Purdue misrepresented the dangers of opioid medications at higher doses." *Id.* (citing *Compl.* ¶ 10). Purdue maintains that federal law preempts this allegation because it undermines the FDA's decision in response to the PROP petition, which concluded that the available information does not demonstrate a causal relationship between dosage and adverse events. *Id.* at 14-15.

Fifth, "[t]he State alleges that Purdue misrepresented the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction." *Id.* at 15 (internal quotation marks omitted) (quoting *Compl.* ¶ 10). The FDA-approved labeling states that the ingredients are "intended to make the tablet more difficult to manipulate for misuse and abuse." Id. (internal quotation marks and citation omitted). Purdue concludes that its claims about the abuse-deterrent opioids are consistent with the FDA-approved labeling. Id. Further, the FDA reviewed the data regarding the abuse-deterrent OxyContin and concluded that it is expected to "deter certain types of misuse." Id. (internal quotation marks and citation omitted). Moreover, FDA's policies encourage expanding access to abuse-deterrent formulations. *Id.*

Sixth, the State alleges "that Purdue misrepresented that OxyContin lasts for 12 hours." *Id.* (citing *Compl.* ¶¶ 10, 41-42, 79, 83, 107, 145-58). Purdue contends that federal law preempts these allegations because the FDA has approved OxyContin for twice daily dosing. *Id.* (citing *Compl.* ¶ 147). Additionally, the FDA rejected a 2004 petition from the Attorney General of Connecticut, which claimed that OxyContin was not a twelve-hour drug and should be dosed more frequently. *Id.* at 15-16.

2. Foreclosure of Public Nuisance Claim

Purdue argues that New Jersey law forecloses the State's public nuisance claim because of the Supreme Court's decision in *In re Lead Paint Litigation*, 191 *N.J.* 405 (2007) (**"*Lead Paint*"**). Purdue contends that *Lead Paint* prevents the State from sustaining "a public nuisance claim against Purdue for the lawful manufacture and promotion of FDA-approved medications." *Purdue's Br.* 17. Purdue maintains that "no New Jersey court has ever allowed a public nuisance claim to proceed against manufacturers for lawful products that are lawfully placed in the stream of commerce." *Id.* (internal quotation marks omitted) (quoting *Camden Cty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001) (**"Beretta"**)). Purdue argues that any claims relating to harms caused by products must be brought under the New Jersey Products Liability Act (**the "PLA"**). *Id.* at 20 (citing *Lead Paint*, *supra*, 191 *N.J.* at 436-37). Purdue contends that the PLA subsumes the State's other causes of action to the extent they seek to impose liability for harms caused by products. *Id.* at 20 n.37 (citations omitted).

***7** Additionally, the State does not have a right to damages because a public entity only has the right to abate. *Id.* at 18-19. If the State wants damages, it must prove a special injury. *Id.* Here, Purdue argues that the State only identifies injuries that are general to the public at large. *Id.* at 19-20.

Finally, Purdue contends that the State's public nuisance claim also fails because the causal chain is too attenuated. *Id.* at 20 (citing *Beretta*, *supra*, 273 F.3d at 541). Purdue argues that it does not control the conduct of health care providers or drug dealers, and that the State has not pleaded otherwise. *Id.* at 21.

3. Statute of Limitations

Purdue argues that some of the State's allegations concern conduct that occurred beyond any applicable statute of limitations. *Id.* at 21-22. Purdue contends that, at most, a ten-year statute of limitations applies to the State's claims. Id. at 22. Purdue maintains that many of the State's allegations concern conduct that occurred before October 31, 2007. *Id.* (citing *Compl.* ¶¶ 6, 35-72, 85-98). Purdue argues that the discovery rule does not apply because the State could have discovered the alleged misconduct before October 31, 2007. *Id.* at 23-24. The State had access to the publications that allegedly contained misrepresentations. *Id.* at 23. Further, the State also had access to information regarding the prescriptions that it paid for. *Id.* at 24. Additionally, the FCA does not apply retroactively to conduct before its effective date of March 13, 2008. *Id.*

4. Pleading Fraud with Particularity

Purdue argues that the State does not meet the heightened pleading requirements of *Rule* 4:5-8 for its fraud allegations. Id at 25 (citing *Compl.* ¶¶ 173, 236-38, 246, 261, 276, 291, 294-96). Purdue contends that the State's allegations about Purdue's marketing are "conclusory broad-brush assertions." *Id.* (citing *Compl.* ¶¶ 6, 10, 14-15). Purdue argues that the State does not plead who made false statements, who received the false statements, what false statements were made, when the false statements were made in New Jersey, where the wrongful conduct occurred, where the false statements were made, why the statements were false, or how Purdue's acts affected prescriptions that the State paid for. *Id.* at 25-26. According to Purdue, the State's allegations do not connect the alleged misrepresentations to a New Jersey doctor, patient, or prescription, which Purdue argues makes these allegations conclusory. Id. at 26 (citing *Compl.* ¶¶ 83-84, 86, 90, 107).

5. Control Over Third Parties

Purdue argues that the State "improperly attempts to hold Purdue legally responsible for statements made by third parties." *Id.* at 27 (citing *Compl.* ¶¶ 44-54, 58, 60-72, 94-98). The State has not proven "an apparent agency relationship" between Purdue and these third parties. *Id.* (citation omitted). The State has not alleged that Purdue exercised control over these third parties; it merely alleges that Purdue funded, sponsored, or influenced them. *Id.* at 28. Purdue contends that funding is insufficient as a matter of law to attribute statements of third parties to it. *Id.* (citing *Gen. Bldg. Contractors Ass'n, Inc. v. Pennsylvania*, 458 *U.S.* 375, 395 (1982)).

6. Causation

The State's FCA claims are based on Purdue's conduct causing doctors to prescribe opioids, which caused the State to pay for these prescriptions. *Id.* at 28-29 (citing *Compl.* ¶¶ 5-7, 17, 33, 35, 37-38, 60, 77, 102, 173-74, 176, 202-04, 237, 293, 295). Purdue contends that this alleged causal chain is too attenuated and that the learned intermediary doctrine breaks the chain of causation. *Id.* at 29. Purdue makes three arguments in support of its position. First, the State fails to allege that a New Jersey doctor heard, read, received, or relied on Purdue's alleged misrepresentations. *Id.* Instead, the State relies on conclusory allegations. *Id.* (citing *Compl.* ¶¶ 1, 5, 86).

***8** Second, the State's claims are "too attenuated as a matter of law to support liability." *Id.* According to Purdue, "any connection between the alleged misconduct and the prescriptions depends on multiple independent intervening events and actors," such as prescribers, patients, and the State. *Id.* at 30-31. Some of the State's allegations add another link: third party physicians and groups. *Id.* at 31 (citing *Compl.* ¶¶ 44, 47, 50, 61-63, 180, 218).

Third, the learned intermediary doctrine breaks any causal connection because of prescribing physicians' independent medical judgment. *Id.* at 31-32.

B. THE STATE'S OPPOSITION

1. Preemption

The State argues that federal law does not preempt its claims because Congress has not expressed its intent to preempt state laws on the subject matter of drug regulation, federal legislation does not occupy the field of drug regulation, complying with both the federal and state laws is possible, and complying with the state laws would not frustrate a clear federal purpose or objective. See id at 7. Moreover, the federal Food, Drug, and Cosmetic Act preserves state law unless it "presents a direct and positive conflict with the federal regulation of drugs." *Id.* at 8 (internal quotation marks omitted) (quoting *Wveth v. Levine*, 555 *U.S.* 555, 567 (2009)). The State contends that its allegations do not conflict with federal law because Purdue's alleged misrepresentations were either inconsistent with the FDA-approved labeling or addressed topics that the labeling did not cover. *Id.* at 12, 26-27. Therefore, there is no conflict between the federal and state laws. *Id.* at 19.

The State responds to each of Purdue's arguments about the specific categories of allegations. First, Purdue's alleged misrepresentations about long-term use are inconsistent with the FDA-approved labeling and are not covered by the 2012 PROP petition that the FDA denied. *Id.* at 19-20 (citing *Compl.* ¶¶ 134, 137, 139).

Second, Purdue's alleged misrepresentations about pseudoaddiction go beyond the labeling. *Id.* at 20-21 (citing *Compl.* ¶¶ 63-64, 84, 86, 89-91, 97-98).

Third, Purdue's alleged misrepresentations about addiction risk screening tools go beyond the FDA's REMS by suggesting that the tools prevent addiction and overdose. *Id.* at 21-22 (citing *Compl.* ¶¶ 101-05).

Fourth, the State alleges that Purdue encouraged prescribers to start patients on low doses of opioids and increase the dosage over time without disclosing the risks associated with higher doses. *Id.* at 22 (citing *Compl.* ¶¶ 107-12). The State contends that this failure to disclose is unrelated to the citizen petition that the FDA rejected regarding setting a maximum daily dose. *Id.* at 23.

Fifth, the State alleges that Purdue stated or implied to prescribers that "Purdue's abuse-deterrent formulations were (1) more difficult to abuse; (2) less likely to be diverted; (3) rendered inactive if crushed; (4) disliked by drug abusers; and (5) helping to thwart addiction." *Id.* at 23 (citing *Compl.* ¶ 131). The State argues that these representations are contrary to the FDA-approved labeling. *Id.* at 23-24. The State contends that, at most, the labeling allows Purdue to say that the formulations will make it more difficult to snort or shoot crushed tablets. *Id.* at 24. The formulations would not affect oral abuse, which the State asserts is the most common type of abuse. *Id.* (citing *Compl.* ¶ 86). Further, the FDA's preference for abuse-deterrent formulations is not inconsistent with the FDA's "insistence that companies accurately portray the limitations of those formulations." *Id.* at 24-25.

***9** Sixth, the State alleges that "Purdue misrepresented that OxyContin provides a full 12 hours of pain relief." *Id.* at 25 (citing *Compl.* ¶¶ 145-58). The State asserts that Purdue knew that OxyContin did not provide such relief. *Id.* at 25-26 (citing *Compl.* ¶ 150). The State argues that neither the prescribing information nor the FDA-approved labeling state that each dose provides twelve hours of continuous pain relief. Id. at 25.

2. Statute of Limitations

The State argues that its claims are not time-barred for four reasons. First, under the FCA, the State may recover for reimbursement claims made after the statute's effective date that are based on Purdue's conduct before the effective date. *Id.* at 27-28 n.15 (citing *State ex rel. Hayling v. Correctional Med. Servs., Inc.*, 422 *N.J. Super.* 363, 372 (App. Div. 2011)).

Second, the pre-2007 allegations provide essential background information about Purdue's marketing scheme. *Id.* at 27.

Third, Purdue's ongoing failure to correct past misrepresentations that were made before the limitations period "constitutes an actionable series of omissions of material facts under the CFA" and "constitute new violations." *Id.* at 28. The State alleges that Purdue built on its pre-2007 misrepresentations and continued to omit risks of opioids and the lack of evidence supporting long-term opioid therapy for chronic pain. *Id.* at 32 (citing *Compl.* ¶ 74). The State argues that Purdue's failure to correct these misrepresentations has caused them to persist and continue to influence prescribers and consumers. *Id.* at 32-33. The State contends that Purdue's failure "to correct its prior misrepresentations in later interactions with prescribers … constitut[es] a knowing omission of material facts from the prescriber's consideration, just as if Purdue were omitting the disclosure of a newly discovered material fact." *Id.* at 33.

Fourth, the Complaint contains many allegations of misrepresentations within the limitations period, such as:
1. Misrepresentations that OxyContin provides twelve hours of relief. Id. at 29 (citing *Compl.* ¶¶ 145-46, 153-57).

2. Promoting the concept of pseudoaddiction. *Id.* at 29-30 (citing *Compl.* ¶¶ 86, 91, 97).

3. Misrepresentations regarding abuse-deterrent formulations of opioids. *Id.* at 30 (citing *Compl.* ¶¶ 120-33).

4. Misrepresentation of addiction statistics for children treated with opioids. Id. (citing *Compl.* ¶ 86).

5. Misrepresentations about the efficacy of screening tools to manage opioid addiction. *Id.* (citing *Compl.* ¶ 105).

6. Omitting the risks of opioids while discussing the risks of non-opioid pain medications. *Id.* (citing *Compl.* ¶ 113).

7. Omitting the risks of dosage increases. *Id.* (citing *Compl.* ¶ 114).

8. Misrepresenting that opioids increase a patient's functioning. *Id.* at 31 (citing *Compl.* ¶ 141).

9. Misrepresenting the benefits and efficacy of opioids when it promoted chronic opioid therapy for the elderly and the opioid naive. Id. (citing *Compl.* ¶¶ 159-63, 167-69).

3. Fraud Pleaded with Particularity

The State argues that its CFA, FCA, and public nuisance claims are adequately pleaded.

a. CFA

The State contends that its CFA claims are adequately pleaded for two reasons. First, the law does not require the State to show who the statements were made to, the dates and locations of the statements, or that the statements were relied upon. *Id.* at 35. New Jersey courts have held that a detailed description of a deceptive scheme is sufficient to survive a motion to dismiss. *Id.* at 36-37 (citing *Talalai v. Cooper Tire & Rubber Co.*, 360 *N.J. Super.* 547, 564 (Law Div. 2001)). The State need not "allege precise facts regarding every instance of potentially unlawful conduct." Id. at 36 (citation omitted).

***10** Second, the Complaint provides enough details of Purdue's deceptive conduct to allow Purdue to deny, disprove, or explain the allegations. *Id.* at 37-39 (citing various portions of the Complaint).

b. FCA

The State notes that there are no published New Jersey opinions that establish the pleading standard for the FCA. Id at 39-40. It suggests that the Court should use Third Circuit precedent under the federal False Claims Act. Id. at 40. The Third Circuit does not require a plaintiff to plead the specifics of each false claim. *Id.* at 40-41 (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 *F.*3d 153, 155-58 (3d Cir. 2014)). The State argues that the *Foglia* approach is appropriate when a plaintiff "alleges a long-running scheme involving numerous claims submitted over the course of several years." *Id.* at 41. It also "provides the responding party sufficient notice to deny or disprove the claims asserted against it, and that standard comports with the Legislature's instruction that the FCA must be 'liberally construed to effectuate its remedial and deterrent purposes.'" *Id.* (quoting *N.J.S.A.* 2A:32C-17).

The State argues that the Complaint adequately alleges that "Purdue's deceptive conduct *induced health care providers* to prescribe opioids in a manner that violates material conditions of State-sponsored reimbursement programs, and that the submission of legally false claims for payment of those prescriptions was the reasonably foreseeable and intended result of that conduct." *Id.* at 42 (emphasis in original) (citing *Compl.* ¶¶ 202-44). The Complaint provides specific examples of false claims submitted for reimbursement. *Id.* at 43 (citing *Compl.* ¶¶ 219, 233). It also provides criteria for identifying the false claims among the millions of claims for opioids under the State's health programs. *Id.* at 44 (citing *Compl.* ¶¶ 220-21, 235).

Additionally, the State contends that some federal courts accept methods of proof other than claim-by-claim analysis, such as statistical sampling and extrapolation. Id at 45. The State expects to prove its false claims allegations through these methods with expert testimony. *Id.*

c. Public Nuisance

The State argues that the heightened pleading standard of *Rule* 4:5-8(a) does not apply to its public nuisance claim. Id at 46. It notes that Purdue does not cite any cases that apply a heightened pleading standard to a public nuisance claim. *Id.* The State contends that the Complaint adequately pleads a public nuisance claim because its allegations, if proven, would be an interference with the public's health, safety, peace, comfort, and convenience. *Id.* at 46-48 (citing various portions of the Complaint).

4. Causation

The State argues that it has adequately pleaded causation for each claim to the extent required by law. *Id.* at 48. Additionally, it contends that the learned intermediary doctrine does not defeat its claims. Finally, the State maintains that it sufficiently alleges that Purdue exercised controlled over unlawful promotional activity.

a. CFA

The State argues that causation is not required for a CFA claim brought by the government. [2] *Id.* at 49 (citations omitted).

b. FCA

***11** The State contends that it has adequately alleged that Purdue's deceptive conduct resulted in physicians submitting medically unnecessary claims for reimbursement. Id at 49. The State argues that the actions of third parties do not necessarily break the chain of causation. *Id.* at 50. It maintains that the proper standard for causation is whether Purdue's scheme was a substantial factor in influencing the physicians to file false claims. Id. (citing *United States ex rel. Bergman v. Abbott Labs.*, 995 *F. Supp.* 2d 357, 359, 368 (E.D. Pa. 2014)). The physicians' intervening acts do not defeat causation if "it is 'foreseeable that claims could be submitted"' because of Purdue's conduct. *Id.* at 51 (quoting *Bergman*, *supra*, 995 *F. Supp.* 2d at 369).

Here, the State argues that the Complaint alleges that "Purdue's unlawful marketing and promotional activities were a 'substantial factor' that foreseeably caused physicians to make express or implied false certifications about the medical necessity of opioid treatment, resulting in claims submitted to the State for reimbursement." *Id.*; *see id.* at 51 -53 (citing *Compl.* ¶¶ 32, 81-105, 113, 177, 179, 219, 233, 236). The State accuses Purdue of directly targeting physicians so that they would prescribe Purdue's opioids and submit prescriptions to the State for reimbursement. *Id.* at 54. Thus, the State contends that a reasonable trier of fact could "conclude that Purdue's conduct caused physicians to issue medically unnecessary opioid prescriptions." *Id.* at 53. The State notes that Purdue does not cite any false claims cases to support its causation argument. *Id.*

c. Public Nuisance

The State argues that the proper standard of causation for a public nuisance claim is whether the defendant's conduct is a substantial factor in creating the nuisance, even if there are other intervening causes. *Id.* at 55-56 (citing *James v. Arms Tech.. Inc.*, 359 *N.J. Super.* 291, 311 (App. Div. 2003)). Here, the State alleges that Purdue's marketing and promotional activities were a substantial factor in causing the nuisance. *Id.* at 57 (citing *Compl.* ¶¶ 298, 301-04).

d. Learned Intermediary Doctrine

The State argues that the learned intermediary doctrine does not defeat its claims for two reasons. First, the doctrine is limited to failure to warn claims under the PLA. *Id.* at 59 (citations omitted). The State contends that it is not asserting a failure to warn claim. Id

Second, if the doctrine does apply, it does not defeat the State's claims because Purdue made misrepresentations to physicians and patients. *Id.* at 60 (citing *Perez v. Wyeth Labs.*, 161 *N.J.* 1, 19 (1999)).

e. Control Over Promotional Activity

For two reasons, the State argues that it has sufficiently pleaded that Purdue controlled unlawful promotional activity. Id. at 62. First, the Complaint alleges that Purdue directly distributed third-party material to physicians and used these materials in promoting its products. *Id.* at 62-63 (citing *Compl.* ¶¶ 67, 69-71, 97, 112).

Second, Purdue allegedly "funded, assisted, encouraged, and even exercised direct editorial oversight over material created by third-party organizations." *Id.* at 62; see id. at 63-64 (citing ¶¶ 61-66, 69-72, 95, 97-113). The State contends that whether an agency relationship exists is a question for the trier of fact unless the facts are undisputed and there are no conflicting inferences. Id at 63-64 (citing *Luchejko v. City of Hoboken*, 207 *N.J.* 191, 211 (2011); *Miller v. Linde*, 33 *N.J. Super.* 41, 43 (App. Div. 1954)).

Third, Purdue allegedly "published misleading material—in-house—through its own unbranded marketing under the banners *Partners Against Pain* and *In the Face of Pain*." *Id.* at 65 (citing *Compl.* ¶¶ 88-104).

5. Foreclosure of Public Nuisance Claim

***12** The State argues that the PLA does not foreclosure the State's public nuisance claim for four reasons. First, the State is not suing because of harm caused by a product. *Id.* at 66. The PLA defines harm as personal injury or property damage. Id (citing *N.J.S.A.* 2A:58C-1(b)(2)).

