

IN THE SUPREME COURT OF THE STATE OF NEVADA

CITY OF RENO,

Appellant,

vs.

TEVA PHARMACEUTICALS USA,
INC.; CEPHALON, INC.; ENDO
HEALTH SOLUTIONS, INC.; ENDO
PHARMACEUTICALS INC.;
ALLERGAN USA, INC.; ALLERGAN
FINANCE, LLC F/K/A ACTAVIS,
INC. F/K/A WATSON
PHARMACEUTICALS, INC.;
ACTAVIS PHARMACY, INC. F/K/A
WATSON PHARMA, INC.; AND
ACTAVIS LLC,

Respondents.

Supreme Court No. 85412

District Court Case No.
CV18-01895

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Clerk of Supreme Court

APPELLANT'S APPENDIX VOLUME 3

Robert T. Eglet, Esq.
Robert M. Adams, Esq.
Cassandra S.M. Cummings, Esq.
Richard K. Hy, Esq.
EGET ADAMS
400 S. 7th Street, 4th Floor
Las Vegas, NV 89101
Tel: (702) 450-5400
Fax: (702) 450-5451
Email: eservice@egletlaw.com

Bill Bradley, Esq.
Mark C. Wenzel, Esq.
**BRADLEY, DRENDEL &
JEANNEY**
6900 S. McCarren Blvd., Suite 2000
Reno, NV 89509
Tel: (775) 335-9999
Email: office@bdjlaw.com

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 15th day of April 2023, I served a true and correct copy of the foregoing **APPELLANT'S APPENDIX VOLUME 3** upon each of the parties by electronic service through the E-Flex rules of service.

By: /s/ Jennifer Lopez
An Employee of EGLET ADAMS

EXHIBIT 8

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IN THE COURT OF COMMON PLEAS
ROSS COUNTY, OHIO

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FILED
ROSS COUNTY COMMON PLEAS
CLERK OF COURTS
TY D. HINTON

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 facie 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 OSCP 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 OSCP, 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, OSCP 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 facie* 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 facie 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 facie 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.

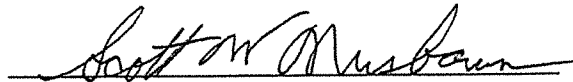
Article VII of the Ohio Rules of Evidence provides for and governs the presentation of evidence by expert witnesses in litigation. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, establishes that the trial court is the gatekeeper in determining what expert testimony from witnesses is admissible 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, 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

SHORT FORM ORDER

INDEX No. 400000/2017SUPREME COURT - STATE OF NEW YORK
NEW YORK STATE OPIOID LITIGATION PART 48 - SUFFOLK COUNTY**PRESENT:****E-FILE**Hon. JERRY GARGUILO
Justice of the Supreme Court

IN RE OPIOID LITIGATION

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:	MOTION DATE	<u>2/7/18</u>
:	ADJ. DATE	<u>3/21/18</u>
:	Mot. Seq. #001 - MD	
:	Mot. Seq. #002 - MD	
:	Mot. Seq. #004 - MD	
:	Mot. Seq. #005 - MD	
:	Mot. Seq. #007 - MotD	
:	Mot. Seq. #018 - MD	
:	Mot. Seq. #019 - MD	

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Upon the reading and filing of the following papers in this matter: (1) Notice of Motion by defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. (Mot. Seq. #001), dated November 10, 2017, and supporting papers (including Memorandum of Law); (2) Memorandum of Law in Opposition (Mot. Seq. #001), dated January 19, 2018; (3) Reply Memorandum of Law (Mot. Seq. #001), dated February 23, 2018; (4) Notice of Motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and the Purdue Frederick Company, Inc. (Mot. Seq. #002), dated November 10, 2017, and supporting papers (including Memorandum of Law); (5) Affidavit in Opposition by the plaintiffs (Mot. Seq. #002, #018, #019), dated January 18, 2018, and supporting papers (including Memorandum of Law); (6) Reply Memorandum of Law (Mot. Seq. #002), dated February 23, 2018; (7) Notice of Motion by defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. (Mot. Seq. #004), dated November 10, 2017, and supporting papers (including Memorandum of Law); (8) Memorandum of Law in Opposition (Mot. Seq. #004), dated January 19, 2018; (9) Reply Memorandum of Law (Mot. Seq. #004), dated February 23, 2018; (10) Notice of Motion by defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (Mot. Seq. #005), dated November 10, 2017, and supporting papers (including Memorandum of Law); (11) Memorandum of Law in Opposition (Mot. Seq. #005), dated January 19, 2018; (12) Reply Memorandum of Law (Mot. Seq. #005), dated February 23, 2018; (13) Notice of Motion by defendants Allergan plc and Actavis, Inc. (Mot. Seq. #007), dated November 10, 2017, and supporting papers (including Memorandum of Law); (14) Affidavit in Opposition by the plaintiffs (Mot. Seq. #007), dated January 19, 2018, and supporting papers (including Memorandum of Law); (15) Reply Memorandum of Law (Mot. Seq. #007), dated February 23, 2018; (16) Notice of Motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan plc, and Actavis, Inc. (Mot. Seq. #018), dated November 10, 2017, and supporting papers (including Memorandum of Law); (17) Memorandum of Law in Opposition (Mot. Seq. #018), dated January 19, 2018; (18) Reply Memorandum of Law (Mot. Seq. #018), dated February 23, 2018; (19) Notice of Motion by defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (Mot. Seq. #019), dated November 10, 2017, and supporting papers (including Memorandum of Law); (20) Memorandum of Law in Opposition (Mot. Seq. #019), dated January 19, 2018; (21) Reply Memorandum of Law (Mot. Seq. #019), dated February 23, 2018; it is

ORDERED that the motion by defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc., the motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and the

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Purdue Frederick Company, Inc., the motion by defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc., the motion by defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc., the motion by defendants Allergan plc and Actavis, Inc., the motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan plc, and Actavis, Inc., and the motion by defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc., are hereby consolidated for purposes of this determination; and it is

ORDERED that defendants' motions for an order pursuant to CPLR 3211, dismissing as against each and all of them the master form long complaint filed in this action, are granted to the limited extent set forth below, and are otherwise denied.

The plaintiffs are counties within the State of New York that have commenced separate actions against certain pharmaceutical manufacturers for harm allegedly caused by false and misleading marketing campaigns promoting semi-synthetic, opium-like pharmaceutical pain relievers, including oxycodone, hydrocodone, oxymorphone, and tapentadol, as well as the synthetic opioid prescription pain medication fentanyl, as safe and effective for long-term treatment of chronic pain. Also named as defendants in those actions are certain pharmaceutical distributors that allegedly distributed those opium-like medications (hereinafter referred to as prescription opioids, pharmaceutical opioids, or opioids) to retail pharmacies and institutional health care providers for customers in such counties, and individual physicians allegedly "instrumental in promoting opioids for sale and distribution nationally" and in such counties. Briefly stated, the plaintiffs allege that tortious and illegal actions by the defendants fueled an opioid crisis within such counties, causing them to spend millions of dollars in payments for opioid prescriptions for employees and Medicaid beneficiaries that would have not been approved as necessary for treatment of chronic pain if the true risks and benefits associated with such medications had been known. They also allege that the defendants' actions have forced them to pay the costs of implementing opioid treatment programs for residents, purchasing prescriptions of naloxone to treat prescription opioid overdoses, combating opioid-related criminal activities, and other such expenses arising from the crisis.

One such lawsuit was commenced in August 2016 by Suffolk County and assigned to the Commercial Division of the Supreme Court. By order dated July 17, 2017, the Litigation Coordinating Panel of the Unified Court System of New York State directed the transfer of eight opioid-related actions brought by other counties, and any prospective opioid actions against the manufacturer, distributor, and individual defendants, to this court for pre-trial coordination. That same day, the undersigned issued a case management order reiterating that the individual actions are joined for coordination, not consolidated, and directing that a master file, known as "In re Opioid Litigation" and assigned index number 400000/2017, be established for the electronic filing of all documents related to the proceeding. The undersigned further directed the plaintiffs to file and serve a master long form complaint subsuming the causes of action alleged in the various complaints, and directed the manufacturer defendants, the distributor defendants, and the individual defendants to file joint motions pursuant to CPLR 3211, seeking dismissal of the master complaint, all by certain dates.

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The master long form complaint filed by the plaintiffs names as defendants the pharmaceutical manufacturers Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively referred to as Purdue), Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. (collectively referred to as Cephalon), Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc. (collectively referred to as Janssen), Endo Health Solutions, Inc., and Endo Pharmaceuticals, Inc. (collectively referred to as Endo), Allergan plc f/k/a Actavis plc, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively referred to as Actavis), and Insys Therapeutics, Inc. (referred to as Insys). Purdue allegedly manufactures, promotes, and sells various prescription opioids, including OxyContin and MS Contin, both of which are sold as extended release tablets and indicated for around-the-clock, long-term pain treatment, and Hysingla, which also is indicated for around-the-clock treatment of severe pain. Cephalon allegedly manufactures, promotes, and sells Actiq and Fentora, fentanyl drugs approved by the FDA for "breakthrough pain" in cancer patients who are tolerant to opioid therapy; it also allegedly sold generic opioids, including a version of OxyContin, from 2005 through 2009. Janssen allegedly manufactures, promotes, and sells Duragesic, a fentanyl drug approved for opioid-tolerant patients requiring around-the-clock opioid treatment, which is sold in the form of a transdermal patch. Until 2015, it also sold the prescription opioids Nucynta ER and Nucynta, both of which initially were approved for the management of moderate to severe pain, with Nucynta ER indicated for around-the-clock, long-term opioid treatment. Endo allegedly manufactures, markets, and sells the branded opioids Opana, Percodan, and Percocet, all three of which are marketed for moderate to severe pain, as well as generic opioids. Until June 2017, it also sold Opana ER, an oxymorphone drug in the form of an extended-release tablet, which was approved for around-the-clock treatment of moderate to severe pain, but it was removed from the market following a request by the FDA. Actavis allegedly markets and sells the branded drugs Kadian and Norco, and generic versions of Opana and Duragesic. Kadian, an extended-release morphine sulfate drug, allegedly is approved for the management of pain requiring around-the-clock, long-term treatment, and Norco is a generic version of Kadian. Insys allegedly develops, markets, and sells the branded prescription opioid Subsys, a sublingual spray of fentanyl.