Second, the State argues that *Lead Paint* differs from this action in the following ways:
1. *Lead Paint* did not involve a fraudulent marketing or promotional scheme;

2. Lead paint was an ordinary, unregulated consumer product when it was sold;

3. A statute addressing the lead paint problem placed responsibility for the problem on property owners, not paint manufacturers;

4. The evidence did not show that the manufacturers' conduct, at the time they distributed the paint, "bears the necessary link to the current health crisis;" and

5. The municipalities sought vindication of personal injuries and property damage.

Id. at 67-68 (citations omitted).

Third, the State contends that this action is similar to *James*, which held that the plaintiff's failure to warn allegations did not turn the entire complaint into a PLA action. *Id.* at 69 (citing *James*, *supra*, 359 *N.J. Super.* at 304). Additionally, the Appellate Division held that the plaintiff's public nuisance claim was based on "defendants' affirmative conduct in promoting and distributing firearms." *Id.* (citing *James*, *supra*, 359 *N.J. Super.* at 328).

Fourth, the State argues that it need not show a special injury because a special injury is only required when a private party sues for damages. *Id.* at 71 (citing *Lead Paint*, *supra*, 191 *N.J.* at 426). The State seeks abatement, which includes requiring Purdue to pay the costs of the abatement and to reimburse the State for costs it incurred in addressing the nuisance. Id.

The State also rejects Purdue's suggestion, which was in a footnote of its moving brief, that the PLA forecloses the State's other claims. *Id.* at 70. The State argues that the CFA and FCA claims do not seek to redress harm caused by a product under the PLA. *Id.* Additionally, the FCA claim does not require a showing of harm as the PLA defines harm. *Id.* (citation omitted).

C. PURDUE'S REPLY

1. Preemption

Purdue argues that the State's claims are preempted for three reasons. First, Purdue's marketing is consistent with the FDA-approved indications and labeling for its products. *Purdue's Reply Br.* 2. The FDA has approved OxyContin for "daily, around-the-clock, ***long-term opioid treatment*** and for which alternative treatment options are inadequate." *Id.* at 2-3 (emphasis in original) (internal quotation marks and citation omitted). The approval covers long-term treatment for chronic pain. *Id.* at 3.

Second, the State "cannot maintain a claim that a prescription medicine's labeling or marketing consistent with FDA-approved labeling is inadequate or misleading unless the manufacturer could have unilaterally changed the labeling to address the alleged inadequacy or misleading statement." *Id.* (citing *Purdue's Br.* 10-14, 11 n.22).

Third, the State's claims would require Purdue to act in direct conflict with FDA mandates. *Id.* at 5.

2. Foreclosure of the Public Nuisance Claim

Purdue argues that New Jersey case law and the PLA foreclose the State's public nuisance claim because "the State cannot bring a public nuisance claim against Purdue for the manufacture and promotion of a lawful product." *Id.* at 5.

a. Case Law

***13** Purdue contends that case law bars the State's public nuisance claim for three reasons. First, *Lead Paint* requires the State to proceed as a private plaintiff and show a special injury because it is seeking damages. *Id.* at 6 (citing *Lead Paint*, *supra*, 191 *N.J.* at 435; *State's Br.* 71, n.34).

Second, under *Beretta*, the State's claim is "too attenuated to attribute sufficient control to the manufacturers to make out a public nuisance claim." Id. at 7 (internal quotation marks omitted) (quoting *Beretta*, *supra*, 373 *F.*3d at 541).

Third, *Lead Paint* trumps *James* because it was decided later, was a New Jersey Supreme Court decision, and the facts of this action are more similar to *Lead Paint*. *Id.* at 8. Additionally. the Appellate Division in *Lead Paint* had relied heavily on *James* but was reversed by the Supreme Court. *Id.*

b. The PLA

Purdue contends that the PLA subsumes the public nuisance claim because the PLA "encompass[es] virtually all possible causes of action relating to harms caused by consumer and other products." Id. at 9 (brackets in original) (internal

quotation marks omitted) (quoting *Lead Paint*, *supra*, 191 *N.J.* at 436-37). Purdue maintains that "the PLA is paramount when the underlying claim is one for harm caused by a product." *Id.* at 11 (internal quotation marks omitted) (quoting *Sinclair v. Merck & Co., Inc.*, 195 *N.J.* 51, 66 (2008)). Purdue argues that the PLA covers all claims "for harm caused by a product, ***irrespective of the theory underlying the claim***, except actions for harm caused by breach of an express warranty." *Id.* at 9 (emphasis in original) (internal quotation marks omitted) (quoting *N.J.S.A.* 2A:58C-1(b)(3)). Purdue contends that the Complaint seeks to redress harm as defined by the PLA. *Id.* at 9-10 (citing *State's Br.* 1; *Compl.* ¶¶ 173, 195, 279, 300).

3. FCA Claim

Purdue argues that the State has failed to state an FCA claim against it because the allegations do not meet the particularity requirement of *Rule* 4;5-8(a). Purdue contends that the State has failed to show that Purdue's marketing resulted in the submission and reimbursement of medically unnecessary opioid prescriptions. *Id.* at 13. Purdue claims that the State does not provide any specific examples of medically unnecessary opioid prescriptions. *Id.* at 11. Purdue maintains that "[b]road, conclusory allegations of a fraudulent 'scheme' are insufficient to state FCA claims." *Id.* at 12 (citing *United States v. Eastwick College*, 657 *F. APP'X* 89, 95 (3d Cir. 2016)). Purdue argues that the "alleged availability of different methods of proof at trial does not relieve the State of its present pleading burden." Id (citation omitted). Purdue distinguishes *Foglia* because in that case it was only the defendant who had access to the documents that could prove or disprove the case. *Id.* at 13 (citing *Foglia*, *supra*, 754 F3d at 158). Here, the State possesses such documents. *Id.* at 13-14 (citing various portions of the Complaint).

4. Causation

Purdue argues that the State has not and cannot adequately plead causation for its FCA and public nuisance claims. Moreover, the learned intermediary doctrine severs any causal chain.

a. FCA

Purdue contends that the State fails to adequately plead causation for its FCA claim for four reasons. First, the State cannot show that Purdue's conduct was the proximate cause of an FCA violation. *Id.* at 15. But-for causation is insufficient under the FCA. *Id.* at 14. The State has failed to adequately plead that any New Jersey physician prescribed a State-reimbursed opioid based on Purdue's misrepresentations. Id. at 15.

***14** Second, the causal chain is too attenuated and is broken by physicians' independent decisions to prescribe the drugs. Id.

Third, the foreseeability of medically unnecessary prescriptions does not establish "proximate cause because the State needs to show directness between Purdue's misrepresentations and the false claim. *Id.* at 16.

Fourth, the State cannot base its FCA allegations on the long-term use of the opioids because the FDA approved Purdue's opioids for long-term use. *Id.* at 17-18.

b. Public Nuisance

Purdue argues that the State fails to adequately plead causation for its public nuisance claim for three reasons. First, the State relies on *James*, which Purdue contends is no longer valid. *Id.* at 18.

Second, *James* concerned an illegal and unregulated firearms market. Id This action concerns a highly regulated pharmaceutical market. *Id.*

Third, the drugs at issue require a physician's prescription. Id. The Attorney General's

office stated in 2017 that "irresponsibly run doctors' offices are ground zero for the abus[e] [of] prescription drugs." *Id.* at 18-19 (brackets in original) (internal quotation marks and citation omitted). By contrast, in *James*, the firearms manufacturers controlled the "creation and supply of th[e] illegal market." *Id.* at 19 (brackets in original) (internal quotation marks and citation omitted).

c. The Learned Intermediary Doctrine

Purdue argues that the learned intermediary doctrine severs the causal chain for three reasons. First, contrary to the State's argument, the doctrine is not limited to the PLA because the Legislature did not abrogate the common law. Id. at 19.

Second, Purdue contends that the State overreads *Perez*, which stated that the only exception to the learned intermediary doctrine is when a company advertises directly to consumers. *Id.* at 20 (citing *Banner v. Hoffman-La Roche. Inc.*, 383 *N.J. Super.* 364, 376 (App. Div. 2006)). Here, the State does not allege that Purdue conducted mass advertising to consumers. *Id.* at 21.

Third, Purdue provided adequate warnings physicians through the FDA-approved labeling, which included a "black box warning" about the dangers of addiction, abuse, misuse, overdose, and death. *Id.* at 20. A black box warning is the most serious warning required by the FDA. *Id.*

5. Particularity

Purdue reiterates that the State fails to plead its allegations of fraud with particularity because it does not provide the who, what, when, and where details. *Id.* at 22. The State's only allegations with "a semblance of the particularity required to satisfy Rule 4:5-8(a) either fall outside of the applicable statute of limitations, fail to connect the alleged conduct to any date or New Jersey doctor, patient, or prescription, or fail to show any misleading statement." *Id.* Purdue distinguishes *Talalai*, which the State cited, by contending that the case does not hold that granular pleading is always impracticable. *Id.* at 23. Finally, Purdue repeats that the State has the records that would "show the 'specificities of any particular wrongs.'" *Id.*

6. Control Over Third-Party Statements

Purdue argues that the State has not pleaded any basis to hold it liable for the statements of third parties. *Id.* at 24. The State alleges that Purdue funded or sponsored third-party materials, but Purdue contends that retention of control is critical in determining whether an agency relationship exists. *Id.* (citing *Lucheiko*, *supra*, 207 *N.J.* at 212). Purdue argues that Purdue's allegations of funding and sponsorship of third-party materials are conclusory and "insufficient to meet the State's pleading obligations." Id. at 25.

7. Statute of Limitations

***15** Purdue reiterates that allegations predating October 31, 2007 are time-barred. *Id.* at 25. Purdue argues that the State does not assert a legal theory that would toll or renew the statute of limitations for the allegations. Id Further, Purdue contends that the State does not plead the discovery rule. *Id.* at 26.

Additionally, Purdue argues that the State's continuing violation argument is meritless because it is not grounded in continued wrongful acts. *Id.* (citations omitted). According to Purdue, continued ill effects from an original violation do not constitute a continuing violation. *Id.* (citation omitted). Purdue maintains that "whether third parties continued to be misled by Purdue's alleged uncorrected misrepresentations … is irrelevant to the ***State's*** claims against Purdue, its knowledge of the misconduct, and the operation of the statute of limitations against it in this action." Id at 26-27 (emphasis in original).

III. ANALYSIS

A. LEGAL STANDARD FOR A MOTION TO DISMISS

When reviewing a complaint that is faced with a motion to dismiss for failure to state a claim upon which relief can be granted under *Rule* 4:6-2(e), the Court's "inquiry is limited to examining the legal sufficiency of the facts alleged on the face of the complaint." *Printing Mart-Morristown v. Sharp Electronics Corp.*, 116 *N.J.* 739, 746 (1989) (citation omitted). The plaintiff is "entitled to every reasonable inference of fact." *Id.* (citation omitted). The Court does not evaluate the plaintiff's ability to prove its allegations. *Id.* (citation omitted). However, the plaintiff must set forth the essential facts supporting his or her cause of action. *Scheidt v. DRS Techs., Inc.*, 424 *N.J. Super.* 188, 193 (App. Div. 2012) (citation omitted). Conclusory allegations are not sufficient. *Id.* (citation omitted).

If the Court relies on materials outside of the pleadings, the motion to dismiss converts into a motion for summary judgment. *R.* 4:6-2. However, the conversion does not occur when the materials relied on are referred to in the pleadings. *E. Dickerson & Son. Inc. v. Ernst & Young, LLP*, 361 *N.J. Super.* 362, 365 n.1 (App. Div. 2003) (citation omitted). Here, the parties agree that the motion to dismiss standard applies to this motion. *Purdue's Br.* 8-9; *State's Br.* 4-6.

B. PREEMPTION

1. Legal Standard

Under the Supremacy Clause of the federal Constitution, "state laws that conflict with federal laws are 'without effect.'" *Mut. Pharm. Co. v. Bartlett*, 570 *U.S.* 472, 479-80 (2013) (citation omitted); see *U.S. Const.*, Art. VI, cl. 2. Preemption may be express or implied. *In re Reglan Litie.*, 226 *N.J.* 315, 328 (2016) (citation omitted). Implied preemption consists of field preemption or conflict preemption, the latter of which may be relevant here. Conflict preemption occurs "where compliance with both federal and state regulations is a physical impossibility or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." hi at 329 (internal quotation marks and citations omitted). When Congress legislates in a field in which states have exercised their police powers, courts assume that Congress did not intend to supersede the states' police powers "unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 *U.S.* 555, 565 (2009) (internal quotation marks and citation omitted). The Food, Drug, and Cosmetic Act preserves state laws unless there is "a direct and positive conflict" with the Act. *Id.* at 567 (internal quotation marks and citation omitted).

2. Application

***16** Here, the Court finds that the State's allegations do not conflict with federal law. The State does not claim that the FDA-approved labeling was inadequate. Nor does the State seek to change the labeling. The State alleges that Purdue's

marketing was inconsistent with or not covered by FDA approvals. *See State's Br.* 16-27. At this stage of the litigation, the Court must accept the allegations as true and give the State all reasonable inferences. If the State is successful on the merits, Purdue would not be forced to violate federal law. Thus, it would be possible for Purdue to comply with both New Jersey and federal laws. Therefore, the Court rejects Purdue's preemption argument.

C. THE PLA'S EFFECT ON THE STATE'S PUBLIC NUISANCE CLAIM

Purdue argues that the PLA subsumes the State's public nuisance claim. It also suggested in a footnote in its initial brief and at oral argument that the PLA subsumes the State's CFA and FCA claims. *Purdue's Br.* 20 n.37. The State included a short response to the argument in its opposition brief. *State's Br.* 70. Purdue did not argue these issues in its reply brief. The Court declines to rule on whether the PLA subsumes the State's CFA and FCA claims because the issues were not fully briefed.

1. The PLA

The Legislature enacted the PLA in 1987 after finding "that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products." *N.J.S.A.* 2A:58C-1(a). The Legislature did not intend the PLA to "codify all issues relating to product liability, but only to deal with matters that require clarification." Id. The Legislature sought to "re-balance the law in favor of manufacturers." *Rowe v. Hoffman-La Roche, Inc.*, 189 *N.J.* 615, 623 (2007) (internal quotation marks and citation omitted). It "intended to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality." Id. at 623- 24 (brackets in original) (internal quotation marks and citation omitted).

The PLA defines harm as
(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

[*N.J.S.A.* 2A:58C-1(b)(2).]

A product's manufacturer or seller is liable in a product liability action for manufacturing defects, design defects, or a failure "to contain adequate warnings or instructions." *N.J.S.A.* 2A:58C-2. Under the PLA,
[a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

[*N.J.S.A.* 2A:58C-4.]

In other words, "[a] failure to warn, or a failure to warn properly, can constitute a defect in a product sufficient to support an action in strict liability." *Becker v. Baron Bros.*, 138 *N.J.* 145, 151-52 (1994) (citation omitted).

The PLA defines "product liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." *N.J.S.A.* 2A:58C-1(b)(3). Our Supreme Court has noted that this language "is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *Lead*

Paint, *supra*, 191 *N.J.* at 436-37 (citing *N.J.S.A.* 2A:58C-1(b)(3)). The Legislature "manifested its intent to replace all pre-existing claims by 'one unified, statutorily defined theory of recovery for harm caused by a product.'" *McDarby v. Merick & Co., Inc.*, 401 *N.J. Super.* 10, 96 (App. Div. 2008) (quoting *Lead Paint, supra*, 191 *N.J.* at 436). New Jersey courts have held that the PLA may subsume other causes of action when the allegations underlying those causes of action fall within the definition of a product liability action. *Lead Paint*, *supra*, 191 *N.J.* at 436-37 (public nuisance); *McDarby*, *supra*, 401 *N.J. Super.* at 95-99 (CFA); *Sinclair*, *supra*, 195 *N.J.* at 65-66 (CFA); *Bailey v. Wyeth, Inc.*, 424 *N.J. Super.* 278, 328-333 (Law Div. 2008) (CFA); *DeBenedetto v. Denny's, Inc.*, 421 *N.J. Super.* 312, 318-23 (Law Div. 2010) (CFA).

2. Public Nuisance

a. Definition

***17** The Supreme Court discussed the definition of public nuisance at length in *Lead Paint*. *Lead Paint*, *supra*, 191 *N.J.* at 421-29. It noted that "[o]ur modern concepts of public nuisance are set forth in the *Restatement (Second) of Torts.*" *Id.* at 424. Section 821B defines public nuisance as "an unreasonable interference with a right common to the general public." *Restatement (Second) of Torts* § 821B(1). Circumstances that may constitute an unreasonable interference are
(a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect on the public right.

[*Id.* at § 821B(2).]

b. The State's Claim

The State alleges that Purdue's conduct has caused the following injuries to the public:
(a) widespread dissemination of false and misleading information about the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

[*Compl.* ¶ 300.]

Purdue's alleged wrongful conduct consisted of "(a) overstat[ing] the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscur[ing] or omit[ing] the serious risk of addiction arising from such use." *Id.* at ¶ 301.

The Court finds that the PLA subsumes the State's public nuisance claim because the claim falls within the definition of a product liability action. *See N.J.S.A.* 2A:58C-1(b)(3). The State alleges that Purdue's marketing did not adequately portray the benefits and risks of its opioids. *See McDarby*, *supra*, 401 *N.J. Super.* at 95-96 (the plaintiff's CFA claim alleged that a manufacturer misrepresented the safety of a drug and failed to be truthful while marketing the drug to

prescribing physicians). The PLA covers an inadequate warning or instruction to a consumer or physician. *N.J.S.A.* 2A:58C-4: *Becker*, *supra*, 138 *N.J.* at 151-52. Additionally, the State's claimed injuries stem from "personal physical illness, injury or death; … pain and suffering, mental anguish or emotional harm;" and other losses deriving from these injuries. *N.J.S.A.* 2A:58C-1(b)(2); see *Compl.* ¶ 300. The roots of the State's claimed injuries are the physical effects of the opioids on patients.

The Court rejects the State's argument that *James* governs in this action. *James* is distinguishable because, in that case, the plaintiff (the City of Newark) accused firearms manufacturers of encouraging an illegal firearms market by not adequately supervising their distribution and producing and selling more firearms than were needed by the legitimate gun market. *James*, *supra* 359 *N.J. Super.* at 306. The plaintiff alleged that the manufacturers knew or should have known that irresponsible people would obtain the firearms and commit crimes, which would result in violence, injuries, and death. Id. The plaintiff would suffer damages because of these crimes. Id. The Court finds that the claims in *James*, unlike here, did not involve misrepresentations or omissions regarding the dangers of the product at issue. In other words, the alleged injuries in *James* did not arise from a failure to adequately warn or instruct a consumer about the product. Moreover, the trial court had dismissed the plaintiff's claim under the PLA and claim that the defendants' failed to adequately warn of the firearms' dangerous propensities. *Id.* at 328. Here, the State alleges that Purdue did not properly represent the benefits and risks of its opioid medications, which caused injuries like addiction and overdoses. The Court concludes that the allegations in this action are similar to the allegations in *Lead Paint*, *McDarby*, *Sinclair*, *Bailey*, and *De Benedetto* because they concern a products liability action as defined by the PLA. *N.J.S.A.* 2A:58C-1(b)(2)-(3).

***18** Therefore, the Court dismisses the State's public nuisance claim with prejudice for failure to state a claim upon which relied can be granted under *Rule* 4:6-2(e).

D. TIME-BARRED CLAIMS

1. Statute of Limitations

Purdue argues that "the State's claims are subject to, at most, a ten year statute of limitations period for any alleged wrongful act." *Purdue's Br.* 22. Thus, it contends that any acts or omissions before October 31, 2007 are time-barred. *Id.* The State argues that "Purdue's failure to correct its prior misrepresentations constitutes a series of material and actionable omissions during the relevant time period." *State's Br.* 32. The State alleges that Purdue's "misrepresentations have persisted and have continued to influence and prescribers and consumers to this day." Id. at 32-33.

The general statute of limitations for civil actions commenced by the State provides that
[e]xcept where a limitations provision expressly and specifically applies to actions commenced by the State or where a longer limitations period would otherwise apply, and subject to any statutory provisions or common law rules extending the limitations periods, any civil action commenced by the State shall be commenced within ten years next after the cause of action shall have accrued.

[*N.J.S.A.* 2A:14-1.2(a).]

The CFA does not contain a statute of limitations within the statute itself. Rather, it uses the six-year general limitation from *N.J.S.A.* 2A:I4-1. *Mirra v. Holland America Line*, 331 *N.J. Super.* 86, 90 (App. Div. 2000). The FCA's statute of limitations provides that
[a] civil action under this act may not be brought:

a. More than six years after the date on which the violation of the act is committed; or

b. More than three years after the date when facts material to the right of action are known or reasonably should have been known by the State official charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

[*N.J.S.A.* 2A:32C-11.]

Here, the Court finds that all alleged acts or omissions that occurred prior to October 31, 2007 are time-barred. The State cites no authority for its argument that failing to correct a prior misrepresentations constitutes a new, independent violation. The State does not explain how merely failing to correct a prior misrepresentation is a new violation. Additionally, the Court finds that Purdue's "mere failure to right a wrong and make plaintiff whole cannot be a continuing wrong which tolls the statute of limitations," or else "the exception would obliterate the rule." *Russo Farms v. Vineland Bd. of Educ.* 144 *N.J.* 84, 114 (1996) (internal quotation marks and citation omitted). If Purdue repeated these alleged misrepresentations within the limitations period, the repeated misrepresentation may constitute an act or omission that violates the CFA or FCA. However, the mere failure to correct a prior misrepresentation is not a new act or omission.

The Court will, however, allow the State to keep allegations of conduct prior to October 31, 2007 in the Complaint to provide context for the later conduct. However, these acts or omissions are time-barred and Purdue's mere failure to correct these alleged misrepresentations is not a continuing or new violation.

2. FCA's Effective-Date

***19** Purdue argues that the FCA does not apply retroactively. *Purdue's Br.* 24. The State counters that the Legislature intended to permit "causes of action occurring after the effective date of the statute that are premised upon either completed acts of fraud or ongoing conduct." *State's Br.* 27-28 n. 15 (internal quotation marks omitted) (quoting *Hayling*, *supra*, 422 *N.J. Super.* at 372).

The FCA was enacted on January 13, 2008 but did not take effect until March 13, 2008. *Hayling*, *supra*, 422 *N.J. Super.* at 367, 369. In *Hayling*, the Appellate Division held that "the NJFCA is not retroactively applicable to conduct occurring prior to its effective date." *Id.* at 369-70 (citation omitted): *see id.* at 376.

The portion quoted by the State concerned testimony of the FCA's co-sponsor, Assemblyman Herb Conaway, Jr. Mr. Conaway had testified before the Assembly Judiciary Committee, where he described the FCA
as New Jersey's whistle blower statute which tracks the federal law that allows private individuals with the knowledge of *past or present fraud* to the federal, and in this case, state government to sue on behalf of the government to recover the losses to the public for fraudulently obtained public monies.

[*Id.* at 372 (emphasis in original) (internal quotation marks and citation omitted).]

The plaintiff in *Hayling* argued that this testimony constituted legislative intent to apply the FCA retroactively. *Id.* The Appellate Division rejected this argument. *Id.* It "decline[d] to give any interpretive weight to the Assemblyman's testimony as construed by Hayling." *Id.* at 373 (citation omitted). Instead, it said that "it is far more reasonable to construe the phrase in which the word 'past' is found as an expression of the Legislature's intent to permit statutory causes of action occurring after the effective date of the statute that are premised upon either completed acts of fraud or ongoing conduct." *Id.* at 372. The court noted that Mr. Conaway's comments were not an official sponsor's statement and were not included in the Assembly Judiciary Committee's statement for the bill. Id. at 373.

The quotation cited by the State is dictum because the Appellate Division held that the FCA "provides clear evidence of the Legislature's intent that the Act be applied prospectively." *Id.* at 371. As such, the court needed "no further analysis to buttress [its] conclusion that the motion judge properly decided this issue." *Id.* The portion of the opinion cited by the State was *on page 372 of the opinion. Thus, it was not part of the holding.*

Here, the Court rejects the State's argument that Purdue's conduct before the FCA's effective date may subject it to liability under the FCA. The FCA's language does not make the statute effective until March 13, 2008. *Id.* at 367, 369. Purdue's liability would come under section 3 of the FCA for knowingly presenting or causing to be presented "a false or fraudulent claim for payment or approval" or knowingly making, using, or causing "to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State." *N.J.S.A.* 2A:32C-3(a)-(b). Purdue's misrepresentations allegedly caused health care providers to present medically unnecessary claims for reimbursement to the State. Thus, the State is seeking to hold Purdue liable under the FCA for misrepresentations it made before the FCA's effective date for reimbursement claims that were made after the effective date. The Court finds that the FCA's language does not impose liability for knowingly causing the presentation of a false or fraudulent claim or knowingly causing the making or use of a false record or statement if the conduct occurred before the effective date. Purdue did not have notice of the potential FCA liability when its conduct allegedly occurred. Additionally, as the Court determined above for the statute of limitations issue, Purdue's conduct was not a continuing wrong. Therefore, the Court concludes that Purdue is not liable under the FCA for its conduct that occurred before March 13, 2008.

E. PARTICULARITY

1. Legal Standard

***20** For allegations of misrepresentation or fraud, *Rule* 4:5-8(a) provides that the "particulars of the wrong, with dates and items if necessary, shall be stated insofar as practicable. Malice, intent, knowledge, and other condition of mind of a person may be alleged generally." *R.* 4:5-8(a). The purpose of the rule "is to require the pleader to state the facts which are relied on as constituting the wrong with enough particularity to enable the person charged to deny or disprove or explain these facts. It was not intended to encourage motions to strike pleadings or motions for judgment on the pleadings." *Evangelista v. Public Service Coordinated Transport*, 7 *N.J. Super.* 164, 168-69 (App. Div. 1950) (analyzing the former Rule 3:9-1).

2. CFA Claims

Rule 4:5-8(a) applies to CFA claims, so they must "be pled with specificity to the extent practicable." *Hoffman v. Hampshire Labs. Inc.*, 405 *N.J. Super.* 105, 112 (App. Div. 2009). The CFA provides that
[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any such person has in fact been misled, deceived or damaged thereby, is considered to be an unlawful practice.

[*N.J.S.A.* 56:8-2.]

The Attorney General may prosecute the CFA. He "must prove that the Act has been violated, but does not have to prove that the victim of the fraudulent conduct had in fact been misled, deceived or damaged thereby." *Meshinsky v. Nichols Yacht Sales, Inc.*, 110 *N.J.* 464, 473 (1988) (internal quotation marks and citation omitted). The Attorney General may bring a "broader category of actions" than a private plaintiff. *Thiedemann v. Mercedes-Benz USA. LLC*, 183 *N.J.* 234,

250 (2005). This category "encompasses circumstances where there is no ascertainable loss to an individual but there exists an industry practice that the State seeks to curtail." *Id.*

The Court finds that the State has adequately pleaded its CFA claims. The Court agrees with the State that these details are matters of discovery. This action is similar to *Talalai*, where the Law Division held that the plaintiffs adequately pleaded their CFA claims. There, the defendant argued that the plaintiffs did not meet the standard of *Rule* 4:5-8(a) because the complaint did not "include any information regarding the dates plaintiffs purchased their Cooper tires, the types of tires purchased, how much they paid, where they bought the tires, whether they still use them, or any other identifying information regarding them." *Talalai*, *supra*, 360 *N.J. Super.* at 555. The court held that these items were matters of discovery. *Id.* at 564. The complaint had included "a detailed description of the alleged faulty manufacturing process and the fact that the defendant [did] not disclose this information to consumers." *Id.*

Here, the Court finds that the Complaint provides enough details of Purdue's marketing scheme to survive a motion to dismiss. *See State's Br.* 37-38 (citing various portions of the Complaint). There are enough details for Purdue to deny, disprove, or explain the allegations. The Court rejects Purdue's contention that the State, rather than Purdue, "has access to any records that would purport to show the 'specificities of any particular wrongs.'" *Purdue's Reply Br.* 23; *see id.* at 13-14. The Court disagrees because Purdue would possess or have access to the records detailing the who, what, when, and where of its representatives' conduct. See *Purdue's Br.* 25-26. These alleged misrepresentations were not made directly to the State. As mentioned above, the State need not prove reliance, so the recipient of Purdue's messages is not critical at this stage.

3. FCA Claims

***21** The FCA imposes joint and several liability for a civil penalty on a person who
a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State.

[*N.J.S.A.* 2A:32C-3(a)-(b).]

The parties did not present any published opinions from New Jersey courts concerning the pleading requirements for the New Jersey FCA. However, the State acknowledges that courts in other jurisdictions have required heightened pleading in false claims litigation. *State's Br.* 39. The Court agrees that *Rule* 4:5-8(a) should apply to FCA claims.

The Court finds the Third Circuit's interpretation of the federal FCA to be instructive on this issue. Federal Rule of Civil Procedure 9(b) is similar to *Rule* 4:5-8(a). It requires a party alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Fed. R. Civ. P.* 9(b). The Third Circuit does not require a plaintiff to "identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief." *Foglia*, *supra*, 754 *F.*3d at 156 (emphasis in original) (internal quotation marks and citation omitted), The plaintiff "must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 157-58 (internal quotation marks and citation omitted). The plaintiff must allege "[s]ufficient facts to establish a plausible ground for relief." *Id.* at 158 (internal quotation marks and citation omitted).

Here, the Court finds that the State has adequately pleaded FCA claims. The State has alleged that Purdue's marketing misrepresented its drugs, which caused prescribers to write medically unnecessary prescriptions. See *State's Br.* 42-44

(citing various portions of the Complaint). The State asserts that medically unnecessary prescriptions are not eligible for reimbursement under its health programs. *See Compl.* ¶¶ 205, 212, 215, 217-18, 226, 228-29. The Court finds that this theory is plausible. Whether the State should have known that the prescriptions were medically unnecessary is an inappropriate question for a motion to dismiss. As previously stated in the Court's analysis for the CFA claims, Purdue possesses or has access to the information regarding its representatives' conduct. It is true that the State has or should have the records for the actual reimbursement claims. However, Purdue's liability stems from the alleged misrepresentations that it made to health care providers. The State needs more information from Purdue during discovery to help it identify the false claims. As with the CFA claims, the Court finds that these details are matters of discovery.

F. CONTROL OVER THIRD PARTIES

1. Legal Standard

***22** The New Jersey Supreme Court has ruled that "[a]n agency relationship is created when one party consents to have another act on its behalf, with the principal controlling and directing the acts of the agent." *Sears Mortgage Corp. v. Rose*. 134 *N.J.* 326, 337 (1993) (citations omitted). An agreement specifying the relationship is unnecessary because "the law will look to their conduct and not to their intent or their words as between themselves but to their factual relation." Id. (internal quotation marks and citation omitted). The trier of fact determines whether an agency relationship exists unless one of the litigants establishes the standard to obtain summary judgment. *See Miller v. Linde*, 33 *N.J. Super.* 41, 43-44 (App. Div. 1954) (citations omitted).

2. Application

The Court is applying the motion to dismiss standard, which assumes that the State's allegations are true and gives the State every reasonable inference of fact. The published decisions cited by the parties were reviewing decisions made at the summary judgment or trial stages. *Sears Mortgage Corp.*, *supra*, 134 *N.J.* at 336-37; *Miller*, *supra*, 33 *N.J. Super.* at 43; *Gen. Bldg. Contractors Ass'n, Inc.*, *supra*, 458 *U.S.* at 378, 380-82; *Luchejko*, *supra*, 207 *N.J.* at 195; *Baldasarre v. Butler*, 132 *N.J.* 278, 287-88 (1993).

The Court finds that the State has adequately pleaded that Purdue controlled third party publications and events. The State alleges that Purdue controlled the unbranded marketing platforms named *Partners Against Pain* and *In the Face of Pain*, which "disseminate[d] misleading messages about the risk of addiction." *Compl.* ¶ 87; *see id.* ¶¶ 88, 92; *State's Br.* 65. These allegations satisfy the motion to dismiss standard. The State alleges that Purdue funded or sponsored symposiums and continuing medical education seminars. *Compl.* ¶¶ 105, 113. The Court finds that, at the motion to dismiss stage of this action, it is reasonable to infer that Purdue had control over the messaging at these events. Additionally, the State alleges that Purdue funded organizations that disseminated misleading material. *Id.* at ¶¶ 65-67, 70-72, 95, 97-98. The Court finds that, at the motion to dismiss stage of this action, it is reasonable to infer that Purdue had control over the statements made by these organizations.

G. CAUSATION

Purdue argues that the State's FCA claim fails for two reasons. First, the learned intermediary doctrine breaks the causal chain. Second, the State does not adequately plead but-for causation. Third, the allegations do not adequately plead proximate causation.

1. Learned Intermediary Doctrine

Purdue argues that "the learned intermediary doctrine alone breaks any causal connection." *Purdue's Br.* 31. Under the learned intermediary doctrine, "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." *Niemiera v. Schneider*, 114 *N.J.* 550, 559 (1989) (citation omitted). The manufacturer must give "proper warning of the danger or side effects of the product." Id. at 562. The warning must include the "risks attendant to" the drug. *Perez*, *supra*, 161 *N.J.* at 14 (citation omitted).

Here, assuming that the learned intermediary doctrine applies to the causation analysis, the Court finds that the doctrine does not break the causal connection. The State alleges that Purdue misrepresented the benefits and risks of its drugs. These alleged misrepresentations were inconsistent with the warnings on the FDA-approved labeling. If these allegations are true, the warning to the health care providers would not have been proper or adequate. Therefore, the Court rejects Purdue's argument that the learned intermediary doctrine breaks any causal connection.

2. But-For Causation

***23** Purdue contends that the Complaint does not adequately plead but-for causation because "the State fails to allege that, prior to prescribing a State-reimbursed opioid medication, *any* New Jersey doctor *ever* read, heard, or otherwise received—let alone relied on—any purported misrepresentation made by Purdue." *Purdue's Br.* 29 (emphasis in original). For the reasons stated above in section 111(E)(3), the Court finds that the State has adequately pleaded but-for causation. One can reasonably infer from the allegations in the Complaint that the State would not have reimbursed some prescriptions if Purdue's representatives had not made misrepresentations to physicians.

3. Proximate Causation

Purdue argues that the allegations do not adequately plead proximate causation because the causal chain is too attenuated. *Purdue's Br.* 29. The parties did not cite published opinions from New Jersey state courts on the issue of causation under the New Jersey FCA. However, the Court agrees with the State that Third Circuit cases interpreting the federal FCA are instructive. The Third Circuit and the Eastern District of Pennsylvania have held that the FCA applies the substantial factor test. An "illegal marketing scheme must be a 'substantial factor' in influencing third parties, such as physicians[,] to file false claims." *Bergman*, *supra*, 995 *F. Supp.* 2d at 368 (citation omitted). Under the substantial factor test, "the intervention of a force which is a normal consequence of a situation created by the actor's … conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about." *United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 244 (3d Cir. 2004) (ellipses in original) (internal quotation marks and citation omitted) (quoting *Restatement (Second) of Torts* § 443).

Bergman is similar to the allegations in this action. The plaintiff alleged that the defendant "falsely and misleadingly market its prescription drug TriCor for off-label and medically unnecessary uses." *Bergman*, *supra*, 995 *F. Supp.* 2d at 359; *see id.* at 361. Plaintiff alleged that the defendant knew and hoped that its marketing scheme "would cause the submission of many thousands of false claims to be submitted to" government funded health insurance programs. Id. at 362. The district court denied defendant's motion to dismiss the plaintiff's federal FCA issues. *Id.* at 370, 372.

Here, the Court finds that the State's allegations meet the substantial factor test. The Complaint sufficiently alleges that Purdue marketed its prescription drugs to health care providers. *State's Br.* 52-53 (citing *Compl.* ¶¶ 32, 85-105, 113, 177). The State alleges that Purdue intended its marketing scheme to increase the amount of prescriptions for its drugs. *Compl.* ¶ 236. Moreover, the State's payment for some of these prescriptions was a foreseeable and intended consequence. *Id.* In other words, the end result—State-reimbursed prescription claims—allegedly was anticipated and desired by Purdue. The Court concludes that it is a reasonable inference that the prescribing of these drugs, the filling of these prescriptions, the submission of the reimbursement forms, and the State's payment of the claims for reimbursement are foreseeable

and normal consequences of such marketing efforts. At the pleading stage, the Court does not find that this causal chain is too attenuated.

IV. DECISION

For the foregoing reasons, the Court grants in part Purdue's motion to the following extent:
1. Count Five of the Complaint is dismissed with prejudice;

2. For Count Four, Purdue's conduct before March 13, 2008 is time-barred; and

3. For all counts, Purdue's conduct before October 31, 2007 is time-barred.

***24** The Court denies the remainder of Purdue's motion. An order memorializing this decision has been prepared by the Court and shall be entered today.

Dated: October 2, 2018

<<signature>>

Hon. Thomas M. Moore, J.S.C.

Footnotes

1 At the time of filing, Christopher Porrino was the Attorney General and Sharon Joyce was the Acting Director of the New Jersey Division of Consumer Affairs.

2 Purdue agrees with this point in its reply. *Purdue Reply Br.* 14 n.4.

End of Document

EXHIBIT 7

2018 WL 4566129 (N.H.Super.) (Trial Order)
Superior Court of New Hampshire.
Merrimack County

STATE of New Hampshire,
v.
PURDUE PHARMA INC., Purdue Pharma L.P., and The Purdue Frederick Company.

No. 217-2017-CV-00402.
September 18, 2018.

Order

John C. Kissinger, Jr., Judge.

***1** The State of New Hampshire (the "State") alleges Purdue Pharma Inc., Purdue Pharma L.P., and The Purdue Frederick Company (collectively "Purdue") are culpable for the deleterious effects of widespread opioid abuse within the State and asserts the following claims: Count I, deceptive and unfair acts and practices contrary to the Consumer Protection Act; Count II, unfair competition contrary to the Consumer Protection Act; Count III, false claims in violation of the Medicaid Fraud and False Claims Act; Count IV, public nuisance; Count V unjust enrichment; and Count VI, fraudulent or negligent misrepresentation. Purdue moves to dismiss all claims and the State objects. The Court held a hearing on this matter on April 24, 2018. For the following reasons, Purdue's motion to dismiss is DENIED regarding Counts I, II, III, IV, and VI, and GRANTED regarding Count V.

I. *Background*

Prescription opioids are derived from and possess properties similar to opium and heroin and, by binding to receptors on the spinal cord and brain, they dampen the perception of pain following absorption. (Compl. ¶ 2.) Opioids can also be addictive, produce euphoria, and, in high doses, slow a users breathing and possibly cause death. (*Id.*) Withdrawal symptoms such as anxiety, nausea, headaches, tremors, delirium, and pain often result if sustained opioid use is discontinued or interrupted, and users generally grow tolerant of opioids' analgesic effects after extended continuous use, thereby necessitating progressively higher doses. (*Id.*) Purdue manufactures, advertises, and sells prescription opioid medications, including the brand-name drug OxyContin. (*Id.* ¶ 1.)

Due to the drugs' downsides, the State maintains that before the 1990s opioids were generally used only to treat short-term acute pain and during end-of-life care. (*Id.* ¶ 3.) At odds with this understanding, however, Purdue developed OxyContin in the mid-1990s to treat chronic long-term pain. (*Id.* ¶ 4.) To foster the drug's market for this then unconventional use, the State alleges Purdue instigated a deceptive multidimensional marketing effort to unlawfully alter the public's and the medical community's perception of the risks, benefits, and efficacy of opioids for treating chronic pain. (*E.g.*, *id.* ¶¶ 4-41.)