As relevant to the motions that are the subject of this order, the master long form complaint (hereinafter the complaint) alleges that Purdue, Cephalon, Janssen, Endo, and Actavis (hereinafter collectively referred to as the manufacturer defendants), to maximize their profits, intentionally misrepresented to the public and the medical community the risks and benefits of opioids for the treatment of chronic pain. It alleges that to reverse the stigma historically associated with opioid use so that more patients would request opioids, more physicians would write prescriptions for them, and more healthcare insurers would pay for such treatment, the manufacturer defendants developed marketing campaigns, which included such strategies as branded and unbranded advertisements, educational programs and materials, and detailing of physicians, that overstated the benefits of prescription opioids for chronic pain (i.e., pain lasting three or more months) and misrepresented—even trivialized—the dangers associated with the long-term use of such medications. It further alleges that the defendants sold their pharmaceutical opioids to consumers within the plaintiffs' jurisdictions.

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The complaint also names as defendants the pharmaceutical distributors McKesson Corporation, Cardinal Health, Inc., Amerisource Drug Corporation, American Medical Distributors, Inc., Belco Drugs Ltd., Kinray, LLC, PSS World Medical, Inc., and Rochester Drug Cooperative, Inc., and alleges that such defendants distributed pharmaceuticals to pharmacies and institutional providers within plaintiff counties. In addition, it names the physicians Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster as defendants. The court notes that a stipulation discontinuing the claims against Dr. Portenoy without prejudice to any related action was filed by plaintiffs on March 16, 2018.

The complaint sets forth seven causes of action against all defendants. The first cause of action alleges deceptive business practices in violation of General Business Law § 349, and the second cause of action alleges false advertising in violation of General Business Law § 350. The third cause of action asserts a common-law public nuisance claim, the fourth cause of action asserts a claim for violation of Social Services Law § 145-b, and the fifth cause of action asserts a claim for fraud. The sixth cause of action is for unjust enrichment, and the seventh cause of action is for negligence.

The manufacturer defendants now jointly and separately move, pre-answer, for an order dismissing the complaint pursuant to CPLR 3211 (a) (1), (5), (7), and (8). While the court recognizes that subdivision (e) of CPLR 3211 permits a defendant to make only one motion under subdivision (a), it also recognizes the complexity of this matter as well as its unusual procedural framework; as the plaintiffs have been afforded ample opportunity to respond and have, in fact, submitted substantive opposition to each of the motions, the court will, for current purposes, waive compliance with the single-motion rule.

Before addressing the more comprehensive issues raised by the defendants, the court notes, insofar as certain of the manufacturer defendants seek dismissal on the ground that they are mere affiliates, the lack of evidence in the record to support any such claims, and the motions are denied to that extent without prejudice to any motions for summary judgment after joinder of issue.

When considering a motion to dismiss, a court must give the pleading a liberal construction, presume the allegations of the complaint are true, afford the plaintiff the benefit of every favorable inference, and determine only whether the facts as alleged fit within a cognizable legal theory (*EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d 11, 19, 799 NYS2d 170 [2005]; *Leon v Martinez*, 84 NY2d 83, 87-88, 614 NYS2d 972 [1994]). “Whether a plaintiff can ultimately establish [the] allegations is not part of the calculus in determining a motion to dismiss” (*EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d at 19, 799 NYS2d at 175).

Dismissal under CPLR 3211 (a) (1) may be granted only if the documentary evidence “utterly refutes plaintiff’s factual allegations” and conclusively establishes a defense to the asserted claim as a matter of law (*Goshen v Mutual Life Ins. Co.*, 98 NY2d 314, 326, 746 NYS2d 858 [2002]; *Leon v Martinez*, 84 NY2d at 88, 614 NYS2d at 972). A party seeking dismissal under CPLR 3211 (a) (5) based on the doctrine of res judicata must demonstrate that a final adjudication of a claim in a prior action between the parties on the merits by a court of competent jurisdiction precludes relitigation of that claim in the instant action (*Miller Mfg. Co. v Zeller*, 45 NY2d 956, 958, 411 NYS2d 558 [1978]).

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Likewise, a defendant raising a statute of limitations defense under CPLR 3211 (a) (5) bears the initial burden of establishing a prima facie case that the time to commence the cause of action expired (see *Texeria v BAB Nuclear Radiology, P.C.*, 43 AD3d 403, 840 NYS2d 417 [2d Dept 2007]).

On a motion to dismiss under CPLR 3211 (a) (7), the initial test is whether the pleading states a cause of action, not whether the plaintiff has a cause of action (*Guggenheimer v Ginzburg*, 43 NY2d 268, 275, 401 NYS2d 182 [1977]; *Sokol v Leader*, 74 AD3d 1180, 904 NYS2d 153 [2d Dept 2010]). If documentary proof is submitted by a party seeking relief under CPLR 3211 (a) (7), the truthfulness of the pleadings need not be assumed. Instead, the test applied by the court is whether the plaintiff has a cause of action, not whether one is stated in the complaint (*Guggenheimer v Ginzburg*, 43 NY2d at 275, 401 NYS2d at 185; *Peter F. Gaito Architecture, LLC v Simone Dev. Corp.*, 46 AD3d 530, 530, 846 NYS2d 368, 369 [2d Dept 2007]; *Rappaport v International Playtex Corp.*, 43 AD2d 393, 395, 352 NYS2d 241, 243 [3d Dept 1974]).

If a defendant challenges the propriety or adequacy of service of a summons and complaint under CPLR 3211 (a) (8), it is the plaintiff's burden to prove, by a preponderance of the evidence, that jurisdiction over the defendant was obtained by proper service of process (e.g. *Aurora Loan Servs., LLC v Gaines*, 104 AD3d 885, 962 NYS2d 316 [2d Dept 2013]). The plaintiff, however, is not required to allege in the complaint the basis for personal jurisdiction (*Fishman v Pocono Ski Rental*, 82 AD2d 906, 440 NYS2d 700 [2d Dept 1981]), and to withstand a pre-answer motion to dismiss, the plaintiff need only demonstrate that facts "may exist" to support the exercise of jurisdiction over the defendant (CPLR 3211 [d]; *Peterson v Spartan Indus.*, 33 NY2d 463, 354 NYS2d 905 [1974]; *Ying Jun Chen v Lei Shi*, 19 AD3d 407, 796 NYS2d 126 [2d Dept 2005]).

In the analysis that follows, the court will first discuss those issues bearing on multiple causes of action before examining each of the causes of action separately for legal sufficiency.

Preemption

The manufacturer defendants contend that many of the plaintiffs' claims concerning alleged misrepresentations are not actionable under federal preemption principals. They seek dismissal of the plaintiffs' claims to the extent that they challenge such defendants' promotion of opioid medications consistent with Food and Drug Administration ("FDA") approved indications. Purdue also seeks dismissal on the ground that the plaintiffs' claims are preempted by federal law. Purdue argues that the plaintiffs wrongfully demand that it unilaterally change the FDA-approved uses for its prescription opioid medications. It also contends that the plaintiffs' claims would prohibit it from marketing opioids for their FDA-approved uses and indications, and would impose a duty upon the manufacturer defendants to alter the labels of their drugs in a manner that conflicts with their duties under federal law. The manufacturer defendants collectively insist that their marketing of opioids is consistent with FDA-approved labeling; therefore, any state law that would require them to make statements that are inconsistent with existing labeling, would directly conflict with the FDA regulations.

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The plaintiffs oppose the motion, arguing the United States Supreme Court has ruled that state tort claims do not stand as an obstacle to accomplishing the purposes of the Food, Drug, and Cosmetic Act (FDCA), 21 USC § 301 et seq., and FDA approval of a drug was not intended to displace state claims regarding the drug. The plaintiffs assert that despite FDA approval of the manufacturer defendants' opioid medications, such defendants were not required to repeat information they knew to be false in advertising and promoting their products after they became aware of new information that did not support their statements. The plaintiffs further assert that the manufacturer defendants failed to identify any federal obligations with which the plaintiffs' claims conflict, and that they ignore the plaintiffs' allegations that they engaged in off-label marketing and made representations designed to undermine information in drug labels.

The Supremacy Clause of the United States Constitution establishes that federal law "shall be the supreme Law of the Land" (US Const, art VI, cl 2). "A fundamental principle of the Constitution is that Congress has the power to preempt state law" through its enactments (*Crosby v National Foreign Trade Council*, 530 US 363, 372, 120 S Ct 2288, 2293 [2000]; see *Lee v Astoria Generating Co., L.P.*, 13 NY3d 382, 892 NYS2d 294 [2009]; see also *Doomes v Best Tr. Corp.*, 17 NY3d 594, 601, 935 NYS2d 268 [2011]; *Balbuena v IDR Realty LLC*, 6 NY3d 338, 812 NYS2d 416 [2006]). In certain instances, Congress may expressly preempt the state law; however, even where federal law does not contain an express preemption provision, state law must still yield to federal law to the extent of any conflict therewith (see *Warner v American Fluoride Corp.*, 204 AD2d 1, 616 NYS2d 534 [2d Dept 1994]). This doctrine of implied conflict preemption is generally found in two forms: impossibility preemption, which exists where "it is impossible for a private party to comply with both state and federal requirements," and obstacle preemption, which exists where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Doomes v Best Tr. Corp.*, 17 NY3d at 603, 935 NYS2d at 273 [internal quotation marks omitted]; see *Altria Group, Inc. v Good*, 555 US 70, 129 S Ct 538 [2008]; *City of New York v Job-Lot Pushcart*, 88 NY2d 163, 643 NYS2d 944 [1996]). In making a determination whether conflict preemption applies to bar a cause of action, the court must consider congressional intent, i.e., whether Congress intended to set aside the laws of a state to achieve its objectives (*Barnett Bank of Marion County, NA v Nelson*, 517 US 25, 30, 116 S Ct 1103, 1107 [1996]; *Louisiana Pub. Serv. Commn. v FCC*, 476 US 355, 369, 106 S Ct 1890, 1899 [1986]; *Lee v Astoria Generating Co., L.P.*, 13 NY3d at 391, 892 NYS2d at 299). The Supreme Court has "observed repeatedly that pre-emption is ordinarily not to be implied absent an actual conflict" (*English v General Elec. Co.*, 496 US 72, 90, 110 S Ct 2270, 2281 [1990]; see *Cipollone v Liggett Group, Inc.*, 505 US 504, 112 S Ct 2608 [1992]). "The mere fact of tension between federal and state law is generally not enough to establish an obstacle supporting preemption, particularly when the state law involves the exercise of traditional police power" (*Madeira v Affordable Hous. Found., Inc.*, 469 F3d 219, 241 [2d Cir 2006] [internal quotation marks omitted]).