The State claims Purdue's efforts resulted in a dramatic increase in ill-advised or unlawful opioid prescriptions and, correspondingly, in pervasive opioid abuse. (*E.g.*, *id.* ¶¶ 168-86-) The State further claims that Purdue's manipulative conduct wrongfully caused the State's Medicaid program to pay for opioid prescriptions it would have otherwise not or sought to avoid, (*e.g.*, *id.* ¶ 248), necessitated that the State implement costly social, law enforcement, and emergency services to support, police, and treat those impacted by opioid abuse, (*e.g.*, *id.* ¶ 261), and generally hampered the wellbeing and productivity of many individuals, families, and businesses within New Hampshire, (*e.g.*, *id.* ¶ 261).

II. *Analysis*

Purdue raises three categories of arguments in favor of dismissal. Initially, Purdue contends that federal law preempts all the State's claims. Next, Purdue argues that, to the extent causation is a necessary element of the State's legal theories, the State has failed to sufficiently plead that Purdue proximately caused the harms for which the State seeks to hold Purdue responsible. Lastly, Purdue raises a series of claim specific arguments. The Court will address these matters in turn.

i. Preemption

***2** Article VI, Clause 2 of the Federal Constitution provides that federal law "shall be the supreme Law of the Land." The Federal Constitution, therefore, "preempts state laws that interfere with, or are contrary to, federal law." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268, 282 (3d Cir. 2017) (quotations omitted). There are three general varieties of preemption:

> (1) express preemption, which occurs when the language of the federal statute reveals an express congressional intent to preempt state law; (2) field preemption, which occurs when the federal scheme of regulation is so pervasive that Congress must have intended to leave no room for a State to supplement it; and (3) conflict preemption, which occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Cerveny v. Aventis, Inc., 855 F.3d 1091, 1097-98 (10th Cir. 2017) (quotation and ellipsis omitted).

Purdue raises only a conflict preemption theory. Specifically, Purdue argues that the United States Food and Drug Administration's (the "FDA") various decisions regarding OxyContin's risks and medically appropriate uses conflict with the State's claims that Purdue improperly promoted its opioid medications because "[a] plaintiff cannot maintain a claim that a prescription medicine's … marketing consistent with the [drug's FDA sanctioned] labeling is inadequate or misleading unless the manufacturer could have unilaterally changed the labeling — that is, changed the labeling without first obtaining FDA approval." (Defs.' Mem. of Law and Authorities in Support of Mot. to Dismiss [hereinafter "Mot. to Dismiss"] at 10.)

Purdue is correct that numerous courts have concluded that state law claims involving an FDA approved prescription drug are preempted when a plaintiff asserts that a defendant unlawfully included misleading information, or failed to include important warnings, in the drug's label" [1] and where the defendant could not unilaterally alter the drug's label and/or there is "clear evidence" that the FDA would not approve a change to the label if sought by the defendant. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623 (2011); *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *Cerveny v. Aventis, Inc.*. 855 F.3d 1091, 1095 (10th Cir. 2017): *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 38 (1st Cir. 2015); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1165-66 (S.D. Cal. 2016): *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1266 (W.D. Okla. 2011).

***3** Notably, these cases involved purported misrepresentations within, or material omissions from, a drug's label; meaning to ameliorate the wrongdoing alleged under state law, the drug manufacturer defendants would have been required to alter their product's FDA approved label. In this instance, however, the State maintains that it "does not seek a change to the FDA-approved labeling of Purdue's drugs," but rather that the State "contend[s] that Purdue

aggressively marketed its opioids for long-term use to treat chronic pain through misrepresentations that were intended to lead doctors to prescribe the drugs even in circumstances where they were inappropriate, *i.e.*, to disregard cautions that the FDA itself has recognized as appropriate and necessary." (PL's Resp. in Opp'n to Purdue Defs.' Mot- to Dismiss Pl.'s Compl. [hereinafter "Obj."] at 8.) In other words, the State alleges "Purdue marketed opioids in a manner that *is contrary to, inconsistent with, or outside of* their FDA-approved labels." (*Id.* at 10 (emphasis in original).)

Notwithstanding the State's characterization of its claims, Purdue insists it is nevertheless entitled to dismissal because "each of the … alleged misrepresentations the State has identified involves statements or conduct that *are consistent* with the FDA-approved labeling for its medications or with other regulatory decisions of the FDA." (Defs.' Reply in Supp. of Mot. to Dismiss [hereinafter "Reply"] at 7 (emphasis added).) Thus, at bottom, Purdue grounds its preemption argument on the notion that the Court should decide that Purdues marketing of its opioid medications was consistent, as opposed to inconsistent, with FDA decisions relating to the drugs' labeling. Even assuming it is proper to take up such a necessarily fact intensive inquiry in a motion to dismiss, it is reasonable to construe Purdue's purported marketing efforts as *inconsistent* with the FDA's approvals when drawing ail inferences in the State's favor. *See Tessier v. Rockefeller*, 162 N.H. 324, 330 (2011) (setting forth the Court's standard for reviewing motions to dismiss).

For example, beginning sometime in the mid-2000s, Purdue updated OxyContin to include a new coating designed to make the drug difficult to crush and added certain elements intended to make the drug unsuitable for injection. (Compl. ¶ 110.) These changes were purportedly meant to deter OxyContin abuse via snorting and injection. The State alleges, however, that evidence shows, and "Purdue knew or should have known," that the "reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused," (*id.* ¶ 114 (quotation omitted)), because the abuse-deterrent "properties can be defeated" and the drug "can be abused orally notwithstanding their abuse-deterrent properties," (*id.* ¶ 113). Therefore, the State claims Purdue deceptively marketed OxyContin, considering its "sales representatives regularly use the so-called abuse-deterrent properties … as a primary selling point" to differentiate the drug from its competitors, (*id.* ¶ 112), and, more specifically, that Purdue's sale representatives:

> (1) claim that Purdue's [abuse-deterrent] formulation *prevents* tampering and that its [abuse-deterrent] products *cannot he* crushed or snorted; (2) claim that Purdue's [abuse-deterrent] opioids *prevent or reduce* opioid abuse, diversion, and addiction; (3) assert or suggest that Purdue's [abuse-deterrent] opioids are "safer" than other opioids; and (4) fail to disclosed that Purdue's [abuse-deterrent] opioids do not impact oral abuse or misuse and that its [abuse-deterrent] properties are and can be easily overcome.

(*Id.* (emphasis in original as well as added).)

Purdue counters that these allegations are "consistent with FDA-approved labeling," (Mot. to Dismiss at 17), because, in 2013, the FDA approved a change to OxyContin's label, stating "OXYCONTIN is formulated with inactive ingredients intended to make the tablet more difficult to manipulate for misuse and abuse." (Mot. to Dismiss, Ex. 6 § 9.2.)

***4** Drawing all inferences in the State's favor statements to the effect that OxyContin's abuse-deterrent properties "*prevent* tampering," result in a drug that "*cannot* be crushed or snorted," and in practice "*prevent or reduce* opioid abuse" may reasonably be read as attributing more significance to the abuse-deterrent properties than the FDA intended when it seemingly found the abuse-deterrent properties merely make the drug somewhat "more difficult to manipulate." In this way, Purdue's alleged conduct could be found materially inconsistent with FDA approved labeling.

The parties' dispute over the proper inferences to draw from the State's claims regarding OxyContin's abuse-deterrent properties relates to only one of many allegations of wrongdoing raised in the complaint. It is inappropriate at this

stage to comprehensively parse each of the remaining allegations in writing. However, having thoroughly reviewed the complaint and its many allegations, and considered the parties' voluminous filings relevant to Purdue's motion and their accompanying exhibits, the Court concludes Purdue has not shown that the State's allegations wholly reflect conduct consistent with FDA approved labeling. Accordingly, because Purdue's conflict preemption theory presupposes its alleged marketing efforts were consistent with its drugs' labeling, Purdue's motion is DENIED to the extent it raises preemption.

ii. Causation

Next, Purdue maintains that the State has not properly pled causation for three general reasons. First, Purdue argues that "the State fails to adequately allege a causal connection between any misrepresentation by Purdue and any reimbursement decision by, or other alleged harm to, the State." (Mot. to Dismiss at 19.) Second, Purdue contends that, even if the State has articulated a "causal connection," independent acts and actors necessarily intervened such as to "break any connection between any alleged misrepresentation by Purdue and the litany of alleged harms." (*Id.* at 3.) Lastly, Purdue asserts that "[e]ven if the State had alleged a causal chain linking any alleged wrongdoing with any alleged harm … its claims would still fail because any such chain would be far too attenuated as a matter of law." (*Id.* at 3-4.)

a. Alleged Causal Connection

As a preliminary matter:

> It is axiomatic that in order to prove actionable negligence,[2] a plaintiff must establish that the defendant['s wrongdoing] proximately caused the claimed injury. The proximate cause element involves both cause-in-fact and legal cause. Cause-in-fact requires the plaintiff to establish that the injury would not have occurred without the negligent conduct. The plaintiff must produce evidence sufficient to warrant a reasonable juror's conclusion that the causal link between the negligence and the injury probably existed.

Estate of Joshua T., 150 N.H. 405, 407-08 (2003) (citations and quotations omitted).

Contrary to Purdue's position, the State has in fact articulated a causal connection linking Purdue's purported misconduct to the State's alleged harms. For example, the State asserts that, beginning in approximately 2011, an "increase in prescribing opioids correspond[ed] with [a] Purdue[] marketing push." (Compl. ¶ 171.) Allegedly, "the largest component of this [marketing push] was sale representative visits to individual prescribes," (*id.*), because Purdue "knows that in-person marketing works," (*id.* ¶ 173.) Indeed, an Amherst, New Hampshire, physician opines in the complaint that Purdue's in-person sales representatives impact prescribing behavior because, "[i]f it didn't, they wouldn't do it." (*Id.* ¶ 176.) Furthermore, as detailed in the previous section, the State alleges Purdue's sale representatives misleadingly marketed OxyContin. (*See also*, *e.g.*, id. ¶ 30 ("To spread its false and misleading messages supporting chronic opioid therapy, Purdue marketed its opioids directly to health care providers and patients … in New Hampshire. It did so principally through its sales force … who made in-person sales calls to prescribers in which they misleadingly portrayed chronic opioid therapy.").)

***5** The State also alleges that

> Purdue buttressed its direct promotion of its opioids with an array of marketing approaches that bolstered the same deceptive messages by filtering them through seemingly independent and objective sources. Purdue recruited and paid physician speakers to present talks on opioids to their peers at lunch and dinner events. It funded biased research and sponsored [continuing medical education ("CME")] that misleadingly portrayed the risks and benefits of chronic opioid therapy. It collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation ("APF"), to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids. And it created "unbranded" websites and materials, copyrighted by Purdue but implied to be the work of separate organizations, that echoed Purdue's branded marketing. Among these tactics, all of which organized in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in New Hampshire: Purdue's capture, for its own ends, of physicians' increased focus on pain treatment; its efforts to seed the scientific literature on chronic opioid therapy; and its corrupting influence on authoritative treatment guidelines issued by professional associations. [3]

(*Id.* ¶¶ 40-41.)

Considering the State claims that "[s]cientific evidence demonstrates a close link between opioid prescriptions and opioid abuse," [4] and because the allegations outlined above indicate Purdue successfully increased opioid prescriptions using misleading methods, the complaint asserts a prima facie causal connection between Purdue's purported wrongdoing and increased opioid prescriptions and abuse. [5]

***6** Nevertheless, Purdue contends that the State's supposedly "general allegations do not satisfy the State's burden to plead the essential element of a causal connection between an actual alleged fraudulent or improper statement or action by Purdue and an actual alleged injury to the State" and that the State cannot "avoid its pleading obligation by arguing that it will be able to rely on statistical evidence and extrapolation to prove causation and injury at trial." (Reply at 10 (quotation omitted).) in other words, Purdue seemingly maintains that to satisfy its burden the State must principally rely upon individualized evidence, *i.e.* evidence that specific doctors were influenced by specific Purdue misconduct and that any alleged injury to the State must be tied directly to these specific incidents.

Purdue, however, cites no authority mandating such a standard. [6] Conversely, the First Circuit found "aggregate" evidence of the sort the State apparently intends to rely sufficient to prove wrongdoing on the part of a different drug manufacturer alleged to have undertaken comparable deceptive marketing efforts. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 46 (1st Cir. 2013); *State v. Exxon Mobil Corp.*, 168 N.H. 211, 255-56 (2015) ("[T]he trial court's determination that the use of statistical evidence and extrapolation to prove injury-in-fact was proper was not an unsustainable exercise of discretion." (Citing *Neurontin*, 712 F.3d at 42 ("[C]ourts have long permitted parties to use statistical data to establish causal relationships."))). Accordingly, the Court is not persuaded that the State has insufficiently articulated a causal connection nor that it has referenced inadequate factual support for its assertions at this stage.

b. intervening Acts or Actors

Purdue next argues that "any connection between Purdue's alleged misconduct and the State's alleged injuries depends on multiple independent, intervening events and actors." (Mot. to Dismiss at 21.) Specifically, Purdue maintains that, in New Hampshire, individuals may only legally obtain opioids via a prescription following an in-person doctor's visit and, therefore, "the role of the prescribing physician as a 'learned intermediary' breaks the causal chain that the State attempts to use to connect Purdue to the State's payments for prescriptions." (*Id.*)

"The learned intermediary' doctrine creates an exception to the general rule that one who markets goods must warn foreseeable ultimate users about the inherent risks of his products" and, in the prescription drug context "provides that a drug manufacturers duty is limited to the obligation to advise the prescribing physician of any potential dangers that may result from the use of the drug." *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 519 (11th Cir. 2007) (emphasis omitted). In other words, 'application of the 'learned intermediary doctrine' may have the effect of destroying the causal link between the allegedly defective product, and the plaintiff's claimed injury." *Id.*

Under the doctrine, however, a drug manufacturer's duty is only fulfilled "once it *adequately* warns the physician." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) (emphasis added). The State argues that "the adequacy of any warning provided by Purdue is an issue of fact that cannot be resolved on a motion to dismiss." (Obj. at 19.) Given the fact intensive nature of such an inquiry, the Court agrees. See *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006) (reasoning that where, as here, the plaintiff's claim is not whether a prescription drug warning "is inadequate because [certain dangers were] not mentioned" but, "[r]ather, [that the warning was] misleading as to the risk level [of those dangers]," the "adequacy questions [should] go to the jury"); *see generally Carignan v. New Hampshire Int'l Speedway, Inc.*, 151 N.H. 409, 414 (2004) ("Proximate cause is generally for the trier of fact to resolve").

***7** Moreover, "[o]ne escape hatch from the application of the learned intermediary rule is if the Plaintiff can demonstrate it was reasonably foreseeable that physicians, despite awareness of the dangers of [the drug], would be consciously or subconsciously *induced* to prescribe the drug when it was not warranted." *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 272 (D. Me. 2004) (quotation omitted) (emphasis added). Indeed, the court attributed as the first to formulate the doctrine [7] only did so after making the following observation:

it is difficult to see on what basis this defendant can be liable to plaintiff. It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsover. To physicians it did make representations. *And should any of these be false it might be claimed with propriety that they were made for the benefit of the ultimate consumers.* But there is no such claim.

Marcus v. Specific Pharm., 77 N.Y.S.2d 508, 509 (N.Y. Spe. Term 1948) (emphasis added).

The State alleges here that Purdue's purported deceptive marketing efforts were "intended to lead doctors to prescribe [opioids] even in circumstances where they were inappropriate, *i.e.*, to disregard cautions that the FDA itself has recognized as appropriate and necessary." (Obj. at 8.) Thus, because the State maintains that Purdue sought to induce physicians to ignore or rely less heavily on the well understood risks of opioid use when making prescribing decisions, the learned intermediary doctrine may offer no safe harbor notwithstanding Purdue's contention that "it is beyond dispute that FDA-approved labeling for Purdue's opioid products discloses [the drugs'] risks prominently." (Mot. to Dismiss at 22.)

This conclusion finds support in jurisdictions that have considered the issue. As referenced in the previous section, several years ago the First Circuit considered comparable claims of wrongdoing on the part of a different drug manufacturer. *In re Neurontin Mktq. & Sales Practices Litiq.*, 712 F.3d 21 (1st Cir. 2013). [8] Like Purdue, that drug manufacturer "agrue[d] that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes." *Id.* at 39. The *Neurontin* court rejected this argument, concluding that the defendant's "scheme relied on the expectation that physicians would base their prescribing decisions in part on

[its] fraudulent marketing" and "[t]he fact that some physicians may have considered factors other than [the defendant's] detailing materials in making their prescribing decisions does not add such attenuation to the causal chain as to eliminate proximate cause." *Id.*

More recently, the District of California also addressed claims akin to the State's. *U.S. ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK SSX, 2014 WL 3605896 (C.D. Cal. July 10, 2014). In that case, the drug manufacturer defendant similarly argued that the court should "presume that physicians based their prescription decisions on their own independent medical judgment and the needs of their patients." *Id.* at *8. That court likewise rejected this argument, reasoning that "[t]o suggest that [the defendant's] alleged expansive, multi-faceted efforts to create an off-label market for [certain relevant drugs] did not cause physicians to prescribe [the drugs] for [those] uses strains credulity. It is implausible that a fraudulent scheme on the scope of that alleged … would be entirely feckless." *Id.*; *see also U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 1:09-CV-1086 AJT, 2011 WL 3911095, at *5 (E.D. Va. Sept. 6, 2011) (remarking that causation will be sufficiently pled, notwithstanding the learned intermediary doctrine, where there are "allegations that the judgment of a physician was altered or affected by the defendant's fraudulent activities"); see *generally Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) ("[A]n adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.").

c. Attenuation

***8** Lastly on the topic of causation, Purdue cites cases from other jurisdictions it contends demonstrate that claims founded upon overly attenuated and/or indirect chains of causation may be dismissed as a matter of law and that the rationales of these cases demand such a result in this instance. (See Motion to Dismiss at 23-26; Reply at 11-13.) The Court finds Purdue's argument unavailing.

Purdue principally relies on *Bank of America Corporation v. City of Miami, Florida*, 137 S. Ct. 1296, 1305 (2017), in which the City of Miami accused certain banks of unlawfully "lending to minority borrowers on worse terms than equally creditworthy nonminority borrowers and inducing defaults by failing to extend refinancing and loan modifications to minority borrowers on fair terms." Miami asserted that this "misconduct led to a disproportionate number of foreclosures and vacancies in specific Miami neighborhoods," causing Miami to "lose property-tax revenue when the value of the properties in those neighborhoods fell and [forced it] to spend more on municipal services in the affected areas." *Id.* In that case, the United States Supreme Court concluded that the Eleventh Circuit erred in solely considering the foreseeability of the City's alleged injury when determining whether the City had adequately pled causation. *Id.* at 1306. Citing *Holmes v. Securities Investor Protection Corporation*, 503 U.S. 258, 268 (1992), the United States Supreme Court reasoned that the Eleventh Circuit should have also examined whether "some direct relation between the injury asserted and the injurious conduct alleged" existed and remanded the issue for further deliberation. *City of Miami* at 137 S. Ct. *at* 1306.

In *Holmes*, plaintiff brought a statutory action against a defendant it claimed participated in a scheme to manipulate prices of certain stocks, which the plaintiff alleged ultimately necessitated its payment of claims to the clients of various broker-dealers who became insolvent as a result of the defendant's fraud. 503 U.S. at 262-63. The United States Supreme Court concluded that the relevant statute only conferred the plaintiff standing under the circumstances if the defendant's fraud was the "proximate cause" of the plaintiff's injury, *Id.* at 268. The United State Supreme Court employed "proximate cause" in this context as a stand-in for the common law "judicial tools used to limit a person's responsibility for the consequences of that person's own acts," and noted that, "[a]t bottom, the notion of proximate cause reflects ideas of what justice demands, or of what is administratively possible and convenient." *Id.* (quotation omitted). Further gleaning that "among the many shapes this concept [has taken] at common law, [is] a demand for some direct relation between the injury asserted and the injurious conduct alleged," the United States Supreme Court summarized that "a plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's

acts [is] generally said to stand at too remote a distance to recover." *Id.* at 268-69 (citation omitted); *see also generally Perry* v. Am. T*obacco Co.*, 324 F.3d 845, 850 (6th Cir. 2003) ("Because the *Holmes* Court emphasized that the RICO statute incorporates general common law principles of proximate causation, remoteness principles are not limited to cases involving the RICO statute." (Citation omitted)).

***9** Applying this standard, the United States Supreme Court held that, even assuming the plaintiff in that case could "stand in the shoes" of the clients injured as a result of the broker-dealers' insolvency, such a "link … between the stock manipulation alleged and the customers' harm" was nonetheless "too remote" because it was "purely contingent on the harm suffered by the broker-dealers." *Id.* at 271. That is, the alleged wrongdoers "injured the[] customers only insofar as the stock manipulation first injured the broker-dealers and left them without the wherewithal to pay customers' claims." *Id.*

Relying upon this line of authority, Purdue now maintains that, "[g]iven the series of intervening acts and actors involved in the State's allegations, including the independent decisions and actions of prescribing physicians, patients, and even criminals, there is no 'direct relation' between Purdue's alleged marketing statements and the injuries alleged by the State" and, therefore, "[t]he State fails to plead facts showing how Purdue — as opposed to the various superseding actors at issue here — proximately caused the injuries it alleged." (Mot. to Dismiss at 25.)

To properly consider this challenge, it is necessary to further construe the United States Supreme Court's basis in *Holmes* for holding that proximate cause ordinarily demands a direct relation between the alleged wrongdoing and the plaintiff's injury. To that end, the United State Supreme Court articulated three policy rationales justifying its conclusion:

> First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Holmes, 503 U.S. at 269-70.

It is equally necessary to differentiate the State's two general alleged chains of causation, *i.e.* that Purdue's purportedly deceptive marketing efforts resulted in the State; (1) paying for or reimbursing the costs of medically unnecessary and/or improper opioid prescriptions; and (2) bearing the costs of responding to societal strife wrought by increased opioid abuse.

Regarding the first chain, Purdue emphasizes that the "Complaint does not allege any facts that would support a conclusion that the State or any of its agents was ever exposed to or relied on any alleged misrepresentation when reimbursing opioid prescriptions." (Reply at 12.) Indeed, "[c]ourts considering [third-party payor]'s off-label … claims have reached differing conclusions as to whether the link between the alleged misrepresentations made by pharmaceutical company defendants and the ultimate injury suffered by [the third-party payor] plaintiffs is sufficiently direct to meet [the] proximate cause requirement," and "[o]ne key distinction between the facts in these … cases is whether the defendant pharmaceutical companies made the alleged misrepresentations directly to the [third-party payor] or indirectly to physicians who then prescribed the drugs that the [third-party payor] covered." *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs. & Abbvie Inc.*, 192 F. Supp. 3d 963, 968-69 (N.D. III. 2016).

***10** The First Circuit's reasoning on this issue in *In re Neurontin Marketing & Sales Practices Litigation.*, 712 F.3d 21 (1st Cir. 2013) is persuasive. Comparable to the State's allegations here, in that case a healthcare third-party payor ("TPP") alleged a pharmaceutical company's deceptive marketing efforts had resulted in the TPP wrongly reimbursing prescriptions. Also like this case, the pharmaceutical company argued "that its supposed misrepresentations went [only] to prescribing doctors, and so the causal link to [the TPP] must have been broken." *Id.* at 37.

The *Neurontin* court rejected this argument, finding that proximate cause's direct relation mandate does not impose a "direct reliance requirement." *Id.*; *accord Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 576 (7th Cir. 2017). This conclusion was influenced by *Bridge v. Phoenix Bond & indemnity Co.*, 553 U.S. 639, 657-58 (2008), which expressly held that "first-party reliance [is not] necessary to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy the proximate-cause principles articulated in *Holmes*."

The *Neurontin* court next went on to apply the three *Holmes* factors laid-out above, ultimately concluding that they did not demand dismissal because "the causal chain [was] anything but attenuated," considering the defendant's "fraudulent marketing plan, meant to increase its revenues and profits, only became successful once [the defendant] received payments for the additional… prescriptions it induced" and that "[t]hose payments came from [the plaintiff] and other TPPs." *Neurontin*, 712 F.3d at 38-39. Thus, the court reasoned, "the adoption of [the defendant's] view would undercut the core proximate causation principle of allowing compensation for those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendant's wrongful conduct." *Id.* at 38.

This reasoning resonates here. Because at least some doctors presumably exercised independent medical judgment in choosing to prescribe Purdue's opioids and some patients prescribed these medications for long-term chronic pain likely benefited, the State will seemingly shoulder a heavy burden at trial. The Court is aware that other jurisdictions consider these impediments as proximate cause maladies demanding dismissal. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (collecting cases and noting that the First Circuit's stance is unique among the Federal Courts of Appeals to consider the issue). The Court nevertheless adopts the First Circuit's view that, "[r]ather than showing a lack of proximate causation, this [issue] presents a question of proof regarding the total number of prescriptions that were attributable to [the defendant's] actions" and that, ultimately, "[t]his is a damages question." *Neurontin*, 712 F.3d at 39.

The Court next turns to the State's second general chain of causation, which alleges Purdue is culpable, *inter alia,* for "high rates of opioid abuse, injury, overdose, and death, and their impacts on New Hampshire families and communities; lost employee productivity; the creation and maintenance of a secondary, criminal market for opioids; greater demand for emergency services, law enforcement, addiction treatment, and social services; and increased health care costs for individuals, families, and the State." (Compl. ¶ 261 (list-headings omitted).) Purdue contends that "[t]hese are serious challenges facing the State, fueled by any number of third-party actions, both innocent and criminal, but they are too remote from Purdue's alleged marketing activity to satisfy the proximate cause requirement." (Mot. to Dismiss at 24.)

***11** Some of these alleged injuries are Sess remote from Purdue's purportedly deceptive marketing efforts than others, considering a significant percentage of the State's claims are not necessarily derivative of harm suffered by third parties. For instance, where municipalities accuse gun manufacturers of fostering illicit firearm markets, courts often reason that, "[e]ven if no individual is harmed, [the municipalities] sustain many of the damages they allege," including "costs for law enforcement increased security, prison expenses and youth intervention services," and that the municipalities' claims, therefore, do not fail for lack of a direct relation to the gun manufacturers' alleged wrongdoing. *City of Boston v. Smith & Wesson Corp.*, No. 199902590, 2000 WL 1473568, at *6 (Mass. Super. July 13, 2000); *accord*, *e.g.*, *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1148 (Ohio 2002) (The complaint in this case alleged that as a *direct* result of the misconduct of appellees, appellant has suffered actual injury and damages including, but not limited to, significant

expenses for police, emergency, health, prosecution, corrections and other services." (Emphasis added and quotation omitted)). [9] This reasoning is applicable here because, for example, the State's law enforcement efforts to combat the illegal distribution and possession of opioids are not purely contingent on harm from opioid abuse to any third party.

Moreover, although some of the State's supposed damages — for example the costs of administering emergency medical services to overdose victims — are contingent on the injuries of third persons, the Court is simply not persuaded that application of the *Holmes* factors to this case demands dismissal. [10]

Regarding the first factor — which concerns the difficulty of ascertaining what percentage of the plaintiff's damages are attributable to the defendant — given the preliminary stage of this litigation, the Court does not yet fully grasp the State's trial strategy and the precise manner it hopes to prove its allegations. It is, therefore, premature to foreclose the State's endeavor purely on the assumption that the scope of its allegations and the harms for which it seeks to hold Purdue accountable are so expansive that its efforts may hypothetically prove too complex for the Court to oversee.

The second factor considers the difficulty of forestalling multiple recoveries. In light of the multitudes seemingly implicated within the State's allegations, there is likely some risk of multiple recoveries. Nevertheless, for many of these individuals — such as those who abused opioids via illegal means or with sufficient understanding of the drug's harmful effects — it is possible their conduct and/or knowledge precludes their right to seek redress. As well, many of the State's alleged injuries, although contingent on the harm to third parties, are easily distinguishable from such wrongs. For example, the State claims that "[f]rom 2007-2013 [its] Medicaid spending on drugs to counter overdose or addiction increased six-fold." (Compl. ¶ 192.) Should the State prove this increase is sufficiently attributable to Purdue's alleged wrongdoing and should the State recover damages in the amount of this increase, there would be little apparent risk that an individual who received such drugs at the State's expense would herself recover damages based on the costs of their administration.

***12** The third factor asks whether deterring wrongdoing justifies grappling with the difficulties covered by the first two factors. It is no secret that opioid abuse is a particularly pernicious problem in New Hampshire. The State alleges Purdue shoulders significant blame for this reality. Considering the gravity of this matter and the scope of Purdue's alleged wrongdoing, the Court is not convinced there are parties other than the State better suited to litigate these issues and that the interests of justice weigh in favor of dismissal.

Accordingly, Purdue's motion to dismiss is DENIED to the extent it raises lack of causation. [11]

iii. Claim Specific Arguments

a. Consumer Protection Act

Purdue challenges the State's Consumer Protection Act ("CPA") claims on several grounds. First, Purdue maintains that statements and transactions before August 6, 2012, cannot form the basis of a CPA claim. Pursuant to RSA 358-A:3, IV-a "transactions … exempt from the provisions of [the CPA]" include

> [t]ransactions entered into more than 3 years prior to the time the plaintiff knew, or reasonably should have known, of the conduct alleged to be in violation of this chapter; provided, however, that this section shall not ban the introduction of evidence of unfair trade practices and deceptive acts prior to the 3-year period in any action under this chapter.

Relying on this provision, Purdue contends that "the latest the State knew or reasonably should have known of the [complaint's allegations] is August 6, 2015," because, "[o]n that date, the State served Purdue with a subpoena" relating to the State's investigation into these matters, and, therefore, all alleged statements and transactions attributed to Purdue more than three years prior to that date, *i.e.* August 6, 2012, are exempt from the CPA's ambit. (Mot. to Dismiss at 28.) The State counters that the date it knew or should have known of Purdue's actions is a question of fact not appropriate for resolution at this time. The Court agrees. [12]

Next Purdue argues that neither the State's allegation that Purdue failed to report its knowledge of suspicious opioid prescriptions nor its assertion that Purdue should be held accountable for unbranded publications properly state a CPA claim. (Mot. to Dismiss at 26-27, 29-30.) Purdue's positions are both unavailing. The former issue requires little analysis considering the State acknowledges — contrary to Purdue's characterization — that it does not premise its CPA claim on Purdue's purported failure to comply with the federal Controlled Substances Act and associated regulations. (*See* Obj. at 23.) The Court finds the State's stance is fairly reflected in the complaint. Regarding its latter position, Purdue cites *Green Mountain Realty Corporation v. Fifth Estate Tower LLC*, 161 N.H. 78 (2010) seemingly for the proposition that marketing efforts that do not directly include offers to sell or distribute a product as part of an entity's day-to-day business are not actionable under the CPA. *Green Mountain*, however, offers no such support, considering the New Hampshire Supreme Court in that case merely concluded that "a publicity campaign directed at a general electorate" for the purpose of influencing "the passage of … warrant articles does not violate the CPA" and the New Hampshire Supreme Court did not contemplate whether all marketing efforts presented in not-strictly-business arenas fall outside the CPA's scope. 161 N.H. at 87. Because Purdue offers no additional support, the Court will not consider the issue further.

***13** Lastly, Purdue seeks to strike the State's request — pursuant to RSA 358-A:4, III(b) — of "an order assessing a civil penalty of $10,000 against Purdue for each violation of the [CPA]." (Compl. ¶ 225; Mot. to Dismiss at 30-31.) Purdue maintains that, although New Hampshire courts have yet to consider the issue, some jurisdictions apply an "individualized proof rule" to statutes comparable to the CPA and that this rule purportedly "prevents civil penalties where calculating them would require individualized proof as to each transaction at issue." (Mot. to Dismiss at 30 (citing *In re Zyprexa Prods. Liab. Lititg.*, 671 F. Supp. 2d 397, 456, 458-59 (E.D.N.Y. 2009)).) Purdue argues that the State cannot sustain such a burden and, therefore, its request for civil penalties must be stricken. Even assuming that it is appropriate to adopt an individualize proof rule with regards to the CPA (notwithstanding the New Hampshire Supreme Court's holding in *Exxon Mobil* that it is otherwise proper to employ "statistical evidence and extrapolation to prove injury-in-fact"), it is nevertheless inappropriate to strike the State's request at this time as discovery could provide the State the individualize proof it may ultimately require. 168 N.H. at 255-56.

b. Medicaid Fraud and False Claims Act

Purdue advocates for the complete dismissal of the State's Medicaid Fraud and False Claims Act ("FCA") count for two alternative reasons. Initially, Purdue reiterates its position that the State's claims, including its FCA count, demand individualized proof. In the FCA context, Purdue contends this proof must at least comprise specifically identified instances of "a physician or pharmacy submitting a claim for reimbursement for opioid medications to New Hampshire's Medicaid program." (Mot. to Dismiss at 32.) The Court disagrees. Even assuming Purdue is correct that the pleading requirements imposed by some federal jurisdictions on claims implicating the federal analogue to the FCA equally apply in this matter, where, as here, "the defendant allegedly induced third parties to file false claims with the government" the plaintiff can satisfy these requirements merely "by providing factual or statistical evidence to strengthen the inference of fraud … without necessarily providing details as to each false claim." *United States ex rel. Narqol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 39 (1st Cir. 2017) (quotations, emphasis, and ellipsis omitted). The State's allegations satisfy this standard and contain "reliable indicia that lead to a strong inference that [false] claims were actually submitted for … reimbursement" despite the absence of any specific claim for reimbursement being described in the complaint. *Id.* at 41 (quotation and citation omitted).

Purdue also argues that, because the State supposedly "admits that it continues to pay for opioid medications prescribed for chronic pain, despite the Attorney General's belief that Purdue has been falsely marketing opioid medications for years," the State does not sufficiently plead that Purdue's alleged wrongdoing was "material" to the State's purported reimbursement decisions. (Mot. to Dismiss at 33 (citing Compl. ¶ 254).) These are issues of fact not amenable for consideration at this stage. *See generally Ellis v. Candia Trailers & Snow Equip., Inc.*, 164 N.H. 457, 466 (2012) ("[M]aterial[ity] is a question of fact....").

c. Public Nuisance

Regarding the State's public nuisance claim, Purdue contends that such a cause of action must "arise from the active or passive use of real property, whereas the State challenges only manufacturing and marketing activity." (Mot. to Dismiss at 33.) In *Robie v. Lillis*, 112 N.H. 492, 495 (1972), the New Hampshire Supreme Court explained that "[a] public nuisance … is 'an unreasonable interference with a right common to the general public"' and "is *behavior* which unreasonably interferes with the health, safety, peace, comfort or convenience of the general community." (Quoting Restatement (Second) of Torts § 821 B(1)) (emphasis added). The use of "behavior" in this context suggests Purdue's position, *i.e.* that the origin of a public nuisance must arise from the use of real property, is a too narrow reading of the law. Indeed, numerous other jurisdictions that, like the New Hampshire Supreme Court, look to the Restatement (Second) of Torts to guide their analysis of public nuisance claims have expressly concluded that "[a]n action for public nuisance may lie even though neither the plaintiff nor the defendant acts in the exercise of private property rights." *Philadelphia Elec. Co. v. Hercules, Inc.*, 762 F.2d 303, 315 (3d Cir. 1985) (reasoning further that "'[a] public nuisance is a species of catch-all low-grade criminal offense, consisting of an interference with the rights of the community at large, which may include anything from the blocking of a highway to a gaming-house or indecent exposure."' (Quoting Prosser, *Private Action for Public Nuisance*, 52 Va. L. Rev. 997, 999 (1966))); *see*, *e.g.*, *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002) ("[T]here need not be injury to real property in order for there to be a public nuisance."); *City of Boston v. Smith & Wesson Corp.*, No. 199902590, 2000 WL 1473568, at *14 (Mass. Super. July 13, 2000) ("[A] public nuisance is not necessarily one related to property."); Restatement (Second) of Torts §821B, Comment h ("Unlike a private nuisance, a public nuisance does not necessarily involve interference with use and enjoyment of land.").

***14** Purdue also maintains that the State's claim fails because "the alleged public nuisance identified in the complaint is not reasonably subject to abatement." (Mot. to Dismiss at 33.) This issue demands little consideration as it is a question of fact whether Purdue can abate the alleged public nuisance for which the State seeks to hold it liable and, drawing all inferences in the State's favor, the complaint adequately alleges that Purdue is in fact capable of doing so. (*See* Compl. ¶ 266 (This public nuisance can be abated through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.").)

d. Unjust Enrichment

Purdue argues that the State's claim for unjust enrichment must be dismissed because "unjust enrichment generally does not form an independent basis for a cause of action." (Mot. to Dismiss at 35 (quoting *Gen Insulation Co. v. Eckman Const.*, 159 N.H. 601, 611 (2010)).) The New Hampshire Supreme Court has not categorically barred independent unjust enrichment claims, however, it has made clear that such claims are predominately rooted in quasi-contract theory. See *Gen. insulation*, 159 N.H. at 611 ("[U]njust enrichment [is] allowed by the courts as [an] alternative remed[y] to an action for damages for breach of contract." (Quotation omitted)). Although a fair reading of the complaint is that Purdue may have enriched itself via "deceptive and illegal acts," (Compl. ¶ 272), this inference alone is insufficient to state a claim. See *Clapp v. Goffstown Sch. Dist.*, 159 N.H. 206, 210 (2009) ("Unjust enrichment is not a boundless doctrine, but is, instead, narrower, more predictable, and more objectively determined than the implications of the words 'unjust

enrichment."' (Quotation omitted)); *Am. Univ. v. Forbes*, 88 N.H. 17, 19 (1936) ("The doctrine of unjust enrichment is that one shall not be allowed to profit or enrich himself at the expense of another contrary to equity. While it is said that a defendant is liable if 'equity and good conscience' requires, this does not mean that a moral duty meets the demands of equity. There must be some specific legal principle or situation which equity has established or recognized to bring a case within the scope of the doctrine."). Considering the State has not articulate an underlying "specific legal principle" nor cited authority allowing an unjust enrichment claim to proceed under comparable circumstances, the Court must agree with Purdue on this issue.

e. Fraudulent or Negligent Misrepresentation

Finally, Purdue argues that the State's fraudulent and negligent misrepresentation claim demands dismissal "because the State fails to allege that it justifiably relied on any statement made by, or attributable to, Purdue." (Mot. to Dismiss at 35; *see also* Reply at 12.) The Court disagrees. The United States Supreme Court in *Bridge* considered and rejected a similar argument, finding that "while it may be that first-party reliance is an element of a common-law fraud claim, there is no general common-law principle holding that a fraudulent misrepresentation can cause legal injury only to those who rely on it.... And any such notion would be contradicted by the long line of cases in which courts have permitted a plaintiff directly injured by a fraudulent misrepresentation to recover even though it was a third party, and not the plaintiff, who relied on the defendant's misrepresentation." 553 U.S. at 656-57 (citing Restatement (Second) of Torts §§ 435A, 548A, 870).

Likewise, the New Hampshire Supreme Court has relied upon the Restatement (Second) of Torts to conclude that "[t]he fact that [an] alleged misrepresentation was not made directly to the plaintiff does not defeat [the] cause of action." *Tessier v. Rockefeller*, 162 N.H. 324, 333 (2011) (citing Restatement (Second) of Torts § 533 ("The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss to another who acts in justifiable reliance upon it if the misrepresentation, although not made directly to the other, is made to a third person and the maker intends or has reason to expect that its terms will be repeated or its substance communicated to the other, and that it will influence his conduct in the transaction or type of transaction involved." [13])).

***15** In light of this authority, the State's claim — which, *inter alia*, alleges that Purdue made misrepresentations to health care providers and patients for the purpose of inducing opioid prescriptions, along with the common sense understanding that some would in turn seek reimbursements from the State for these opioid prescriptions — is satisfactory.