It is well established that "the 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 US 470, 475, 116 S Ct 2240, 2245 [1996]; see *Balbuena v IDR Realty LLC*, 6 NY3d 338, 812 NYS2d 416; *Madeira v Affordable Hous. Found., Inc.*, 469 F3d at 241). The protection of consumers against deceptive business practices is one area traditionally regulated by the

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states (*see California v ARC Am. Corp.*, 490 US 93, 109 S Ct 1661 [1989]). With regard to a conflict preemption analysis, the United States Supreme Court dictates that if Congress has legislated in a field traditionally occupied by the states, 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.* at 101, 109 S Ct at 1665; *Lee v Astoria Generating Co., L.P.*, 13 NY3d at 391, 892 NYS2d at 299). Therefore, a strong “presumption against preemption applies in consumer protection cases” (*In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369, *25 [SD NY 2015]).

Here, the question before the court is whether New York’s consumer protection laws and traditional tort principals pose an obstacle to the FDA’s regulation of prescription drug promotion and advertising or make it impossible for the manufacturer defendants herein to comply with those regulations as a matter of law. “The party arguing that federal law preempts a state law bears the burden of establishing preemption” (*id.* at *23).

In the 1930s, because of increased concern about the availability of unsafe drugs and fraudulent marketing of drugs, Congress enacted the FDCA, which authorized the FDA, among other things, to regulate the prescription drug industry (*Wyeth v Levine*, 555 US 555, 567, 129 S Ct 1187, 1196 [2009]; *Medtronic, Inc. v Lohr*, 518 US at 475, 116 S Ct at 2246; *Dobbs v Wyeth Pharm.*, 797 F Supp 2d 1264, 1270 [WD Okla 2011]). The legislation “enlarged the FDA’s powers to protect the public health and assure the safety, effectiveness, and reliability of drugs” (*Wyeth v Levine*, 555 US at 567, 129 S Ct at 1195-1196). It required manufacturers to submit a new drug application—including proposed labeling—to the FDA for review prior to distribution of the drug, and the FDA could reject the application if it determined that the drug was not safe for use as labeled (*id.*). Under the FDCA, a drug’s labeling is construed broadly, and includes “any article that supplements or explains the product even if the article is not physically attached to it” (*Sandoval v PharmaCare US, Inc.*, 2018 WL 1633011, *2 [9th Cir 2018] [internal quotation marks omitted]; *see* 21 USC § 321 [m]). Labeling also includes descriptions of a drug in brochures and through media, and references published for use by medical practitioners, which contain drug information supplied by the manufacturer, packer, or distributor of the drug (21 CFR § 202.1 [l] [2]). Thus, in many respects, opioid medication marketing and advertising materials perform the function of labeling (*see Kordel v United States*, 335 US 345, 350, 69 S Ct 106, 110 [1948]; *Sandoval v PharmaCare US, Inc.*, 2018 WL 1633011). The FDA, however, generally does not review unbranded promotional materials, i.e., materials that promote the use of a type of drug but do not identify any particular drug by name (*see City of Chicago v Purdue Pharma L.P.*, 2015 WL 2208423, *2 [ND Ill 2015]).

FDA regulation provides that a manufacturer must seek approval from the FDA prior to making any change to its drug labeling by submitting a supplemental application for review; however, the FDA permits pre-approved changes by the manufacturer under certain circumstances (21 CFR § 314.70 [c]; *Wyeth v Levine*, 555 US at 567, 129 S Ct at 1189; *Dobbs v Wyeth Pharm.*, 797 F Supp at 1270). Pursuant to the “changes being effected” (CBE) regulation, a manufacturer is permitted to make a label change where the change is needed “to add or strengthen a contraindication, warning, [or] precaution . . . or to add or strengthen an instruction about dosage and administration that is intended to increase the

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safe use of the drug product” (*PLIVA, Inc. v Mensing*, 564 US 604, 614, 131 S Ct 2567, 2575 [2011] [internal quotation marks omitted]; *Dobbs v Wyeth Pharm.*, 797 F Supp at 1270). In the spirit of the FDCA to promote the safety, effectiveness, and reliability of drugs, Congress made it clear that despite FDA oversight, manufacturers were “responsible for updating their labels” at all times (*Wyeth v Levine*, 555 US at 567, 129 S Ct at 1195-1196; see *Sullivan v Aventis, Inc.*, 2015 WL 4879112 [SD NY 2015]). “[T]he manufacturer is charged ‘both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market’ ” (*Uts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 659 [SD NY 2017], quoting *Wyeth v Levine*, 555 US at 571, 129 S Ct at 1197). Notwithstanding those obligations, if a manufacturer can show clear evidence that the FDA would not have approved a labeling change, the CBE exception does not apply (*id.*). Additionally, labeling changes pursuant to the CBE regulation may only be made on the basis of “newly acquired information” (*Uts v Bristol-Myers Squibb Co.*, 226 F Supp 3d 166, 177 [SD NY 2016]; see 21 CFR § 314.70 [c] [6] [iii]). If a claim against a manufacturer “addresses newly acquired information and addresses a design or labeling change that a manufacturer may unilaterally make without FDA approval, then there may be no preemption of the state law claim” (*id.* at 182; see *Wyeth v Levine*, 555 US 569, 129 S Ct 1197; *Uts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644).

The manufacturer defendants challenge the plaintiffs’ claims on the ground that the plaintiffs seek to require such defendants to change the FDA-approved indications for their opioid medications. The manufacturer defendants assert that central to the plaintiffs’ complaint are the allegations that such defendants fraudulently and improperly promoted opioids to treat chronic pain, and that such defendants failed to disclose that there was no evidence to support the long-term use of opioids. They contend that the plaintiffs’ allegations go against the findings of the FDA, and that the FDA did not require them to make such disclosures. The manufacturer defendants further argue that the plaintiffs cannot show the existence of newly acquired information that would have required them to make unilateral changes to their product labeling.

There is no dispute that in the late 1980s and early 1990s, the FDA approved the prescription opioid medications at issue to treat chronic pain. FDA-approved labeling for these medications warned medical professionals and consumers about some of the risks associated with opioid use, and drug manufacturers provided educational materials to medical professionals on treatment guidelines. Nevertheless, the FDA’s approval of opioids for consumption by the general public does not mean that states, and specifically, the plaintiffs herein, may not seek to protect their residents from the unlawful activities of defendants concerning those drugs (see *Yugler v Pharmacia & Upjohn Co.*, 2001 WL 36387743 [Sup Ct, NY County 2001]; see generally *English v General Elec. Co.*, 496 US 72, 87, 110 S Ct 2270 [1990] [“the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies”]). “[M]anufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly” (*Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202).

On the face of the complaint, it does not appear that the plaintiffs seek to compel the manufacturer defendants to stop selling their medications (see *Mutual Pharm. Co. v Bartlett*, 570 US

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472, 133 S Ct 2466 [2013]), nor do the plaintiffs seek to challenge the FDA's approval of their products (see *Buckman Co. v Plaintiffs' Legal Comm.*, 531 US 341, 121 S Ct 1012 [2001]; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F3d 34, 36 [1st Cir 2015]) or to enforce FDA regulations (see *PDK Labs, Inc. v Friedlander*, 103 F3d 1105 [2d Cir 1997]; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, *7 [ND Ill 2017]). The plaintiffs claim that the manufacturer defendants' business practices in promoting, advertising, and marketing their FDA-approved opioids have run afoul of New York law and traditional tort principals, and that they should be held liable.

The plaintiffs allege that when promoting prescription opioids, the manufacturer defendants made representations that were not supported by scientific studies, thus preventing clinicians and consumers from making informed decisions about whether to prescribe or to use opioids as a primary form of chronic pain treatment, that they used marketing strategies to evade consumer protection laws, and that they used front groups or third parties to promote opioids as superior pain relief medication through unbranded materials. The plaintiffs do not demand that the manufacturer defendants remove their products from the market as the defendants seem to suggest. Instead, the plaintiffs' claims are predicated "on a more general obligation—the duty not to deceive" their residents (*Cipollone v Liggett Group, Inc.*, 505 US 504, 528-529, 112 S Ct 2608, 2624 [1992]; see *In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369). As previously indicated, FDA approval of drug labeling does not necessarily mean that the FDA has authorized the manufacturer's marketing practices (see generally *Kramer v Bausch & Lomb, Inc.*, 264 AD2d 596, 695 NYS2d 553 [1st Dept 1999]; *City of Chicago v Purdue Pharma L.P.*, 2015 WL 2208423, *2 [ND Ill 2015]). The manufacturer defendants have failed to show that the FDA has approved their means, methods, and/or the content of their drug promotion to warrant a finding that the plaintiffs' claims are preempted by virtue of the FDA's approval of their drug.

With respect to information contained in the manufacturer defendants' drug labels, particularly concerning addiction and the long-term use of opioids, it is certainly a closer call whether preemption applies. The court finds that the plaintiffs' claims are not preempted under the circumstances.