Conclusion

For the foregoing reasons, Purdue's Motion to Dismiss is DENIED as it pertains to Count I (deceptive and unfair acts and practices contrary to the Consumer Protection Act), Count II (unfair competition contrary to the Consumer Protection Act), Count III (false claims in violation of the Medicaid Fraud and False Claims Act), Count IV (public nuisance), and Court VI (fraudulent or negligent misrepresentation), and GRANTED as it relates to Count V (unjust enrichment).

SO ORDERED.

9/18/18

Date

<<signature>>

John C. Kissinger, Jr.

Presiding Justice

Footnotes

1 The federal Food, Drug, and Cosmetic Act requires that drug manufacturers obtain FDA approval prior to marketing or selling a drug in interstate commerce. 21 U.S.C. § 355(a). The FDA only approves a drug if the manufacturer demonstrates "substantial evidence that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d)(5). A drug manufacture must also submit for approval "the labeling proposed to be used for [a] drug." 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i). The FDA will approve a proposed label if, "based on a fair evaluation of all material facts," it is not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6). Once approved, a manufacturer may distribute a drug without violating federal law as long as it uses the approved labeling. *See* 21 U.S.C. §§ 331(c), 333(a), and 352(a), (c). Pursuant to 21 U.S.C. § 321(m), a drug's "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

2 The parties dispute to what extent causation is an element of all or some of the State's claims. However, given the Court's conclusion that the State has sufficiently pled causation, it need not reach these issues.

3 Purdue argues that the State has failed, as a matter of law, to allege that Purdue "controlled" these third-parties. (Mot. to Dismiss at 25-26.) Taking all reasonable inferences in the State's favor, the Court disagrees.

4 For example, the State cites a 2007 study that found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse, with particularly compelling data for … OxyContin." (*Id.* (quotation omitted).) The State also relies upon a 2016 letter issued by the then United States Surgeon General opining "that the push to aggressively treat pain, and the devastating results that followed, had coincided with heavy marketing to doctors many of whom were even taught — incorrectly — that opioids are not addictive when prescribed for legitimate pain." (*Id.* ¶ 182 (quotations, ellipsis, and brackets omitted).)

5 Additionally, the State provides numerous examples of expenditures, *i.e.* harms, it has borne in combating opioid abuse. (*E.g.*, id. ¶ 191 ("The number of children removed from homes with substance abuse problems went from 85 in 2010 to 329 in 2015 — a 387% increase."); ¶ 192 ("From 2007-2013 … state Medicaid spending on drugs to counter overdose or addiction increased six-fold."). As another example, the State maintains "damages from false claims submitted, or caused to be submitted, by [Purdue]," and indicates that "[f]rom 2011-2015, the State's Medicaid program spent $3.5 million to pay for some 7, 886 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain." (*Id.* ¶ 254.)

6 For example, *Jane Doe No. 1 v. Backpage.com, LLC*, 817 F.3d 12, 25 (1st Cir. 2016), is easily distinguishable, considering the court in that case found the plaintiffs' allegations insufficient not because they were based upon aggregate or statistical analysis, but rather because they were wholly lacking in *any* factual support and were, therefore, "mere conjecture."

7 *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762 (Ky. 2004).

8 The court in that case summarized the defendant's purported misconduct as a "fraudulent marketing" scheme, which "included, but was not limited to. three strategies, each of which included subcomponents: (1) direct marketing … to doctors, which misrepresented [the relevant prescription drug's] effectiveness for off-label indications; (2) sponsoring misleading informational supplements and continuing medical education ("CME") programs; and (3) suppressing negative information about [the drug] while publishing articles in medical journals that reported positive information about [the drug's] off-label effectiveness." *Id.* at 28.

9 The court in *City of Boston* illustrated this point with the following example:
Plaintiffs allege that Defendants' conduct places firearms in the hands of juveniles causing Plaintiffs to incur increased costs to provide more security at Boston public schools, Thus, wholly apart from any harm to the juvenile (who may even believe himself to be benefited by acquisition of a firearm), and regardless whether any firearm is actually discharged at a school, to ensure school safety Plaintiffs sustain injury to respond to Defendants' conduct.

10 Separately, the Court is not bound by the United States Supreme Court's judgment on these issues nor has Purdue cited New Hampshire authority explicitly echoing *Holmes*'s reasoning. Indeed, Purdue's briefing on this issue (and the State's for that matter) does not even directly address the Holmes factors. Considering, moreover, that the New Hampshire Supreme Court maintains that legal cause simply "requires the plaintiff to establish that the negligent conduct was a *substantial factor* in bringing about the harm" and that this requirement does not demand that "[t]he negligent conduct … be the sole cause of

the injury." but rather merely a "contribut[ion]," the Court is not inclined to adopt *Holmes* at this time. *Carignan v. Mew Hampshire Int'l Speedway, Inc.*, 151 N.H. 409, 414 (2004) (emphasis added): *Young v. Clogston*, 127 N.H. 340, 342 (1985) (The jury determines the facts, *i.e.* … whether the defendant's conduct is a legal cause of the plaintiffs injuries, [and] the trial judge's discretion to remove questions of fact from the jury is very limited."); *see also City of Boston v. Smith & Wesson Corp.*, No. 199902590, 2000 WL 1473568, at *6 (Mass. Super. July 13, 2000) (discussing exceptions to the direct relation requirement that may be applicable to this case).

11 The Court's conclusion is in keeping with those of recent trial courts across the country that have considered similar claims against Purdue. *See*, *e.g.*, *State v. Purdue Pharma L.P.*, No-3AN-17-09966CI (Alaska Super. Ct. July 12, 2018); *In re Opioid Litigation*, Index No. 400000/2017 (N.Y. Sup. Ct. March 21, 2018).

12 Although the State raises additional counterarguments for the proposition that RSA 358-A:3, IV-a's exception provision does not apply to the State at all pursuant to the doctrine of *nullum tempus* (*see* Index # 29 at 1-2; Defs.' Reply to PL's Supp. Oppo. to Mot. to Dismiss at 1-3) and that, in any case, the provision is inapplicable to "misleading marketing statements," (Obj. at 24), the Court need not reach these issues at this time as it is undisputed, even crediting Purdue's August 6. 2012, cutoff, that the State's CPA claims do not wholly rely on exempted transactions.

13 This rule "is applicable not only when the effect of the misrepresentation is to induce the other to *enter* into a transaction with the maker, but also when he is induced to enter into a transaction with a third person." Restatement (Second) of Torts § 533, Comment c.

End of Document

EXHIBIT 8

tls

IN THE COURT OF COMMON PLEAS

ROSS COUNTY, OHIO

STATE OF OHIO, EX REL.
MIKE DEWINE, OHIO ATTORNEY GENERAL,

PLAINTIFF,

CASE NO. 17 CI 261

VS

DECISION AND ENTRY

PURDUE PHARMA L.P., ET AL,

DEFENDANT.

* * * * * *

This action came on for hearing on the Defendants' various motions to dismiss, Defendant Endo's motion to strike, certain defendants' motion for judicial notice, Defendants' motion to stay, Plaintiff's responses, and the Defendants' replies thereto. All parties were represented and heard through counsel.

The Plaintiff's Complaint alleges that Defendants misrepresented to the general public, physicians, and the State of Ohio the effectiveness of opioids for the treatment of chronic pain and the dangers of opioid addiction. Plaintiff alleges that these misrepresentations were directly and indirectly communicated by the Defendants, their representatives, and various third parties. The Complaint alleges the following claims:

1. Public nuisance under the Ohio Product Liability Act, 2307.71 ORC.
2. Public nuisance – common law.
3. Ohio Consumer Sales Practices Act, 1345.02 ORC et seq.
4. Medicaid Fraud, 2913.40/2307.60 ORC.
5. Common Law Fraud.

6. Ohio Corrupt Practices Act, 2923.31 ORC et seq.

Plaintiff seeks declaratory judgment, injunctive relief, compensatory damages, punitive damages, civil penalties, pre and post-judgment interest, and attorney fees.

Defendants argue that all of Plaintiff's claims fail for a multitude of reasons and that the Complaint should be dismissed.

STANDARD

A motion to dismiss for failure to state a claim is procedural and tests the sufficiency of the complaint. A trial court reviews only the complaint and accepts all factual allegations as true. Every reasonable inference is made in favor of the non-moving party. This Court must assume the Plaintiff's allegations are true. However, the unsupported conclusions of the Complaint are not sufficient to withstand a motion to dismiss the complaint. The Complaint must be construed as a whole within the four corners of the Complaint. A trial court may not dismiss a complaint "unless it appears **beyond doubt** that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." (Emphasis added) O'Brien v Univ. Community Tenants Union, Inc., 42 Ohio State 2d, 242 (1975). (Emphasis added). Gannett GP Media, Inc. v Chillicothe, Ohio Police Department, 2018 Ohio 1552; State, ex rel. Hanson v Guernsey Cty. Bd. of Commrs., 65 Ohio State 3d 545 (1992); Struckman v Bd. of Edn. of Teays Valley Local Sch. Dist., 2017 Ohio 1177; Martin v. Lamrite W., Inc., 2015 Ohio 3585.

Ohio remains a notice pleading state. Civil Rule 8(A) requires only the following:

> "(1) A short and plain statement of the claim showing that the pleader is entitled to relief, and

(2) A demand for judgment for the relief to which he deems himself entitled."

Ohio courts have rejected the heightened federal pleading standard set forth in Bell Atlantic Corp. v Twombly, 550 U.S. 544, and have acknowledged that Ohio remains a notice pleading state. Smiley v City of Cleveland, 2016-Ohio 7711; Mangelluuzzi v Morley, 2015 Ohio 3143. This Court notes the language of the Eighth District Court of Appeals in Smiley, supra wherein the court stated that "(the) motion to dismiss is viewed with disfavor and should rarely be granted" and that "few complaints fail to meet the liberal (pleading) standards of Rule 8 and become subject to dismissal,".

Civil Rule 9(B) does impose upon a plaintiff a heightened standard of pleading in cases of fraud.

"(B) **Fraud, mistake, condition of mind.** In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity..."

In Ohio, a complaint alleging fraud must allege with particularity the "circumstances constituting fraud." The complaint must assert "the time, place, and content of the false representation; the fact misrepresented; the identification of the individual giving the false representation; and the nature of what was obtained or given as a consequence of a fraud." Aluminum Line Prods. Co. v Brad Smith Roofing Co., 109 Ohio App. 3d 246 (1996); Dottore v Vorys, Sater, Seymour & Pease, LLP. 2014 Ohio 25; First-Knox Nat'l Bank v MSD Props., Ltd., 2015 Ohio 4574.

Civil Rule 9(B) should be read in conjunction with the general directive of Civil Rule 8, that pleadings should be "simple, concise, and direct." Even if the pleadings are vague, so long as defendants have been placed on notice of the claims, a strict application is not necessary. Aluminum Line Prods. Co., supra; F&J Roofing Co. v

McGinley & Sons, Inc., 35 Ohio App. 3d 16 (1987). This Court notes that the Complaint in Aluminum Line Prods. Co., supra, asserted that the fraud occurred over the course of several years. There was no specific assertion of the date of the fraud. Similarly, the Ninth District Court of Appeals found that a complaint alleging fraud within a six year period did not violate the requirements of Civil Rule 9(B). Bear v Bear, 2014 Ohio 2919. See also Pierce v Apple Valley, Inc., 597 F. Supp. 1480.

A determination whether a complaint satisfies the heightened pleading standards of Civil Rule 9(B) should be made on a case by case basis depending upon the facts of each case. City of Chicago v Purdue Pharma L.P., et al, 14C4361211 F. Supp. 3d. 1058 (N.D. Ill. 2016).

The heightened pleading standards of Civil Rule 9(B) may also be relaxed in circumstances where relevant facts lie exclusively within the control of the opposing party. Wilkins, ex rel. U.S. v State of Ohio, 885 F. Supp. 1055; Craighead v E.F. Hutton and Co., 899 F. 2d. 485.

GROUP PLEADING

In State of Missouri, ex rel. Joshua D. Hawley v Purdue Pharma, LP, Case No. 1722-CC10626, the 22nd Circuit Court of the State of Missouri found that there was no rule against "group pleading" in Missouri. Similarly, this Court finds that there is no specific rule against "group pleading" in the state of Ohio. The Dottore case cited by the Defendants, does not mention "group pleading" and more specifically addresses the heightened pleading requirements of Civil Rule 9(B) in mail fraud cases. The Plaintiff's 101 page Complaint sufficiently asserts that all defendants engaged in conduct which would constitute a claim under the pleading rules in the State of Ohio.

CIVIL RULE 9(B)

In the case at bar, the prima facia case for fraud is:

(1) A representation or concealment of a fact;

(2) Material to the transaction at hand;

(3) Made falsely with knowledge of its falsity;

(4) Intent to mislead another into relying upon it;

(5) Justifiable reliance;

(6) Injury proximately caused by the reliance.
Marjul, LLC v. Hurst, 2013 Ohio 479.

As previously stated, this Court will examine the Plaintiff's compliance with Civil Rule 9(B) under the Ohio pleading standards. The Plaintiff's complaint must assert the time, place, and content of the false representation; the fact misrepresented; the identification of the individual giving the false representation; and the nature of what was obtained or given as a consequence of a fraud. Aluminum Line Prods. Co., supra.

The Plaintiff's complaint adequately identifies the Defendants and their actions and representations. The complaint sufficiently asserts the time frame which in the representations were made and that they were made in the state of Ohio. The complaint sufficiently identifies that the representations were made by representatives of the Defendants and various groups and third parties sponsored by the Defendants.

The complaint contains over 40 pages which explain in detail the marketing tactics utilized by Defendants, their representatives, and various groups connected to Defendants. Similarly, the complaint adequately sets forth the representations made, how these representations were distributed to physicians and citizens of Ohio, that the representations were false and that the Defendants knew the falsity of the representations.

Under Ohio pleading standards, it is not necessary for the complaint to identify physicians who relied upon the misrepresentations of the Defendants. Even so, as argued by Plaintiff, the identification of prescribing physicians is solely within the knowledge of Defendants and can be obtained through discovery. Further, the complaint adequately states that the Plaintiff specifically relied upon the misrepresentations in issuing reimbursement payments under the Medicaid program. Further, reliance is a question of fact or appropriately addressed in a motion for summary judgment. Kelly v. Georgia-Pac. Corp., 46 Ohio St. 3d 134. Lastly, the Plaintiff has sufficiently pled causation in compliance with City of Cincinnati v. Beretta USA Corp., 95 Ohio St. 3d 416 and the damages suffered by the state of Ohio. In summary, this Court finds that Plaintiff has sufficiently pled the fraud related claims under Civil Rule 9(B).

PREEMPTION/FDA APPROVAL

The parties agree that the FDA approved the labeling for opioids for long-term treatment. However, it is evident in the Plaintiff's complaint that its claims are based upon misrepresentations made by the Defendants concerning the use and safety of opioids which go far beyond the labeling. As noted by the court in City of Chicago v. Purdue Pharma LP, supra, the allegations of the Plaintiff's complaint primarily sound in fraud and not the propriety of the labeling of opioids. The Chicago court also concluded that drug labeling does not preclude fraud claims. See also Wyeth v. Levine, 555 U.S. (2009).

The claims set forth in Plaintiff's complaint are not barred by the FDA's approval of labeling or the doctrine of preemption as to Defendants' branded or unbranded labeling.

PUBLIC NUISANCE

This Court finds that Cincinnati vs Beretta, 95 Ohio St. 3d 416, is not substantially distinguishable and applies to the case at bar. In Beretta, supra, the Ohio Supreme Court adopted a broader definition of public nuisance. The court determined that the restatement of the law of torts (2nd) sets forth a broad definition of public nuisance allowing an action to be maintained "for injuries caused by a product if the facts establish that the design, manufacturing, marketing, or sale of the product unnecessarily interferes with a right common to the general public." Under the broad definition of public nuisance and the liberal pleading rules of the state of Ohio, this Court finds that the Plaintiff has adequately pled public nuisance under Ohio common law and the Ohio Product Liability Act.

OHIO CONSUMER SALES PRACTICES ACT

Section 1345.07 ORC specifically authorizes the Ohio Attorney General to initiate an action under the OSCPA. The statute also sets forth the remedies which the Attorney General can seek: declaratory judgment; injunction; and civil penalties. The provisions of the OSCPA must be liberally construed. State, ex rel Celebreeze v. Hughes, 58 Ohio St. 3rd 273. The complaint sets forth a "consumer transaction" as defined by the statute. The complaint need not, at this stage, identify an Ohio citizen as a consumer. A consumer action is alleged by the complaint regardless of whether the plaintiff is an actual consumer. The complaint, as previously stated, sets forth in detail over 40 pages of allegations which are prohibited by Sections 1345.02 and 1345.03 and the administrative regulations promulgated thereunder. Plaintiff's prayer for civil penalties should not be stricken, at this stage, because they are statutorily authorized.

It is premature at this time to determine whether the plaintiff's OSCPA claim is time barred. Savoi v. Univ. of Akron, 2012 Ohio 1962; The complaint alleges a continuing course of conduct by the defendants. Where a plaintiff alleges a continuing violation of the OSCPA, the statute of limitations does not begin to run until the date when the violation ceases. Roelle v. Orkan Exterminating Co., 2000 WL 1664865; Martin v. Servs. Corp. Int'l, 2001 WL 68896.

ABROGATION

Section 2307.72(C) ORC specifically exempts claims for economic loss from abrogation under the Ohio Products Liability Act. Further, "product liability claim" is statutorily defined as a claim seeking "compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress or physical damage to property." Reviewing the four corners of the complaint, it does not appear that the plaintiff is seeking these types of damages. The plaintiff's common law nuisance claim, OSCPA claim, and fraud claims are not abrogated under the OPLA. See Catepillar Fin. Servs. Corp. v. Harold Tatman and Sons Ents., Inc., 2015 Ohio 4884.

MEDICAID FRAUD

Section 2901.23 ORC provides that a corporation may be criminally liable if it meets one of the criteria set forth in subsection (A)(1)-(4). Section 2913.40(B) provides:

> "No person shall knowingly make or cause to be made a false or misleading statement or representation for use in obtaining reimbursement from the Medicaid program."

This language clearly includes persons who cause false or misleading statements or representations to be made for the purpose of reimbursement for the Medicaid program. The complaint adequately sets forth that defendants, their employees or agents and third parties under defendant's control knowingly made or caused to be

made false or misleading statements for the purpose of obtaining for defendants reimbursement under the Medicaid program. These allegations meet the requirements of the liberal pleading rules in the state of Ohio.

Section 2307.60(A)(1) ORC provides:

> "Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law,..."

This Court construes this section liberally to include the state of Ohio. To construe this section to exclude a state from seeking damages from criminal actions would prohibit the state from initiating litigation to collect damages from persons who have been convicted of causing damage to public property. This Court finds that at this juncture, the plaintiff is not barred by this section from pursuing an action for damages caused as the result of the commission of Medicaid fraud. See Jacobson v. Kaforey, 149 Ohio St. 3rd 398.

The plaintiff's Medicaid fraud claim is not time barred. There is no specific statutory provision which imposes a time bar against the state in this case. The only time bar is set forth in a generally worded statute, 2305.11(A) ORC. As stated in State, Dep't. of Transp. v. Sullivan, 38 Ohio St. 3d (1988), the Ohio Supreme Court approved the continued exception of the state from generally worded statutes of limitation.

OHIO CORRUPT PRACTICES ACT

Section 2929.32(A)(1) ORC states:

> "No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity..."

Section 2923.31(C) defines "Enterprise" as follows:

> "Any individual, sole proprietorship, partnership, limited partnership, corporation..."

"Enterprise" includes an illicit or licit enterprises. "Person" includes a corporation.

Section 2923.31(E) ORC defines "Pattern of corrupt activity" as:

> "Two or more incidents of corrupt activity whether or not there has been a prior conviction, that are related to the affairs of the same enterprise, are not isolated, and are not so closely related to each other and connected in time and place that they constitute a single event."