There are two stages to the preemption inquiry before the court. The plaintiffs herein must show that newly acquired information exists such that the manufacturer could unilaterally change its label in accordance with the CBE regulation, and if the plaintiff can prove the existence of newly acquired information, "the manufacturer may [] establish an impossibility preemption defense by presenting clear evidence that the FDA would have exercised its authority to reject the labeling change" (*Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 672 [internal quotation marks omitted]). The plaintiffs allege that the manufacturer defendants acquired new information concerning addiction and the long-term use of opioids, which, if acted upon, would have strengthened instruction about dosing and administration of the drugs, yet defendants continued to market their products without disclosing such information to consumers or marketed their drugs by making statements that were contrary to the newly acquired information (see *Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202; cf. *Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 672). The plaintiffs cite many studies that were conducted subsequent to the FDA's approval of the medications—studies that the manufacturer defendants allegedly knew about—which contradict such defendants' promotional statements and

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materials. The plaintiffs also allege numerous instances where the manufacturer defendants suppressed or indirectly attempted to suppress information about the effects of their drugs that was contrary to their promotional statements. The court finds that at this stage of the proceedings the plaintiffs have satisfied their pleading burden with regard to newly acquired information (*see* CPLR 3211).

The manufacturer defendants further argue that the FDA has addressed the claims that plaintiffs now advance, and their marketing is consistent with FDA-approved labeling; therefore, preemption applies. In July 2012, Physicians for Responsible Opioid Prescribing (PROP), a coalition of concerned doctors, filed a citizen petition requesting that the FDA change some indications for opioid medications. PROP stated that clinicians were under the false impression that chronic opioid therapy was an evidence-based treatment for non-cancer pain, and asked the FDA to prohibit manufacturers from marketing opioids for conditions for which the use of opioids had not been proven safe and effective. In 2013, the FDA responded to the petition, granting it in part and rejecting it in part. Recognizing the grave risks associated with opioid use, the FDA required opioid manufacturers to include in their drug labels a warning that opioids should be used only when alternative treatments were inadequate. The FDA declined to recommend a daily maximum dose or the maximum duration of opioid treatment, and stated that more controlled studies were needed concerning long-term use of opioids. The agency acknowledged that high rates of addiction were concerning, and it ordered opioid manufacturers to conduct post-approval studies on the long-term use of the medications.

In *Wyeth*, the United States Supreme Court articulated that “absent clear evidence that the FDA would not have approved a change to [the drug’s] label” a court cannot conclude that it was impossible for the drug manufacturer to comply with both federal and state requirements (*Wyeth v Levine*, 555 US at 571, 129 S Ct at 1198). Citing *Cerveny v Aventis, Inc.* (855 F3d 1091, 1105 [10th Cir 2017]), the manufacturer defendants argue that the FDA’s rejection of the PROP citizen petition constitutes “clear evidence” that the FDA would have rejected a labeling change concerning the long-term use of opioids, the concept of pseudoaddiction (a preoccupation with achieving adequate pain relief that leads to higher consumption levels of opioids), and addiction withdrawal. By way of background, in *Cerveny*, the Tenth Circuit held that the FDA’s rejection of a citizen petition, which made “arguments virtually identical” to the plaintiffs’ claims, was clear evidence that the FDA would have rejected the plaintiffs’ proposed change to a drug label (*Cerveny v Aventis, Inc.*, 855 F3d at 1105). The plaintiffs in that case admitted that their claims were “based on the same theories and scientific evidence presented in [the] citizen petition” (*id.* at 1101).

“[W]hen considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff. A [] court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted” (*Utt v Bristol-Myers Squibb Co.*, 251 F Supp 3d at 672 [internal quotation marks omitted]). The plaintiffs in this action allege that the manufacturer defendants made presentations to medical professionals and others about the efficacies of long-term use of opioids as though those statements were supported by substantial evidence. However, the manufacturer defendants acknowledge that the FDA found that there was an absence of well-controlled studies of opioid use longer than 12 weeks. The plaintiffs also allege that the manufacturer defendants knew about the addictive effects of

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opioids many years before the FDA's 2013 response to the PROP petition, but minimized those effects when promoting, marketing, and advertising the drugs. For example, the plaintiffs allege that the manufacturer defendants used the concept of pseudoaddiction as an excuse to encourage medical professionals to prescribe more or higher doses of opioids despite knowledge of the high risk of abuse. The manufacturer defendants allegedly distributed treatment guidelines to professionals, which indicated that a clinicians' first response to treating pseudoaddiction was to increase dosing although other adequate treatment options were available. Additionally, unlike the plaintiffs in *Cerveny*, the plaintiffs' allegations here are not based upon the same theories and scientific evidence presented in the PROP petition (see *Cerveny v Aventis, Inc.*, 855 F3d at 1101). The plaintiffs herein make allegations concerning the defendants' business practices.

Moreover, the court concludes that, under the circumstances, the FDA's "less-than-definitive determination" concerning PROP's request for maximum dosage and treatment duration does not meet the *Wyeth* standard of clear evidence (see *Amos v Biogen Idec Inc.*, 249 F Supp 3d 690, 699 [WD NY 2017] ["the Court compares the evidence presented with the evidence in *Wyeth*, to determine whether it is more or less compelling"]). In its response to PROP, the FDA stated that the petitioners did not present sufficient evidence to support their recommendations concerning the long-term use of opioids. However, in light of the concerning high rates of addiction, the FDA requested "further exploration" of the issues. Inasmuch as "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge" this court cannot conclude as a matter of law that the agency would have rejected proposals from the drug manufacturers to change their labeling, which in effect would have strengthened dosing instruction and administration of the drugs (*Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, *7). Accordingly, the court finds that the plaintiffs' state-law claims do not make it impossible for the manufacturer defendants to comply with the FDA's regulations; therefore, the manufacturer defendants' application to dismiss those claims on federal preemption grounds is denied (see CPLR 3211 [a] [7]; *Wyeth v Levine*, 555 US 555, 129 S Ct 1187; *Sullivan v Aventis, Inc.*, 2015 WL 4879112; see generally *Feinberg v Colgate Palmolive Co.*, 34 Misc 3d 1243[A], 950 NYS2d 608 [Sup Ct, NY County 2012]).

Municipal Cost Recovery Rule

The manufacturer defendants' argument that the complaint does not allege a cognizable injury, i.e., that the plaintiffs are barred under the municipal cost recovery rule from recovering the costs of governmental services incurred in connection with the opioid crisis, is rejected. The municipal cost recovery rule, also known as the free public services doctrine, precludes municipalities from recovering as damages from a tortfeasor the cost of public services, such as police and fire protection, required as a consequence of an accident or emergency (see *Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d 548, 560, 479 NYS2d 163 [1984]; *Austin v City of Buffalo*, 182 AD2d 1143, 586 NYS2d 841 [4th Dept 1992]; *City of Buffalo v Wilson*, 179 AD2d 1079, 580 NYS2d 679 [4th Dept 1992]; see also e.g. *County of Erie, New York v Colgan Air, Inc.*, 711 F3d 147 [2d Cir 2013]; *City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 719 F2d 322 [9th Cir 1983]). In *Koch*, the Court of Appeals held that New York City could not recover as damages from Consolidated Edison the costs it incurred "for wages,

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salaries, overtime and other benefits of police, fire, sanitation and hospital personnel from whom services (in addition to those which would normally have been rendered) were required” as a consequence of a 25-hour blackout caused by the company’s gross negligence, holding “[t]he general rule is that public expenditures made in the performance of governmental functions are not recoverable” (*Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d at 560, 479 NYS2d at 170). And in *City of Flagstaff*, a seminal case for the municipal cost recovery rule, the Court of Appeals held that the cost of providing police, fire and emergency services “from fire or safety hazards is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the services,” reasoning that a rule allocating such expenses to the tortfeasor who caused an accident or other public emergency would upset “[e]xpectations of individuals and businesses, as well as their insurers,” and that the legislature, not the court, is the appropriate forum in which to address whether the costs related to public emergencies should be shifted to the responsible party (*City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 917 F2d at 323-324). The municipal cost recovery rule, however, does not bar a cause of action for public nuisance (see *County of Erie, New York v Colgan Air, Inc.*, 711 F3d 147; see also *State of New York v Schenectady Chems.*, 117 Misc 2d 960, 459 NYS2d 971 [Sup Ct, Rensselaer County 1983]), and an exception exists permitting recovery for public expenses authorized by statute or regulation (*Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d at 561, 479 NYS2d at 170).

Here, the plaintiffs allege, among other things, they were harmed by having to pay the costs of prescription opioid therapy for employees and Medicaid beneficiaries complaining of chronic, non-cancer pain when such treatment was not medically necessary or reasonably required, and that, but for the misrepresentations made by the manufacturer defendants about the benefits and risks of long-term prescription opioid therapy, they would not have approved payment for such therapy. Moreover, a review of the current state of the law revealed no case law supporting the manufacturer defendants’ contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating “the normal provision of police, fire and emergency services” (*City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 719 F2d at 324), but to remedy public harm caused by an intentional, persistent course of deceptive conduct. The manufacturer defendants’ argument that, despite allegations they designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids, the municipal cost recovery rule forecloses the plaintiffs from recovering the costs for services to treat residents suffering from prescription opioid abuse, addiction or overdose, or for the increased costs of programs implemented to stem prescription opioid-related criminal activities, if accepted, would distort the doctrine beyond recognition.

Statute of Limitations

The manufacturer defendants also jointly contend that all of the plaintiffs’ causes of action must be dismissed to the extent that they are predicated upon acts or omissions occurring outside the relevant limitations period, i.e., six years for the causes of action based in common-law fraud and unjust enrichment, and three years for the remaining causes of action. The manufacturer defendants further contend that the plaintiffs cannot rely on the two-year discovery period for assertion of a cause of action in fraud, because the allegations in the complaint confirm that they could have discovered the alleged

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fraud from information publicly available well before August 31, 2014, and because the plaintiffs cannot demonstrate that they were unable to discover information pertaining to the prescriptions underlying their claims prior to that date.

Cephalon separately contends that, even if the six-year limitations period applied to all of the plaintiffs' claims, the plaintiffs failed to allege a single fraudulent act or omission on its part occurring after August 2010. Moreover, as the plaintiffs acknowledge that the false statements which they attribute to Cephalon were "available nationally" and "cited widely," and that the risks associated with opioids were clear as early as the 1970s and 1980s, the plaintiffs cannot rely on the two-year discovery period for assertion of a cause of action in fraud.

Purdue separately contends that OxyContin has only been sold in its current "reformulated," "abuse-deterrent" form since 2010—more than six years prior to the commencement of this action—and that the majority of statements attributed to it in the complaint are either undated or were made well outside the six-year statute of limitations.

Actavis separately contends that there are but a scant few paragraphs in the complaint containing allegations that plausibly fit within either of relevant three- or six-year limitations periods, and that even those allegations amount to little more than general observations describing lawful conduct, e.g., what Actavis spent on advertising.

The plaintiffs counter that their causes of action are timely, whether because they did not accrue until the plaintiffs either suffered injury or discovered the wrong, or by application of the "continuing wrong" doctrine, which serves to toll the running of a period of limitations to the date on which the last wrongful act is committed, or because the facts alleged in the complaint serve to toll the statute of limitations based on fraudulent concealment. As to Cephalon, the plaintiffs contend that the complaint does, in fact, allege statements made by or attributable to Cephalon that were made after 2010; additionally, to the extent the complaint alleges misrepresentations in written publications, the plaintiffs claim the date that those statements were first published is not determinative for statute of limitations purposes, as those materials continued to circulate and be relied on long after they were initially introduced. As to Purdue, the plaintiffs note that not all of their allegations relating to that manufacturer pertain to OxyContin. According to the plaintiffs, not only did Purdue deceptively promote its branded opioids but, through its direct marketing and unbranded materials, it also misrepresented the benefits and dangers of opioids generally.

"To dismiss a cause of action pursuant to CPLR 3211 (a) (5) on the ground that it is barred by the statute of limitations, a defendant bears the initial burden of establishing *prima facie* that the time in which to sue has expired. Only if such *prima facie* showing is made will the burden then shift to the plaintiff to aver evidentiary facts establishing that the case falls within an exception to the statute of limitations. In order to make a *prima facie* showing, the defendant must establish, *inter alia*, when the plaintiff's cause of action accrued" (*Swift v New York Med. Coll.*, 25 AD3d 686, 687, 808 NYS2d 731, 732-733 [2d Dept 2006] [internal citations and quotation marks omitted]; *accord Pace v Raisman & Assoc., Esqs., LLP*, 95 AD3d 1185, 945 NYS2d 118 [2d Dept 2012]).

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"In general, a cause of action accrues, triggering commencement of the limitations period, when all of the factual circumstances necessary to establish a right of action have occurred, so that the plaintiff would be entitled to relief" (*Gaidon v Guardian Life Ins. Co. of Am.*, 96 NY2d 201, 210, 727 NYS2d 30, 35 [2001]). While a claim for breach of contract accrues on the date of the breach, irrespective of the plaintiff's awareness of the breach (*Ely-Cruikshank Co. v Bank of Montreal*, 81 NY2d 399, 599 NYS2d 501 [1993]), a tort claim accrues only when it becomes enforceable, that is, when all the elements of the tort can be truthfully alleged in the complaint (*Kronos, Inc. v AVX Corp.*, 81 NY2d 90, 595 NYS2d 931 [1993]). When damage is an essential element of the tort, the claim is not enforceable until damages are sustained (*Kronos, Inc. v AVX Corp.*, 81 NY2d 90, 595 NYS2d 931). In an action to recover for a liability created or imposed by statute, the statutory language determines the elements of the claim which must exist before the action accrues (*Matter of Motor Veh. Acc. Indem. Corp. v Aetna Cas. & Sur. Co.*, 89 NY2d 214, 652 NYS2d 584 [1996]).

Here, it is evident that injury is an essential element of no fewer than four of the causes of action pleaded. To state a cause of action for deceptive acts and practices under General Business Law § 349, the plaintiffs were required to allege that the defendants engaged in consumer-oriented acts or practices that are "deceptive or misleading in a material way and that plaintiff has been injured by reason thereof" (*Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 25, 623 NYS2d 529, 532 [1995]). Similarly, a cause of action for false advertising pursuant to General Business Law § 350 is stated so long as it is pleaded that "the advertisement (1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury" (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d 608, 609, 752 NYS2d 400, 403 [2d Dept 2002]). The elements of a cause of action sounding in fraud are a material misrepresentation of an existing fact, made with knowledge of the falsity, an intent to induce reliance thereon, justifiable reliance upon the misrepresentation, and damages (*Introna v Huntington Learning Ctrs.*, 78 AD3d 896, 911 NYS2d 442 [2d Dept 2010]); thus, a cause of action for fraud cannot accrue until every element of the claim, including injury, can truthfully be alleged (*Carbon Capital Mgt., LLC v American Express Co.*, 88 AD3d 933, 932 NYS2d 488 [2d Dept 2011]). And a cause of action sounding in negligence likewise accrues as soon as the claim becomes enforceable, that is, on the earliest date upon which the claimed negligence causes a plaintiff to sustain damages (see *Brooks v AXA Advisors*, 104 AD3d 1178, 961 NYS2d 648 [4th Dept], *lv denied* 21 NY3d 858, 970 NYS2d 748 [2013]).

As to those causes of action, the manufacturer defendants have not identified any relevant date of injury but, rather, contend only that the acts and omissions on which they are based did not take place within the applicable limitations periods. Consequently, as it has not been established when any of those causes of action accrued, it cannot be said at this juncture that any of them is untimely—except to note, even assuming the applicability of the "continuing wrong" doctrine (see generally *Affordable Hous. Assoc., Inc. v Town of Brookhaven*, 150 AD3d 800, 54 NYS3d 122 [2d Dept 2017]), that the plaintiffs may recover monetary damages only to the extent that they were sustained within the applicable limitations period immediately preceding the commencement of this action (see *State of New York v Schenectady Chems.*, 103 AD2d 33, 479 NYS2d 1010 [3d Dept 1984]; *Kearney v Atlantic Cement Co.*, 33 AD2d 848, 306 NYS2d 45 [3d Dept 1969]). And while some recovery of damages may be time-barred, dismissal—even partial dismissal—is not appropriate at this juncture, as the court is not yet able to

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determine the precise nature and timing of the plaintiffs' respective claims (*see Airco Alloys Div. v Niagara Mohawk Power Corp.*, 76 AD2d 68, 430 NYS2d 179 [4th Dept 1980]).

The manufacturer defendants have likewise failed to show that the cause of action alleging public nuisance is untimely. The rule with respect to nuisance or other continuing wrongs is that the action accrues anew on each day of the wrong, so that the right to maintain the cause of action continues as long as the nuisance exists (*Airco Alloys Div. v Niagara Mohawk Power Corp.*, 76 AD2d 68, 430 NYS2d 179; 17A Carmody-Wait 2d § 107:95). Here, the plaintiffs have alleged a continuing wrong, perpetrated by all the defendants, involving deceptive marketing practices that began over a decade ago and that have continued up to the time of commencement of this action. That such a nuisance may have existed for more than three years, then, does not bar the cause of action; as before, however, the court notes that damages are recoverable only to the extent they were sustained during the three years prior to the commencement of the action (CPLR 214; *State of New York v Schenectady Chems.*, 103 AD2d 33, 479 NYS2d 1010; *Kearney v Atlantic Cement Co.*, 33 AD2d 848, 306 NYS2d 45).

As to the cause of action pleaded under Social Services Law § 145-b, the analysis differs but the result is essentially the same. First, as to the applicable limitations period, the court notes that although fraud is a component of Social Services Law § 145-b, the remedy contemplated by the statute is at once broader and narrower than that in fraud; it serves not only to create a right on behalf of local social services districts and the State to sue for damages in cases of fraud and misrepresentation in connection with Medicaid reimbursement but also to provide a financial deterrent in the form of treble damages in order to curb such abuses (Legislative Mem, McKinney's Session Laws of NY at 1686-1687). Since this remedy did not exist at common law, the three-year statute of limitations for statutory causes of action applies (CPLR 214 [2]; *see Gaidon v Guardian Life Ins. Co. of Am.*, 96 NY2d 201, 727 NYS2d 30). Second, as to date of accrual, it is clear that in an action to recover for a liability created or imposed by statute, the statutory language determines the elements of the claim which must exist before the action accrues (*Matter of Motor Veh. Acc. Indem. Corp. v Aetna Cas. & Sur. Co.*, 89 NY2d 214, 652 NYS2d 584). Since it is unlawful under Social Services Law § 145-b even to attempt to obtain Medicaid reimbursement by fraudulent means, it is conceivable that a violation of the statute may occur without a plaintiff having sustained actual damages, in which case the statute provides for civil damages in the amount of \$5,000.00. Thus, damages is not an element of the cause of action, and the manufacturer defendants are correct in asserting both that the three-year limitations period began to run upon the occurrence of the alleged misconduct, and that the plaintiffs may not recover damages based on alleged acts or omissions occurring more than three years prior to the commencement of this action. Since it is pleaded, however, that the fraudulent conduct underlying the cause of action continued up to the time that this action was commenced, and the manufacturer defendants having failed to demonstrate an earlier accrual date, the court will not dismiss it as time-barred.

Nor has it been demonstrated that the cause of action sounding in unjust enrichment is untimely. The plaintiffs allege, in relevant part, that the manufacturer defendants, as an expected and intended result of deceptive conduct intended to mislead the plaintiffs as to the risks and benefits of opioid use and encourage the plaintiffs to pay for long-term opioid prescriptions, were enriched from opioid purchases made by the plaintiffs and that it would be unjust and inequitable to permit them to enrich

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themselves at the plaintiffs' expense. While there is no limitations period identified in the CPLR within which to bring a claim for unjust enrichment, it is recognized that the three-year statute of limitations governs where, as here, the claim arises from tortious conduct and monetary relief is sought (*DiMatteo v Cosentino*, 71 AD3d 1430, 896 NYS2d 778 [4th Dept 2010]; *Ingrami v Rovner*, 45 AD3d 806, 847 NYS2d 132 [2d Dept 2007]; *Lambert v Sklar*, 30 AD3d 564, 817 NYS2d 378 [2d Dept 2006]). It is also recognized that the claim accrues "upon the occurrence of the wrongful act giving rise to the duty of restitution" (*Ingrami v Rovner*, 45 AD3d at 808, 847 NYS2d at 134). Here, as it is alleged that the wrongful conduct has continued through the time of commencement of this action, the statute of limitations does not operate as a complete defense to the cause of action as pleaded; as noted previously, however, damages may be recovered only to the extent the claim is based on conduct occurring within the three years prior to the commencement of this action.