A *prima facia* case for a civil claim under the OCPA requires:

(1)"(v)" Conduct of the defendant involves the commission of two or more specifically prohibited state or federal offenses;

(2) The prohibited criminal conduct of the defendant constitutes a pattern;

(3) The defendant has participated in the affairs of an enterprise or has acquired and maintained an interest in or control of an enterprise." Morrow v. Reminger & Reminger Co. L.P.A., 2009 Ohio 2665.

The plaintiff's complaint sets forth in detail the conduct of the defendants in violating federal mail fraud provisions (18 U.S.C. 1341), federal wire fraud (18 U.S.C. 1343), and telecommunications fraud in violation of Section 2913.05 ORC. This Court has previously determined that the plaintiff has met the particularity requirements of Civil Rule 9(B) in pleading fraud and similarly finds that the plaintiff has met these particularity requirements in pleading the predicate acts of federal mail fraud and wire fraud and telecommunications fraud under the Ohio Revised Code. This Court finds that the liberal pleading rules in Ohio do not require the plaintiff to set forth specific communications and identify senders and recipients and their locations. Further, this specific information would be within the defendants' knowledge and not available to plaintiff. Further, the plaintiff's complaint sets forth the defendants' intent in committing various criminal acts. Wilkins, supra; Swanson v. McKenzie (4th District Scioto County) 1988 WL 50478.

Section 2923.31 defines "Enterprise" as **any** corporation which may engage in illicit or licit conduct. As stated by plaintiff, the definition of an enterprise is "open-ended" and "should be interpreted broadly." State vs Beverly, 143 Ohio St. 3d, 2015 Ohio 219; CSAHA/UHHS-Canton, Inc. v Aultman Health Found., 2012-Ohio-897. At the pleading stage, the complaint adequately sets forth the purpose of defendants in engaging in a loosely structured hierarchy to achieve a stated purpose. Further, the complaint sets forth in detail the pattern of criminal conduct in violating federal and state laws. The plaintiff's complaint adequately pleads a violation of Ohio's Corrupt Practices Act.

ENDO'S MOTION TO STRIKE

Civil Rule 12(F) allows a party to move for an order striking language from a pleading that is redundant, immaterial, impertinent, or scandalous. Although this Court questions the inclusion of the New York settlement in the complaint, this Court cannot find that it is immaterial, impertinent, or scandalous. Endo's Motion to Strike is overruled.

JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON

The allegations in plaintiff's complaint are very similar to the allegations contained in the complaint considered by the United States District Court, Northern Division, Illinois, Eastern Division. City of Chicago v Purdue Pharma LLP, 211 F. Supp. 3d. Plaintiff's complaint does not seek to pierce the corporate veil of Janssen but rather to hold Johnson & Johnson liable under agency doctrines. The court, in City of Chicago, found that for the purposes of a motion to dismiss, the plaintiff's complaint had sufficient allegations to infer an agency relationship between Johnson & Johnson and Janssen and to assert vicarious liability for Janssen's conduct. This

Court adopts that reasoning and the Motion of Janssen and Johnson & Johnson is overruled.

JURISDICTION ALLERGAN PLC

The parties agree upon the law which this Court must employ in determining jurisdiction over Allergan PLC. The Plaintiff must show that the exercise of jurisdiction complies with Ohio's long-arm statute, Section 2307.382, and the related Civil Rule 4.3(A). U.S. Sprint Commc,n Co. Ltd. P'ship v. Mr. K's Foods, Inc., 3d 181, 1994 Ohio 504. This Court must go further and determine whether the grant of jurisdiction under the long-arm statute and civil rule comports with due process under the 14th Amendment to the United States Constitution. Goldstein v. Christiansen, 70 Ohio St. 3d 232, 1994 Ohio 229; Joffe v. Cable Tech., Inc., 163 Ohio App. 3d 479, 2005 Ohio 4930.

Section 2307.382(A) provides in pertinent part:

> "(A) A court may exercise personal jurisdiction over a person who acts directly or by an agent as to a cause of action arising from the person's:
>
> (1) Transacting any business in this state
> (2) Contracting to supply services or goods in this state
> (3) Causing tortious injury by an act or omission in this state
> (4) Causing tortious injury in this state by an act or omission outside this state if he regularly does or solicits business or engages in any persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state;"

In the case at bar, the Plaintiff must establish a prima facia showing that jurisdiction exists over Allergan PLC. The Court must consider the "allegations in the pleadings and documentary evidence in a light most favorable to the Plaintiff and resolving all reasonable competing inferences in favor of the Plaintiff." Kauffman Racing Equip., L.L.C. v. Roberts, 126 Ohio St. 3d 81, 210 Ohio 2551; Fallang v. Hickey, 40 Ohio St. 3d 106.

In determining whether this Court has jurisdiction over Allergan PLC, this Court must consider whether there are minimum contacts with the state of Ohio so that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice under Goldstein v. Christiansen supra. The Court must employ a tri-partite test to establish minimum contacts.

"1. The defendant must purposefully avail himself of the privilege of acting in the foreign state or causing a consequence in the foreign state.

2. The cause of action must arise from the defendant's activities there.

3. The acts of the defendant or consequences caused by the defendant must have a substantial connection with the foreign state to make the exercise of jurisdiction over the defendant reasonable." Kauffman, supra.

This Court has considered the affidavits submitted by the parties on this issue and the request by Plaintiff for this Court to take judicial notice of the Plaintiff's exhibits 40-49 attached to the Troutman affidavit. The Court takes judicial notice of these filings.

These filings establish, by the requisite degree of proof necessary on a motion to dismiss for lack of jurisdiction, the following: Actavis, Inc. and Actavis PLC are predecessors to Allergan PLC. Both entities referenced the United States as it's "largest commercial market." Allergan PLC maintains a "major manufacturing" site in Cincinnati, Ohio. All three entities maintain that they are engaged in the "global market." This Court also adopts the reasoning of the court in City of Chicago v. Purdue Pharma L.P.N.D. Ill. No. 14C4361, 215 WL 2208423, finding the evidence sufficient at the stage of a motion to dismiss that Actavis PLC is the successor to Actavis, Inc. The same reasoning applies that Allergan PLC is the successor to Actavis PLC and Actavis, Inc.

This Court finds that the Plaintiff has established a prima facia case for jurisdiction over Allergan PLC under the long-arm statute, Section 2307.382(A) ORC. Further, this Court finds that the Plaintiff has established by the requisite degree of proof that the defendant, Allergan PLC, acted and caused consequences in the state of Ohio. This Defendant's actions and the consequences therefrom alleged by the Plaintiff create a sufficient substantial connection with Ohio and allow the assertion of personal jurisdiction over this Defendant to be reasonable.

ACQUIRED ACTAVIS ENTITIES

As already set forth in this opinion, this Court finds that the Complaint meets the relaxed pleading requirements of Ohio set forth in Civil Rules 8 and 9. This applies also to the "Acquired Actavis Entities." The Complaint in Section III(B) sufficiently identifies the entities and sets forth allegations concerning the individual entities and their representation/misrepresentations and actions concerning opioid uses and dangers. These entities are placed on notice, like all of the other defendants, of the claims against them. This is sufficient to overcome the challenges at the pleading stage. However, it might be a different story under different standards in dispositive motion practice.

JURISDICTION-TEVA PHARMACEUTICAL INDUSTRIES LTD.

This Court has in the previous section has set forth the law which governs the analysis concerning jurisdiction under Ohio's Long-arm Statute, the Ohio Civil Rules, and due process under the 14th Amendment to the United States Constitution. This Court takes judicial notice of exhibits 50-59 attached to the Troutman affidavit as requested by the Plaintiff under Evidence Rule 201(B). This Court notes that Teva Ltd. published its "2016 Social Impact Report" stating that the company had 10,855 employees employed in the United States and Canada. Exhibit #50 at #12, Exhibit

#51 to the Troutman affidavit is Teva Limited's filing with the United States Securities and Exchange Commission. This filing states:

> "The specialty business may continue to be affected by price reforms and changes in the political landscape, following recent public debate in the U.S. We believe that our primary competitive advantages include our commercial marketing teams,..."

This filing further states:

> "Our U.S. specialty medicines revenues were 6.7 billion in 2016, comprising the most significant part of our specialty business."

The Court notes that Teva's specialty medicines revenues in the U.S. were almost six times that of its revenue in the European market. Page 46 of Exhibit #51 states that Teva Limited's "worldwide operations are conducted through a network of global subsidiaries." Teva Pharmaceuticals USA, Inc. is listed as a subsidiary in the United States which is owned by Teva Limited. Exhibit #54 to the Troutman affidavit lists Teva USA as the North American headquarters of Teva Limited.

As stated in the previous section, the Plaintiff is required only to make a prima facia showing of jurisdiction. This Court must view the pleadings and documentary evidence in a light most favorable to Plaintiff. At this point in the litigation, the evidentiary materials support the Plaintiff's prima facia showing of personal jurisdiction under 2307.382 ORC, Civil Rule 4.3(a) and the due process clause of the 14th Amendment to the United States Constitution.

All Defendants' Motions to Dismiss are overruled.

JUDICIAL NOTICE

Pursuant to Ohio Evidence Rule 201, the Motions of all parties for judicial notice are granted. The Court takes judicial notice of all materials filed by the moving parties with their Motions.

MOTION TO STAY

The Defendants have filed a joint Motion to Stay this litigation pursuant to the doctrine of primary jurisdiction and this Court's inherent power to control litigation pending in its court. State, ex rel Banc One Corp. v. Rocker, 86 Ohio St. 3d 169 (1999); United States v. W. Pacific R.R. Co., 352 U.S. 59 (1956); Lazarus v. Ohio Cas. Group, 144 Ohio App. 3d 716 (2001); Pacific Chem. Prods. Co. v. Teletronics Servs., Inc., 29 Ohio App. 3 45 (1985). Defendants claim that a stay of litigation should be enacted when claims are pending in a court and the resolution of issues pertaining to the claims are also before the special expertise of an administrative body. A trial court should defer action on an issue when there are administrative proceedings pending before a government regulatory agency which can resolve the lawsuit. The claims pending in the court must require a body of experts capable of handling the complex facts of the case before the court. The stay of litigation under the primary jurisdiction doctrine or the inherent authority of the court rests with the sound discretion of the trial court.

Article VII of the Ohio Rules of Evidence provides for and governs the presentation of evidence by expert witnesses in litigation. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, establishes that the trial court is the gatekeeper in determining what expert testimony from witnesses is admissible at trial. The Daubert Court sets forth numerous factors to consider in evaluating the reliability of scientific evidence. The Supreme Court expressed confidence in the ability of trial courts to evaluate complicated scientific evidence.

Defendants are correct that the FDA currently has pending before it numerous complex issues concerning the application of opioids and the addictive nature of

opioids. There is no guarantee when the FDA will complete its review of the numerous complex issues before it.

This Court agrees with the United States District Court in City of Chicago v. Purdue Pharma LP, supra, that the issue before this Court is whether opioids were marketed truthfully in the state of Ohio and whether Defendants misrepresented the risks, benefits, and superiority of opioids to treat long-term chronic pain. This Court agrees with the district court that federal and state courts are equipped to adjudicate these types of claims. See also State of Missouri v. Purdue Pharma, LP, Missouri Circuit Court, 22nd Judicial Circuit, Case No. 1722-CC10626. This Court is not aware of any pending stay order in any state or federal court concerning these issues. The Court further finds that the Plaintiff would be unduly prejudiced by an open-ended court order which stays these proceedings pending the determination of the FDA. This Court is equipped to handle the issues raised in this litigation. A stay order would unduly prejudice the Plaintiff. The Motion to Stay is overruled. The stay on discovery is vacated. Discovery in this action may commence forthwith.

DATE: 8/24/18

Scott W. Nusbaum

SCOTT W. NUSBAUM, JUDGE
COMMON PLEAS COURT #2
ROSS COUNTY, OHIO
SITTING BY ASSIGNMENT

Recipients of Decision and Entry:

Mark H. Troutman
Attorney at Law
Two Miranova Place, Suite 700
Columbus, OH 43215-5098

Albert J. Lucas
Attorney at Law
1200 Huntington Center
41 South High Street
Columbus, OH 43215

John R. Mitchell
Attorney at Law
3900 Key Center
127 Public Square

John Q. Lewis
Attorney at Law
950 Main Avenue
Suite 1100

Cleveland, OH 44114-1291

Carole S. Rendon
Attorney at Law
Key Tower
127 Public Square, Suite 2000
Cleveland, OH 44114-1214

Cleveland, OH 44113-7213

Daniel J. Buckley
Attorney at Law
301 East Fourth Street
Suite 3500, Great American Tower
Cincinnati, OH 45202

EXHIBIT 9

2018 WL 4468439 (Alaska Super.) (Trial Order)
Superior Court of Alaska.
Third Judicial District
Anchorage Borough

STATE of Alaska, Plaintiff,
v.
PURDUE PHARMA L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and Jane Does 1-10, Defendants.

No. 3AN-17-09966CI.
July 12, 2018.

Order Granting in Part Defendants' Motion to Dismiss Plaintiff's Complaint (Case Motion #8)

Dani Crosby, Judge.

I. INTRODUCTION

Defendants Purdue Pharma L.P., et al., move to dismiss State of Alaska's Complaint under Alaska Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. [1] After reviewing the memoranda of the parties and after oral argument on the issues, the court GRANTS IN PART the motion.

II. BACKGROUND

The State of Alaska ("the State") filed this action on its own behalf against drug manufacturer Purdue Pharma L.P., et al., ("Purdue") alleging the opioid epidemic and a public health crisis in Alaska was caused, in large measure, by a fraudulent and deceptive marketing campaign intended by Purdue to increase sales of its opioid products. The State alleges it has paid and will pay expenses for the medical care of Alaska's population due to overuse, addiction, injury, overdose, and death. The State seeks damages, injunctive relief, and civil penalties. [2]

The State's complaint asserts six claims: (1) violations of Alaska's Unfair Trade Practices and Consumer Protection Act (AS § 45.50.471 *et seq.*); (2) violations of Alaska's Medical Assistance False Claim and Reporting Act (AS § 09.58.010 *et seq.*); (3) public nuisance; (4) fraud, negligence, and negligent misrepresentation; (5) strict products liability for design defect and failure to warn; and (6) unjust enrichment.

Purdue moves to dismiss the complaint asserting seven grounds: (1) the State's claims are preempted by federal law; (2) the State's claims fail to adequately establish causation; (3) all claims must be dismissed, in part, as time-barred; (4) all claims fail because the State does not adequately plead fraud; (5) the State's allegation of failing to report suspicious orders does not state a claim; (6) the State does not allege a cognizable injury; and (7) other additional grounds. [3]

III. LEGAL STANDARD

A motion to dismiss for failure to state a claim upon which relief may be granted, filed pursuant to Alaska Rule of Civil Procedure 12(b)(6), tests the legal sufficiency of the complaint's allegations. [4] Motions to dismiss under CR 12(b)(6)

are viewed with disfavor. [5] In determining the sufficiency of the stated claim in a 12(b)(6) motion, it is enough that the complaint set forth allegations of fact consistent with some enforceable cause of action on any possible theory. [6]

***2** In resolving the merits of such motions, the court considers only well pled allegations of the complaint, while ignoring unwarranted factual inferences and conclusions of law. [7] Generally, such a motion is determined solely on the pleadings; however, the court may consider public record, including court files from other proceedings. [8]

The court must construe the complaint in the light most favorable to the non-moving party and presume the pleading's allegations to be true. [9] The court can affirm dismissal for failure to state a claim only if "it appears beyond doubt" that the plaintiff can prove no set of facts which would entitle relief. [10]

IV. DISCUSSION

A. Specific Claims

1. The Unfair Trade Practices and Consumer Protection Act

The Unfair Trade Practices and Consumer Protection Act ("UTPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce." [11] To establish a prima facie case of unfair or deceptive acts, the State must allege facts which if proven would establish: (1) that the defendant is engaged in trade or commerce; and (2) that in the conduct of trade or commerce, an unfair act or practice has occurred. [12]

Whether an act or practice is deceptive is determined simply by asking "whether it has the capacity to deceive." [13] The plaintiff need not prove that the defendant intended to deceive; it is enough to show that the acts and practices were "capable of being interpreted in a misleading way." [14] As a remedial statute intended to provide consumers more protection than its federal counterpart, Alaska's UTPA is applied broadly. [15]

The State claims Purdue has violated the UTPA by engaging in deceptive trade practices through its marketing and advertising of opioids. [16] The State alleges Purdue:

[M]isrepresents, even today, to Alaska doctors and patients the risk of opioid addiction. Specifically, Purdue affirmatively misrepresents that: (a) pain patients do not become addicted to opioids; (b) its long-acting opioids are steady-state and less addictive; (c) doctors can identify and manage the risk of addiction; (d) patients who seem addicted are merely 'pseudo-addicted,' and should be treated with more opioids; (e) opioid addiction is the product not of narcotic opioids, but problem patients and doctors; and (f) opioid abuse and addiction manifest in snorting and injecting the drugs, when oral abuse is far more common. [17]

Paragraph 162(a)-(i) of the complaint has alleged facts sufficient to establish a prima facie case of deceptive trade practices under the UTPA.

The State also claims Purdue violated the UTPA by engaging in unfair trade practices. [18] An act or practice can be unfair without being deceptive. [19] Unfairness is determined by a variety of factors, including: (1) whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise, whether, in other words, it is within at least the penumbra of some common law, statutory, or

other established concept of fairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; and (3) whether it causes substantial injury to consumers (or competitors or other businessmen). [20]

***3** The State alleges Purdue's promotion of addictive drugs was contrary to public policy in Alaska, was immoral and unethical, and caused substantial injury to consumers. [21] For example, the State cites the Governor's "Declaration on Disaster" due to a "public health disaster emergency" as evidence that Alaska policy and facts alleged in paragraph 164(a)-(i) are sufficient to establish a claim for unfair practices.

The State also alleges violations of the UTPA's prohibition of unfair methods of competition. [22] The State alleges Purdue has promoted "OxyContin as providing 12 hours of pain relief and promoted abuse deterrent formulations of its opioids as more difficult to abuse and less addictive as a means of maintaining a competitive advantage against other opioids." [23] The State also alleges Purdue promoted opioids as superior to other analgesics, such as NSAIDS, by exaggerating the risks of NSAIDS, and omitting the risks of opioids. [24]

The State has alleged facts sufficient to establish a claim for unfair methods of competition.

2. The Alaska Medical Assistance False Claim and Reporting Act.

The State's second cause of action raises an issue of first impression. The Alaska Medical Assistance False Claim and Reporting Act ("FCA") was enacted by the Alaska Legislature in 2016 as part of a package of Medicaid reform. [25] The effective date of the statute is September 19, 2016. [26] The Alaska FCA provides for civil penalties, in addition to criminal penalties, for filing false or fraudulent claims for medical services or products for reimbursement by the State's medical assistance programs.

Purdue raises a number of objections to the State's FCA cause of action, but one is dispositive. Purdue argues the claim must be dismissed as time-barred because a retroactive application of the statute is prohibited. While statute of limitations is usually pled as an affirmative defense, a complaint may be subject to dismissal under Rule 12(b)(6) when "an affirmative defense appears clearly on the face of the pleading." [27] The court will consider whether the statute of limitations subjects the cause of action to dismissal because the issue of retroactivity appears clearly on the face of the pleadings.

In Alaska, a statutory presumption is that "[n]o statute is retrospective unless expressly declared therein." [28] The Alaska Supreme Court has held that "[a]bsent clear language indicating legislative intent to the contrary, a law is presumed to operate prospectively only[.]" [29] The court will "presume that statutes only have prospective effect 'unless a contrary legislative intent appears by express terms or necessary implication.'" [30] There is neither an express statement nor a necessary implication in AS § 09.58.010 which would lead the court to automatically apply it retroactively.