In so ruling, the court does not reach the question of whether any cause of action is subject to either the discovery rule for actions based on fraud (CPLR 203 [g]; 213 [8]) or the doctrine of equitable estoppel.

Res Judicata

Endo's argument pursuant to CPLR 3211 (a) (5), that the plaintiffs' claims against it are barred by an assurance of discontinuance executed in March 2016 concerning its marketing of Opana ER, its branded version of the semi-synthetic, opioid analgesic oxycodone, is rejected. It is fundamental that a final adjudication of a claim on the merits by a court of competent jurisdiction "is conclusive of the issues of fact and questions of law necessarily decided therein" and precludes relitigation of that claim by the parties and those in privity with them (*Gramatan Home Invs. Corp. v Lopez*, 46 NY2d 481, 485, 414 NYS2d 308, 311 [1979]; see *Parker v Blauvelt Volunteer Fire Co.*, 93 NY2d 343, 690 NYS2d 478 [1999]; *Matter of Hodes v Axelrod*, 70 NY2d 364, 520 NYS2d 933 [1987]). The doctrine of res judicata operates to preclude litigation of all other claims arising out of the same transaction or series of transactions that could have or should have been raised in the prior proceeding, even if such claims are based on different theories or seek a different remedy (see *O'Brien v City of Syracuse*, 54 NY2d 353, 445 NYS2d 687 [1981]; *Smith v Russell Sage Coll.*, 54 NY2d 185, 445 NYS2d 68 [1981]; *Lasky v City of New York*, 281 AD2d 598, 722 NYS2d 391 [2d Dept 2001]). Collateral estoppel, a corollary to the doctrine of res judicata, "precludes a party from relitigating in a subsequent action or proceeding an issue clearly raised in a prior action or proceeding and decided against that party or those in privity, whether or not the tribunals or causes of action are the same" (*Ryan v New York Tel. Co.*, 62 NY2d 494, 500, 478 NYS2d 823, 826 [1984]). A party seeking to invoke the benefit of the collateral estoppel doctrine must demonstrate that the identical issue necessarily was decided in the prior action against the opposing party, or one in privity with such party, and is decisive of the present action (*Buechel v Bain*, 97 NY2d 295, 303-304, 740 NYS2d 252, 257 [2001]; see *D'Arata v New York Cent. Mut. Fire Ins. Co.*, 76 NY2d 659, 563 NYS2d 24 [1990]; *Kaufman v Eli Lilly & Co.*, 65 NY2d 449, 492 NYS2d 584 [1985]; *David v State of New York*, 157 AD3d 764, 69 NYS3d 110 [2d Dept 2018]). It is noted that, except in rare circumstances, the defense of estoppel may not be invoked against the state or its political subdivisions to prevent a governmental body from enforcing the law or discharging its duties as a matter

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of policy (*Matter of E.F.S. Ventures Corp. v Foster*, 71 NY2d 359, 370, 526 NYS2d 56, 61 [1988]; *Matter of Hamptons Hosp. & Med. Ctr. v Moore*, 52 NY2d 88, 95, 436 NYS2d 239, 242 [1981]).

Further, Executive Law § 63 (12) authorizes the Attorney General to seek injunctive relief, restitution, and damages for repeated or persistent fraudulent or illegal acts in conducting business activities in New York. The Attorney General, however, may forgo litigation when a violation of a state law is discovered and instead enter into an “assurance of discontinuance of any act or practice in violation of such law” (Executive Law § 63 [15]).

It is undisputed that the Attorney General commenced an investigation in 2013 into Endo’s marketing of Opana ER in New York. Years later, after obtaining documentary and testimonial evidence from Endo, the Attorney General determined that certain “practices, statements and omissions” by Endo and its employees in connection with the marketing of Opana ER, collectively referred to as the “covered conduct,” violated General Business Law §§ 349 and 350 and Executive Law § 63 (12). The Attorney General, in an exercise of his discretion, decided to enter into an assurance of discontinuance with Endo in lieu of civil litigation. In March 2016, Endo and the Attorney General executed the assurance of discontinuance, wherein Endo agreed, among other things, not to make certain statements regarding the addictiveness of Opana ER or opioids, to provide “truthful and balanced summaries of the results of all Endo-sponsored studies regarding the purported tamper-resistant feature of Reformulated Opana ER,” to require all authors of articles concerning Endo-sponsored studies to disclose any financial relationships with Endo, and to “maintain and enhance its program consisting of internal procedures designed to identify potential abuse, diversion or inappropriate prescribing of opioids.” Endo also agreed to pay \$200,000 as penalties, fees, and costs, and to submit to monitoring by the Office of the Attorney General. In addition, the assurance states that “[n]othing contained herein shall be construed to deprive any member or other person or entity of any private right under law or equity,” and that it does not limit in any way the Attorney General’s power to take actions against Endo for either noncompliance with its terms or noncompliance with any applicable law as to “with respect to any matters that are not part of the covered conduct.” Significantly, Endo neither admitted nor denied the Attorney General’s various findings of unlawful “practices, statements and omissions” under General Business Law §§ 349 and 350 regarding the marketing of Opana ER.

Contrary to the assertions by Endo’s counsel, the March 2016 assurance of discontinuance does not constitute a stipulation of settlement that is binding on the plaintiffs. The settlement of an action prior to the entry of judgment operates to finalize the action without regard to the validity of the original claim, “and the action [is] accordingly considered, in contemplation of law, as if it had never begun” (*Peterson v Forkey*, 50 AD2d 774, 775, 376 NYS2d 560, 561-562 [1st Dept 1975]; see *Ott v Barash*, 109 AD2d 254, 491 NYS2d 661 [2d Dept 1985]; see generally *Yonkers Fur Dressing Co. v Royal Ins. Co.*, 247 NY 435 [1928]). When an action is discontinued, “it is as if it had never been; everything done in the action is annulled and all prior orders in the case are nullified” (*Newman v Newman*, 245 AD2d 353, 354, 665 NYS2d 423, 424 [2d Dept 1997]). By contrast, “a stipulation of discontinuance with prejudice without reservation of right or limitation of the claims disposed of is entitled to preclusive effect under the doctrine of res judicata” (*Liberty Assoc. v Etkin*, 69 AD3d 681, 682-683, 893 NYS2d 564, 565 [2d Dept 2010]), and bars future actions between the same parties or those in privity with them

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(*Matter of Chiantella v Vishnick*, 84 AD3d 797, 798, 922 NYS2d 525, 527 [2d Dept 2011]; *Abraham v Hermitage Ins. Co.*, 47 AD3d 855, 855, 851 NYS2d 608, 609 [2d Dept 2008]; *Matter of State of New York v Seaport Manor A.C.F.*, 19 AD3d 609, 610, 797 NYS2d 538, 539 [2d Dept 2005]). Generally, to establish privity with a party to a prior action, “the connection . . . must be such that the interests of the nonparty can be said to have been represented in the prior proceeding” (*Green v Santa Fe Indus.*, 70 NY2d 244, 253, 519 NYS2d 793, 796 [1987]). As explained by the Court of Appeals, “those who are successors to a property interest, those who control an action although not formal parties to it, those whose interests are represented by a party to the action, and possibly coparties to a prior action” may be found to be in privity with a party to a prior action (*Watts v Swiss Bank Corp.*, 27 NY2d 270, 277, 317 NYS2d 315, 320 [1970]).

There is no legal basis for Endo’s argument that the assurance of discontinuance is the equivalent of a stipulation of discontinuance with prejudice. Clearly, the assurance is an enforceable contract between the Attorney General and Endo. By its terms, the Attorney General agreed, without litigation, to resolve the claims that Endo engaged in deceptive consumer practices in violation of General Business Law §§ 349 and 350 in marketing Opana ER in exchange for Endo altering certain business practices. In exercising his authority to enter the assurance, however, the Attorney General retained his right to subsequently commence civil litigation seeking damages, restitution, or injunctive relief against Endo for conduct violating the assurance (*see* Executive Law § 63 [15]), as well as for conduct violating any laws relating to “matters not part of the covered conduct.” It is noted that while evidence of a violation of an assurance is *prima facie* evidence of a violation of the applicable law in a subsequent civil action or proceeding, it only constitutes such evidence in an action or proceeding brought by the Attorney General (Executive Law § 63 [15]). Moreover, the March 2016 assurance of discontinuance does not immunize Endo from civil actions for subsequent fraudulent activities within New York (*see UBS Sec. LLC v Highland Capital Mgt., L.P.*, 86 AD3d 469, 927 NYS2d 59 [1st Dept 2011]; *Matter of State of New York v Seaport Manor A.C.F.*, 19 AD3d 609, 797 NYS2d 538), or bar the counties from bringing law or equity claims against it for practices within their respective jurisdictions (*see Jane St. Co. v Division of Hous. & Community Renewal*, 165 AD2d 758, 560 NYS2d 193 [1st Dept 1990]). Thus, the doctrine of *res judicata* does not bar the instant claims against Endo.

Personal Jurisdiction

Actavis contends that the complaint must be dismissed as to Allergan plc because the plaintiffs failed to serve that entity with process; irrespective of such failure, Actavis claims that Allergan plc, which is incorporated in the Republic of Ireland, lacks the necessary contacts with New York so as to permit this court to exercise personal jurisdiction over it. As to the latter point, Actavis alleges that Allergan plc is a holding company that has a headquarters in Dublin, Ireland and an administrative headquarters in Parsippany, New Jersey, that it does not manufacture, market, distribute, or sell any pharmaceutical products, that it is a distinct legal entity that is independent of and operates separately from the entities whose shares it owns, that it does not finance or control the daily affairs of those entities, that it has no corporate records on file in New York, that it has not designated an agent for service of process in New York, that it does not send agents to solicit or conduct business in New York, and that it has no officers or employees in New York.

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The plaintiffs, for their part, acknowledge that Allergan plc was not served with process, but contend that service on Actavis, Inc., as a “mere department” of Allergan plc, was sufficient to support the exercise of jurisdiction over Allergan plc. The plaintiffs also contend that the exercise of personal jurisdiction over Allergan plc is proper because Actavis, Inc. directed its fraudulent marketing activities at New York residents, because Allergan plc is the successor-in-interest to Actavis, Inc. and, therefore, because the jurisdictional contacts of Actavis, Inc. are properly attributable to Allergan plc.

If a defendant challenges the validity of service of a summons and complaint, it is the plaintiff’s burden to prove, by a preponderance of the evidence, that jurisdiction over the defendant was obtained by proper service of process (*Aurora Loan Servs. v Gaines*, 104 AD3d 885, 962 NYS2d 316 [2d Dept 2013]). Likewise, when a motion is made to dismiss an action for lack of personal jurisdiction, it is the plaintiff who bears the ultimate burden of proving a basis for such jurisdiction (*Carrs v Avco Corp.*, 124 AD3d 710, 2 NYS3d 533 [2d Dept 2015]).

Here, the court finds that the plaintiffs failed to meet their burden of establishing that jurisdiction was obtained over Allergan plc by proper service of process. Absent the usual presumption of proper service arising from the process server’s affidavit (*see Wells Fargo Bank, N.A. v Chaplin*, 65 AD3d 588, 884 NYS2d 254 [2d Dept 2009]), it was incumbent on the plaintiffs to produce new evidence to support a finding of jurisdiction. This they failed to do. Although they claim that Actavis, Inc. is a subsidiary “so dominated” by Allergan plc that service on the former was sufficient to base the exercise of jurisdiction over the latter (*see Low v Bayerische Motoren Werke, AG.*, 88 AD2d 504, 449 NYS2d 733 [1st Dept 1982]), they cite as evidence of such domination only that “the headquarters of the two are the same” and that “the corporate officers are the same.” The court finds this evidence insufficient. For effective service of process on a foreign corporation to be accomplished by delivery to a subsidiary, it must appear that the subsidiary is a mere department or arm of its corporate parent, such that the two “are really the same entities in different guises” (*Geffen Motors v Chrysler Corp.*, 54 Misc 2d 403, 404, 283 NYS2d 79, 81 [Sup Ct, Oneida County 1967]).

In order for the subsidiary’s activities to warrant the exercise of jurisdiction over the parent, the parent’s control over the subsidiary’s activities must be so complete that the subsidiary is, in fact, merely a department of the parent. A subsidiary will be considered a mere department only if the foreign parent’s control of the subsidiary is so pervasive that the corporate separation is more formal than real. Generally, there are four factors used in determining whether a subsidiary is a mere department of the foreign parent: (1) common ownership and the presence of an interlocking directorate and executive staff; (2) financial dependency of the subsidiary on the parent; (3) the degree to which the parent interferes in the selection and assignment of the subsidiary’s executive personnel and fails to observe corporate formalities; and (4) the degree of the parent’s control of the subsidiary’s marketing and operational policies.

(*Porter v LSB Indus.*, 192 AD2d 205, 213, 600 NYS2d 867, 872-873 [4th Dept 1993] [internal citations and quotation marks omitted]; *accord Delagi v Volkswagenwerk AG of Wolfsburg, Germany*, 29 NY2d 426, 328 NY2d 653 [1972]). Here, apart from the sharing of corporate headquarters and officers, the

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plaintiffs have not shown, by evidentiary proof, the level of pervasiveness or control necessary to establish prima facie that Actavis, Inc. was a “mere department” of Allergan plc (*cf. Taca Intl. Airlines, S.A. v Rolls-Royce of England*, 15 NY2d 97, 256 NYS2d 129 [1965]). Assuming further, as the plaintiffs theorize alternatively, that Allergan plc is “simply a successor entity to Actavis, Inc.,” it does not appear under New York law that a party’s status as a successor-in-interest to a person properly served will necessarily justify a court’s exercise of personal jurisdiction over that party. Even the federal courts espousing the plaintiffs’ theory recognize that the court obtains jurisdiction only after the plaintiff makes a prima facie showing of successor liability (*e.g. Leon v Shmukler*, 992 F Supp 2d 179 [ED NY 2014]); here the plaintiffs have made no such showing (*see generally Schumacher v Richards Shear Co.*, 59 NY2d 239, 464 NYS2d 437 [1983]). And while a party may withstand a motion to dismiss by demonstrating that essential jurisdictional facts “may exist but cannot then be stated” (CPLR 3211 [d]), here the plaintiffs do not claim that discovery on the issue of personal jurisdiction is necessary (*cf. Goel v Ramachandran*, 111 AD3d 783, 975 NYS2d 428 [2d Dept 2013]).

In light of the foregoing analysis, the court need not determine whether, had service been properly effected, it could exercise general (CPLR 301) or specific (CPLR 302) jurisdiction over Allergan plc.

The court now turns to an examination of the legal sufficiency of the plaintiffs’ causes of action.

First Cause of Action/General Business Law § 349

General Business Law § 349 (a) provides that it is unlawful to perform “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” Although the statute’s scope is broad, applying to virtually all types of economic activity (*Karlin v IVF Am., Inc.*, 93 NY2d 282, 290, 690 NYS2d 495, 498 [1999]), its application is strictly limited to deceptive acts or practices leading to consumer transactions in New York (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858 [2002]). Enacted in 1970 to protect New York consumers and to secure “an honest market place where trust prevails between buyer and seller” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 24-25, 623 NYS2d 529, 532 [1995], quoting Mem of Governor Rockefeller, 1970 Legis Ann, at 472), the statute initially was enforceable only by the Attorney General. Subsequently, recognizing that the Attorney General’s resources only allowed for limited enforcement of the consumer protection provisions of General Business Law article 22-A, the Legislature amended the statute to allow private plaintiffs to bring consumer fraud actions (General Business Law § 349 [h]; *Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 205, 785 NYS2d 399, 402 [2004]; *Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 324, 746 NYS2d 858, 863; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495, 499).

To state a cause of action under General Business Law § 349, a plaintiff must allege (1) that the defendant engaged in an act that was directed at consumers, (2) that the act engaged in was materially deceptive or misleading, and (3) that the plaintiff was injured as a result (*Stutman v Chemical Bank*, 95 NY2d 24, 29, 709 NYS2d 892, 895 [2000]; *Oswego Laborers’ Local 214 Pension Fund v Marine*

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Midland Bank, 85 NY2d at 24-25, 623 NYS2d at 532). As to the first element, for pleading purposes, the claim of consumer-oriented conduct must be premised on allegations of facts sufficient to show the challenged acts or practices are “directed at the consuming public” (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 343, 704 NYS2d 177, 182 [1999]) or have a broad impact on consumers at large (see *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529). “Consumer-oriented conduct does not require a repetition or pattern of conduct” (*id.* at 25, 623 NYS2d at 533; see *New York Univ. v Continental Ins. Co.*, 87 NY2d 308, 639 NYS2d 283 [1995]). Sufficient consumer-oriented conduct has been found where a defendant employed “multi-media dissemination of information to the public” (*Karlin v IVF Am., Inc.*, 93 NY2d at 293, 690 NYS2d at 500), or employed an “extensive marketing scheme” that had a broad impact on consumers (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d at 344, 704 NYS2d at 182). And though the term “consumers” has been construed to mean those who purchase goods and services for personal, family or household use (see *Benetech, Inc. v Omni Fin. Group, Inc.*, 116 AD3d 1190, 984 NYS2d 186 [3d Dept 2014]), courts have recognized the standing of business entities and business-like entities to sue under General Business Law § 349 for actions and practices which were “directed at or had a broader impact on consumers at large” and caused them harm (see *Accredited Aides Plus, Inc. v Program Risk Mgt., Inc.*, 147 AD3d 122, 46 NYS3d 246 [3d Dept 2017]; *Pesce Bros., Inc. v Cover Me Ins. Agency of NJ, Inc.*, 144 AD3d 1120, 43 NYS3d 85 [2d Dept 2016]; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96 [2d Dept 2012]; see also *Securitron Magnalock Corp. v Schnabolk*, 65 F3d 256, 265 [2d Cir 1995]). “The critical question [] is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer” (*id.* at 265; see *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96).

As to the second element, a plaintiff must allege the challenged act or practice was “misleading in a material way” (*Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 895). “In determining whether a representation or omission is a deceptive act, the test is whether such act is ‘likely to mislead a reasonable consumer acting reasonably under the circumstances’” (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d 608, 609, 752 NYS2d 400, 402 [2d Dept 2002], quoting *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Amalfitano v NBTY, Inc.*, 128 AD3d 743, 9 NYS3d 372 [2d Dept 2015]). The statutory phrase “deceptive acts or practices” does not apply to “the mere invention of a scheme or marketing strategy, but [to] the actual misrepresentation or omission to a consumer” (*Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d at 325, 746 NYS2d at 865). Thus, General Business Law § 349 is limited to conduct which undermines a consumer’s ability “to evaluate his or her market options and to make a free and intelligent choice” in the marketplace (*North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d at 13, 953 NYS2d at 102). And while businesses are not required to guarantee that a consumer has all the relevant information specific to its particular situation, an omission-based claim under section 349 is appropriate “where the business alone possesses material information that is relevant to the consumer and fails to provide this information” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Bildstein v Mastercard Intl., Inc.*, 2005 WL 1324972 [SD NY 2005]). Significantly, while the evidence must show a representation or omission by the offending party likely to mislead a reasonable consumer acting reasonably under the circumstances, the conduct need not

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rise to the level of common-law fraud to be actionable (*Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 896; *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d at 343, 704 NYS2d at 182;), and no proof of intent to defraud by the defendant or justifiable reliance by a consumer is required (see *Koch v Acker, Merrall & Condit Co.*, 18 NY3d 940, 944 NYS2d 422 [2012]; *Small v Lorillard Tobacco Co.*, 94 NY2d 43, 698 NYS2d 615 [1999]; *Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529; *Valentine v Quincy Mut. Fire Ins. Co.*, 123 AD3d 1011, 1 NYS3d 161 [2d Dept 2014]).