The State argues for application of the FCA because the State alleges Purdue's conduct consists of an ongoing course of deceptive activities that began at least ten years ago, and continues today. [31] After review of the Complaint, the court cannot find specific allegations of conduct occurring after September 16, 2016. [32] Accordingly, the court finds the State's cause of action for violations of Alaska's FCA is time-barred. The State will be granted leave to amend, should it so wish, to allege violations occurring after the effective date of the statute.

3. Public Nuisance

***4** The State's third claim for relief alleges Purdue has created a public nuisance. [33] The Alaska Supreme Court has indicated its agreement with federal common law defining a public nuisance as an unreasonable interference with a right common to the general public, such as a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience. [34]

The State alleges Purdue's conduct, as described in the complaint, has "been a substantial factor" in creating a public health crisis and state of emergency in Alaska. [35] The State alleges opioid use, overuse, and addiction has injured the State by causing deaths, [36] overwhelming medical resources and emergency rooms, [37] increasing illegal activity and law enforcement activities, [38] increasing costs for medical care of infants born with neonatal abstinence syndrome and requiring foster treatment, [39] and incurring significant expenses in addiction treatment. [40]

The court finds the facts as alleged could reasonably be construed as demonstrating a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience and therefore an interference with a right common to the general public.

The State has alleged facts sufficient to state a claim for public nuisance.

4. Fraud and Negligence/Negligent Misrepresentation

a. Negligence

The State has pled claims for strict products liability and negligence. Even if Purdue were found strictly liable for its products, Alaska permits a claim of negligence if a plaintiff shows that a defendant breached a duty owed to the plaintiff, and that the breach caused the plaintiff harm. [41]

The State argues Purdue had a duty to the State and its residents: (1) to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs; (2) not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain; and (3) to report suspicious prescribes. [42] The State alleges Purdue breached those duties through its misrepresentations, causing the State to pay not only for the opioids, but also costs to mitigate the public health crisis. [43]

The State alleges facts sufficient to support a claim of negligence.

b. Fraud and Negligent Misrepresentation

The torts of fraud and negligent misrepresentation are similar in many ways. To prevail on a claim of fraud, a plaintiff must establish: (1) misrepresentation; (2) made fraudulently; (3) for the purpose of inducing another to act in reliance on it; (4) justifiable reliance by the recipient; and (5) causing loss. [44] A statement can be literally true and still be a fraudulent misrepresentation if the maker knows the statement is materially misleading. [45]

***5** A claim of negligent misrepresentation requires showing that: (1) defendant made the statement in the course of his business, profession or employment, or in any other transaction in which he had a pecuniary interest; (2) the representation supplied false information; (3) plaintiff justifiably relied on that false information; and (4) defendant failed to exercise reasonable care or competence in obtaining or communicating the information. [46] In both causes of

action, the alleged misrepresentation must relate to a past or present fact "susceptible of exact knowledge" at the time it was made. [47]

The State alleges Purdue engaged in false representation and concealment of material facts about the use of opioids to treat chronic pain. [48] The State alleges Purdue knew "its statements about the risks and benefits of opioids to treat chronic pain were false or misleading," that Purdue intended to induce reliance among doctors, knowing doctors would rely on the misrepresentations, leading to damages caused by overuse of opioids. [49]

The State alleges facts sufficient to support a claim of fraud and negligent misrepresentation.

5. Strict Products Liability. Design Defect and Failure to Warn

In Alaska, "a manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." [50] The defect can be a manufacturing defect, a design defect, or a failure to provide adequate warnings. [51] The State alleges design defect and failure to warn.

Strict liability claims against manufacturers of prescription drugs for design defect and failure to warn are allowed in Alaska. [52] In *Shanks v. Upjohn*, the Alaska Supreme Court established "that a prescription drug is defectively designed and strict liability should be imposed on its manufacturer if the prescription drug failed to perform as safely as an ordinary doctor would expect, when used by the patient in an intended and reasonably foreseeable manner." [53] Regarding failure to warn, the Court found "the warnings should be sufficient to put the physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug." [54] Strict liability may also attach to the inadequacy of the directions or instructions for the safe use of the product. [55]

The State alleges Purdue's opioid products are defectively designed because they fail to perform as safely as an ordinary consumer would expect. [56] The State alleges Purdue's opioids failed to perform safely because they "carry a far greater risk and actual rate of addiction" than the public was led to believe, failed to provide "functional improvement" in patients, and OxyContin failed to provide the promised 12 hour relief. [57]

***6** The State also alleges Purdue failed to "provide adequate warnings that clearly indicate the scope of the risk" and used "misrepresentations and omissions that contradicted and undermined its drug label." [58]

The State has alleged facts sufficient to state a claim for strict products liability.

6. Unjust Enrichment

In *Alaska Sales and Service v. Millet*, the Alaska Supreme Court explained unjust enrichment as follows:

> [a] person who has been unjustly enriched at the expense of another is required to make restitution to that person. A person is enriched if he receives a benefit; a person is unjustly enriched if the retention of the benefit without paying for it would be unjust. [59]

The Court then set forth three elements of unjust enrichment: (1) a benefit conferred upon the defendant by the plaintiff; (2) appreciation of such benefit; and (3) acceptance and retention by the defendant of such benefit under circumstances that it would be inequitable for the defendant to retain it without paying the value thereof. [60] Additionally, "[t]he courts are in accord in stressing that the most significant requirement for recovery in quasi-contract is that the enrichment to the defendant must be unjust; that is, the defendant must receive a true windfall or something for nothing." [61] Unjust enrichment is an equitable doctrine, which ordinarily falls within the court's broad discretion. [62] Whether there has been unjust enrichment is generally a question of fact. [63]

In the instant case, the State argues that Purdue has unjustly retained a benefit, in revenue, while the State absorbed the cost of healthcare, addiction, and illegal activity related to the opioid epidemic. [64]

The State has alleged facts sufficient to state a claim for unjust enrichment.

B. Purdue's Objections

Purdue moved to dismiss the Complaint under CR 12(b)(6) on seven grounds, as outlined above in Section II. Because a Rule 12(b)(6) motion is only intended to test the sufficiency of a Complaint's allegations, not all of Purdue's arguments are properly considered at this stage of proceedings. [65]

As previously discussed, the court did consider Purdue's argument that the statute of limitations barred the State's cause of action for violations of the False Claims Act. [66]

***7** The court will also consider Purdue's arguments relating to the applicability of Alaska Rule of Civil Procedure 9(b) as these relate directly to sufficiency of complaint.

Purdue argues for dismissal of all claims because the State does not adequately plead fraud. Because the State centers its claims around Purdue's alleged "deceptive and fraudulent" marketing, Purdue argues the State must plead all claims to the heightened standard of CR 9(b).

Rule 9(b) provides: "[I]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be pled with particularity." This standard is not high. [67] The rule "simply requires a claim of fraud to specify the time and place where the fraud occurred; it seeks to prevent conclusory pleading by requiring a complaint to do more than 'recit[e] without specificity that fraud existed.'" [68] The rule does not prevent plaintiffs from filing complaints based on available information and belief. [69]

The State's complaint meets the requirement of CR 9(b). It alleges Purdue knowingly misrepresented the efficacy, safety, and risk of its products, through marketing and direct promotion to doctors, for the purpose of increasing sales. The State alleges Purdue intended doctors to rely on their misrepresentations, knew doctors did rely on the misrepresentations, causing prescriptions for medically unnecessary opioids to be paid for by the State. The State has alleged all the elements of fraud with sufficient specificity. [70]

The court will also address Purdue's argument concerning causation because Purdue contends that all of the State's claims fail as a matter of law because the State has not and cannot adequately plead a causal nexus between Purdue's alleged misconduct and the State's alleged injuries.

In essence, Purdue argues the State's injuries are too remote from Purdue's alleged activities to ascribe any liability to Purdue. Holding Purdue liable for the "opioid epidemic disregards many intervening actors and superseding events in the casual chain." [71] Purdue urges this court to find "proximate cause cannot be established as a matter of law because the chain of causation is too attenuated, too indirect, too remote, and speculative…" [72] and to reject a "fraud on the market theory." [73]

The State opposes, arguing that Purdue should not escape liability simply because Purdue has developed a "sophisticated and deceptive marketing scheme." The State's point is well taken and the court is not persuaded to dismiss the complaint for lack of causation.

The State's main argument is that Purdue created a market for long term opioid use for non-acute pain where none existed before, and then filled that market with its products. The State alleges a very sophisticated fraudulent and deceptive marketing scheme to influence the medical community, which included direct marketing of its products to doctors. The State alleges Purdue helped to change the perception of opioid risk and benefit and promoted its use to general practitioners through marketing materials, medical literature, articles, symposia, and direct approach to doctors.

***8** It is sufficient that the complaint alleges there is a connection between Purdue's marketing of its opioid products and the injuries to the State. In Alaska, the issue of proximate cause is usually reserved for the trier of fact. [74]

The State has alleged adequate facts to support its theory of causation.

V. CONCLUSION

In order to prevail against the Rule 12(b)(6) motion, the State would have to set forth allegations of fact consistent with some enforceable cause of action on any possible theory. With the exception of the claim for violations of Alaska's False Claim Act, the State has done so. It does not appear beyond doubt that the State can prove no set of facts which would entitle relief for unfair trade practices, public nuisance, fraud, negligence, negligent misrepresentation, strict products liability, and unjust enrichment. [75]

Therefore, the *Motion to Dismiss* is GRANTED IN PART. The State's second cause of action for violations of Alaska's Medical Assistance and False Claims Act is DISMISSED, with LEAVE TO AMEND.

The *Motion to Dismiss* is DENIED in all other respects.

Defendants' Answer to the Complaint is due TWENTY DAYS from the date of this order.

IT IS SO ORDERED.

DATED at Anchorage, Alaska this *12 July 2018*.

<<signature>>

Dani Crosby

Superior Court Judge

Footnotes

1 Defendant Rhodes Pharmaceuticals, L.P., was dismissed by Plaintiff without prejudice prior to answer.

2 The original complaint was filed under seal. Portions with confidential information have been redacted. The complaint is 85 pages long with 237 points.

3 Purdue has attached 13 exhibits to its motion and two more to its reply. Purdue requests the court take judicial notice of the exhibits as they are publically available. The exhibits are FDA publications and prescription information sheets. No materials outside of the pleadings have been submitted by the parties.

4 *Dworkin v. First Nat. Bank of Fairbanks*, 444 P.2d 777, 779 (Alaska 1968).

5 *State. Dep't of Health & Soc. Services, Div. of Family and Youth Serv. v. Native Village of Curyung*, 151 P.3d 388, 397 (Alaska 2006) (internal citations omitted).

6 *Id.*

7 *Dworkin* at 779.

8 *Nizinski v. Currington*, 517 P.2d 754, 756 (Alaska 1974) (internal citation omitted).

9 *Valdez Fisheries Development Ass'n, Inc. v. Alyeska Pipeline Service Co.*, 45 P.3d 657, 664 (Alaska 2002) (citing *Kollodge v. State*, 757 P.2d 1024, 1026 (Alaska 1998)).

10 *Id.*

11 AS § 45.50.471(a).

12 *Kenai Chrysler Center, Inc. v. Denison*, 167 P.3d 1240, 1255 (Alaska 2007) (quoting *State of Alaska v. O'Neill Inv., Inc.*, 609 P.2d 520 at 534-35 (Alaska 1980)).

13 *Id.*

14 *Id.*

15 *Id.*

16 Complaint ¶ 161; violations of §§ 45.50.471(b)(4), (7), (11), (12). It appears undisputed that Purdue is "engaged in trade or commerce."

17 *Id.* at ¶ 45.

18 *Id.* at ¶ 164; a violation of § 45.50.471 (a).

19 *State v. O'Neill* at 535.

20 *Id.* (internal citation omitted).

21 *Id.* at ¶ 164.

22 *Id.* at ¶¶ 165 - 168.

23 *Id.* at ¶ 165.

24 *Id.*

25 Senate Bill 74, SLA 2016, ch. 25, § 18, effective September 19, 2016. AS 09.58.010, *et seq.*

26 *Id.*

27 *Aspen Exploration Corp. v. Sheffield*, 739 P.2d 150, 152 (Alaska 1987) (internal citation omitted).

28 AS § 01.10.090.

29 *State, Dep't. of Rev. v. Alaska Pulp America, Inc.*, 674 P.2d 268, 272 (Alaska 1983) (internal citation omitted).

30 *Thompson v. U.P.S.*, 975 P.2d 684, 688 (Alaska 1999) (quoting *Pan Alaska Trucking, Inc. v. Crouch*, 773 P.2d 947, 948 (Alaska 1989)).

31 Plaintiffs *Amended Response in Opposition to Purdue Defendants' Motion to Dismiss Plaintiff's Complaint*, p. 27.

32 Complaint at ¶ 186. The State cites data from 2013-2016.

33 *Id.* at ¶ 192.

34 *Friends of Willow Lake, Inc. v. State, Dept. of Transp. & Public Fac., et al.*, 280 P.3d 542, 548 (Alaska 2012) (quoting Restatement (Second) of Torts §821B(1) (1979) (defining public nuisance)). *See also, Taha v. State*, 366 P.3d 544, 547 (Alaska Ct App. 2016) (defining public nuisance according to Black's Law Dictionary (10th ed. 2014) as "[a]n unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property").

35 Complaint at ¶ 196.

36 *Id.* at ¶ 9.

37 *Id.* at ¶ 10.
38 *Id.* at ¶ 11.
39 *Id.* at ¶¶ 13-14.
40 *Id.* at ¶ 156.
41 *Cusack v. Abbott Lab. Inc., et al.*, 2017 WL 3688149 (D. Alaska 2017) (citing *Silvers v. Silvers*, 999 P.2d 786, 793 (Alaska 2000)).
42 Complaint at ¶¶ 204, 205, 206.
43 *Id.* at ¶ 208.
44 *Asher v. Alkan Shelter, LLC*, 212 P.3d 772, 781 (Alaska 2011) (abrogated on other grounds, *Shaffer v. Bellows*, 260 P.3d 1064 (2011) (citing *Lightle v. State, Real Estate Comm'n*, 146 P.3d 980, 983 (Alaska 2006)).
45 *Id.* (citing *Lightle* at 986).
46 *Bubbell v. Wien Air Alaska, Inc.*, 682 P.2d 374, 380 (Alaska 1984) (quoting Restatement (Second) of Torts §552(1) 1977).
47 *Cousineau v. Walker*, 613 P.2d 608, 611 n.4 (Alaska 1980).
48 Complaint at ¶ 200.
49 *Id.* at ¶¶ 201-214.
50 *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1194 (Alaska 1992) (internal citation omitted).
51 *Id.*
52 *Id.* at 1198: "Alaska recognizes such claims and makes no exception for prescription drugs. Neither policy nor reason supports the approach taken by some courts in barring such claims."
53 *Id.*at 1195. The Court noted that in some cases, the ordinary consumer standard may apply, instead of the ordinary doctor standard.
54 *Id.* at 1200 (quoting *Polley v. Ciba-Geigy Corp.*, 658 F.Supp. 420 (D. Alaska 1987)).
55 *Id.* (quoting *Gosewisch v. American Honda Motor Co.*, 737 P.2d 376 (1987)).
56 Complaint at ¶ 217. The State has used the consumer as the standard. However, the Court in *Shanks* uses the ordinary doctor standard. The Court did note that in some cases, the ordinary consumer standard might apply, instead of the ordinary doctor standard. *See Shanks*, fn7.
57 Complaint at ¶ 217.
58 Complaint at ¶¶ 218-219.
59 735 P.2d 745, 746 (Alaska 1987).
60 *Id.*
61 *Id.* (the Court uses the term quasi-contract, explaining "[c]ourts generally treat actions brought upon theories of unjust enrichment, quasi-contract, contracts implied in law, and quantum meruit as essentially the same.").
62 *Id.* at 747.
63 *State, Dep't of Rev. Child Sup. Enfc't Div. v. Wetherelt*, 931 P.2d 383, 390 fn. 11 (Alaska 1997).
64 Complaint at ¶ 223.
65 Though presented as grounds for failure to state a claim, Purdue's remaining arguments, specifically, Purdue's objections on the grounds of federal preemption, as well as objections to the State's method of proving injury, are premature. Purdue may properly renew their arguments in further motion practice.
66 The court will not consider the statute of limitations regarding the State's UTPA claim, as it does not appear clearly on its face from the Complaint that the claim is time-barred. Purdue may raise it an affirmative defense or renew the argument by further motion practice.
67 *Asher v. Alkan Shelter*, LLC, 212 P.3d 772, 778 (Alaska 2009).
68 *Id.* (internal citation omitted).
69 *Id.*
70 Purdue asserts the State must identify, for example, specific doctors who relied on Purdue marketing materials, or specific sale representatives who allegedly made misleading statements. Such a level of detail is not required; the State may through discovery develop its evidence through any method of proof it chooses.
71 Purdue's *Memorandum of Law in Support of the Purdue Defendants' Motion to Dismiss Plaintiff's Complaint* at p.19.
72 *Id.* at p. 21.
73 *Id.* at p. 22.
74 *See Winschel v. Brown*, 171 P.3d 142, 148 (Alaska 2017) (holding fact questions as to proximate cause and superseding causation precluded summary judgment).

75 Purdue also argued the State's allegation for reporting suspicious orders did not state a claim. The Complaint did not include a cause of action for the alleged violations; the allegations were made to support the State's claim of unfair and deceptive trade practices. Complaint at ¶ 147.

End of Document

EXHIBIT 10

2017 WL 10152334 (Okl.Dist.) (Trial Order)
District Court of Oklahoma.
Cleveland County

STATE of Oklahoma, ex rel., Mike Hunter, Attorney General of Oklahoma, Plaintiff,
v.
(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.

No. CJ-2017-816.
December 6, 2017.

Order

Thad Balkman, Judge.

***1** The State and the Defendants appear by counsel for oral arguments on Defendants' Motions to Dismiss and Motion to Stay. After review of the briefs and oral arguments from the parties, the Court finds and orders that the State's Petition sufficiently states its claims and those claims should not be dismissed based on preemption or pursuant to the Primary Jurisdiction doctrine or the Court's inherent power. However the State's cause of action under the Oklahoma Consumer Protection Act 15 OS § 751-65 is dismissed with prejudice. The Defendants are to respond to the State's discovery requests pursuant to a protective order; a formal protective order setting out the terms will be prepared by Defendants and submitted to the State by December 15, 2017.

The parties are to appear and enter a scheduling order on January 11, 2018 at 10:00am.

<<signature>>

Thad Balkman, District Judge

CERTIFICATE OF SERVICE

I, Jeffrey Thomas Walker, Assistant Attorney General, hereby certify that I have this day, April 16, 2019, served the foregoing document upon all parties by email to:

Counsel for Defendants Purdue Pharma L.P. and Purdue Pharma Inc.
Timothy C. Blank, BBO # 548670
DECHERT LLP
One International Place, 40th Floor
100 Oliver Street
Boston, MA 02110-2605
timothy.blank@dechert.com

Counsel for Defendants Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Peter Boer, Paulo Costa, Cecil Pickett; Ralph Snyderman and Judith Lewent
Robert J. Cordy
Matthew L. Knowles
Annabel Rodriguez
MCDERMOTT WILL & EMERY LLP
28 State Street, Suite 3400
Boston, MA 02109
(617) 535-4033
rcordy@mwe.com
mknowles@mwe.com
anrodriguez@mwe.com

Counsel for Defendants Craig Landau, John Stewart, and Mark Timney
James R. Carroll, BBO # 554426
Maya P. Florence, BBO # 661628
SKADDEN, ARPS, SLATE MEAGHER & FLOM LLP
500 Boylston Street
Boston, Massachusetts 02116
james.carroll@skadden.com
maya.florence@skadden.com

Counsel for Defendant Russell J. Gasdia
Juliet A. Davison, BBO # 562289
DAVISON LAW, LLC
280 Summer St., 5th Floor
Boston, MA 02210
juliet@davisonlawllc.com
porter@spplawyers.com

Jeffrey T. Walker
Asst. Attorney General