As to the third element, a plaintiff is required to allege and prove "actual injury," though not necessarily pecuniary harm, to such plaintiff as a result of the defendant's deceptive act or practice (*City of New York v Smokes-Spirits.Com, Inc.*, 12 NY3d 616, 623, 883 NYS2d 772 [2009]; *Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 896; *Small v Lorillard Tobacco Co.*, 94 NY2d at 55-56, 698 NYS2d at 620; *Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Wilner v Allstate Ins. Co.*, 71 AD3d 155, 893 NYS2d 208 [2d Dept 2010]). A plaintiff need not quantify the amount of harm to the public at large or specify consumers who suffered pecuniary loss due to the defendant's alleged deceptive conduct (see *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96). The courts, however, have rejected efforts to expand the scope of General Business Law § 349 to include recovery for derivative or indirect injuries, finding that a plaintiff asserting such a claim must establish an actual loss or harm that is separate from the deception (see *City of New York v Smokes-Spirits.Com, Inc.*, 12 NY3d 616, 883 NYS2d 772; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96; *Smith v Chase Manhattan Bank, USA*, 293 AD2d 598, 741 NYS2d 100 [2d Dept 2002]). Stated differently, a plaintiff lacks standing to bring an action under General Business Law § 349 if the claimed loss "arises solely as a result of injuries sustained by another party" (*Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 207, 785 NYS2d 399, 404 [2004]). Thus, an insurer or third-party payor of medical expenditures may not recover derivatively, but must proceed by way of an equitable subrogation action for injuries allegedly suffered by its insured due to a violation of General Business Law § 349 (*id.* at 206, 785 NYS2d at 403).

Initially, contrary to the assertions by the manufacturer defendants, the strict pleading requirements imposed by CPLR 3016 are inapplicable to a cause of action premised on General Business Law § 349 (see *Joannou v Blue Ridge Ins. Co.*, 289 AD2d 531, 735 NYS2d 786 [2d Dept 2001]; *McGill v General Motors Corp.*, 231 AD2d 449, 647 NYS2d 209 [1st Dept 1996]). Moreover, like its sister statute General Business Law § 350, General Business Law § 349 is a remedial statute (*Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d at 207, 785 NYS2d at 403; see *Morelli v Weider Nutrition Group*, 275 AD2d 607, 712 NYS2d 551 [1st Dept 2000]). Thus, it should be "liberally construed to carry out the reforms intended and to promote justice" (McKinney's Cons Laws of NY, Book 1, Statutes § 321).

The court finds the allegations in the complaint are legally sufficient to state a cause of action under General Business Law § 349 as against each of the manufacturer defendants. The plaintiffs allege the manufacturer defendants employed assiduously crafted, multi-pronged marketing strategies that targeted the general public through websites, print advertisements, and educational materials and

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publications as part of their respective campaigns to change the perception of the risks associated with prescription opioids and to de-stigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. According to the complaint, to perpetuate an increase in the amount and dosage of opioid prescriptions written for patients, and to optimize the market share for their respective products, the manufacturer defendants also aggressively targeted physicians and other prescribers, essential conduits in the sale of prescription opioids to the public, by having their sales representatives “detail” prescribers in face-to-face meetings, by inviting prescribers to attend informational programs, by hiring “product loyalists” to serve as paid speakers for such programs, and by using data mining to track opioid prescriptions and reward prolific prescribers of their products. Other alleged marketing strategies designed to affect physicians’ prescribing practices included advertising in print journals and online, sponsoring continuing medical education courses, and hiring so-called “key opinion leaders” (KOLs) to act as consultants and serve as lecturers.

The plaintiffs further allege that the manufacturer defendants’ marketing campaigns included funding so-called “front groups,” such as the American Pain Foundation and the American Academy of Pain Medicine, which wrote and disseminated favorable educational materials, published “scientific literature” without scientific bases, and created opioid treatment guidelines supporting opioid therapy for chronic pain. According to the complaint, in addition to providing those groups with substantial funding, the manufacturer defendants exercised significant influence over the educational programs and written materials, such as journal articles and treatment guidelines, regarding opioids presented by front groups and KOLs. Moreover, the plaintiffs allege that the manufacturer defendants sponsored websites created by front groups and accessible by the public that promoted prescription opioids as a means for improving patients’ normal daily functions and quality of life. Such allegations are sufficient to plead consumer-oriented conduct within the scope of General Business Law § 349 (*see Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529; *Accredited Aides Plus, Inc. v Program Risk Mgt., Inc.*, 147 AD3d 122, 46 NYS3d 246 [3d Dept 2017]). The court rejects the manufacturer defendants’ argument that, as only physicians and other medical providers can prescribe prescription drugs, misrepresentations concerning the risks and benefits of opioids made in connection with the their marketing campaigns cannot constitute “consumer-oriented” conduct under the informed or knowledgeable intermediary doctrine, a defense against a failure to warn claim (*see Martin v Hacker*, 83 NY2d 1, 607 NYS2d 598 [1993]; *cf. Amos v Biogen Idec Inc.*, 28 F Supp 3d 164 [WD NY 2014]).

The plaintiffs also sufficiently allege materially deceptive acts and practices by the manufacturer defendants that undermined consumers’ ability to assess the benefits and dangers of prescription opioids and to make informed decisions as to the efficacy and safety of opioid therapy for chronic pain (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177; *Goldman v Simon Prop. Group, Inc.*, 58 AD3d 208, 869 NYS2d 125 [2d Dept 2008]). Among the numerous allegations of materially deceptive practices set forth in the complaint are claims that the manufacturer defendants made and disseminated statements online, in personal presentations, in advertisements, in publications, and in educational materials that misrepresented the risks of opioid addiction and falsely portrayed prescription opioids as a preferred

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treatment option for chronic pain, in particular by depicting such drugs as appropriate for long-term use and effective in improving patients' quality of life and ability to function on a day-to-day basis. The plaintiffs allege the manufacturer defendants fallaciously promoted the concept of pseudoaddiction to allay physicians' and patients' concerns about the addictiveness of prescription opioids and to destigmatize their use, and deliberately omitted information regarding potential adverse effects, including abuse and addiction, from promotional publications and presentations. They also allege that the manufacturer defendants employed front groups and KOLs to disseminate misleading information through educational forums, publications and websites that reinforced their marketing messages, and to deceive the medical community and the public about the effectiveness of opioids in treating chronic pain, the proper dosing and titration of opioids, and the danger of addiction. In addition, the plaintiffs allege that the misleading communications by the manufacturer defendants, the front groups, and the KOLs were made or disseminated within the plaintiff counties or were posted on public websites. The manufacturer defendants' argument that the plaintiffs must allege and prove a particular misstatement led a specific physician to write a particular opioid prescription for a patient is rejected (*see generally North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD2d 5, 953 NYS2d 96).

Moreover, the plaintiffs adequately allege that the plaintiffs suffered direct injuries as a result of the manufacturer defendants' alleged materially deceptive acts or practices (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD2d 5, 953 NYS2d 96; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642 [D Mass 2007]). Contrary to the assertions by the manufacturer defendants, it is sufficiently alleged that the plaintiffs, as a result of the manufacturer defendants' deceptive marketing campaigns regarding opioid effectiveness, misuse and addiction, paid for medications that were not medically necessary and that would not have been approved for the treatment of chronic, non-cancer pain if all the relevant facts about such medications had been known by them. The plaintiffs allege, for example, that they paid for brand-name opioid prescriptions, such as OxyContin, Opana, Nucynta, and Kadian, for employees covered by county-funded health insurance plans and for residents receiving Medicaid benefits based on material misrepresentations disseminated by the manufacturer defendants to the public and the health care community that such products had lower potential for abuse and addiction based on their supposed "long-acting" or "steady-state" properties, and that they paid for brand-name prescriptions of "rapid-onset" or short-acting opioids, such as Actiq, Fentora, and Duragesic, based on material misrepresentations that such medications are safe for treating non-cancer, chronic-pain patients complaining of "breakthrough" pain episodes (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *cf. Baron v Pfizer, Inc.*, 42 AD3d 627, 840 NYS2d 445 [3d Dept 2007]). Similarly, the plaintiffs allege that they paid for prescriptions of OxyContin and Opana based on Purdue's and Endo's misrepresentations that such medications were tamper-resistant or crush-proof and, therefore, less likely to be abused (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *cf. Baron v Pfizer, Inc.*, 42 AD3d 627, 840 NYS2d 445). It further can be inferred from the complaint that the plaintiffs, having been deceived by the defendant manufacturers about the risks associated with long-term prescription opioid use, were injured by having to pay for more prescriptions than would have otherwise been necessary as patients, particularly county employees and Medicaid beneficiaries, became addicted to such painkillers (*see Wilner v Allstate Ins. Co.*, 71 AD3d 155, 893 NYS2d 208 [2d Dept 2010]). In addition, it is alleged that the manufacturer defendants' deceptive

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marketing campaigns created a public health crisis within the plaintiff counties, leading to substantial increases in opioid addiction, abuse, overdose and death among residents, and that such crisis has forced the plaintiffs to allocate substantial resources to implement measures to reduce opioid abuse and opioid-related crimes, and to combat opioid addiction and overdoses with medications, such as naltrexone, naloxone, and buprenorphine, and with treatment programs. Thus, the plaintiffs here are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (*cf. Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399).

Second Cause of Action/General Business Law § 350

Having a scope as broad as that of General Business Law § 349 (*Karlin v IVF Am., Inc.*, 93 NY2d at 290, 690 NYS2d at 498), the statute defines false advertising as “advertising, including labeling, of a commodity” which is “misleading in a material respect.” As with a General Business Law § 349 claim, a plaintiff asserting a claim under this statute must establish that the alleged false advertisement had an impact on consumers at large, was deceptive or misleading in a material way, and caused injury (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d at 609, 752 NYS2d at 402; *Scott v Bell Atl. Corp.*, 282 AD2d 180, 183-184, 726 NYS2d 60, 63 [1st Dept 2001], *lv granted in part, dismissed in part* 97 NY2d 698, 739 NYS2d 95, *mod* 98 NY2d 314, 747 NYS2d 858 [2002]). General Business Law § 350-a (1) provides that, in determining whether advertising is misleading, “there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal [material facts] in the light of such representations with respect to the commodity . . . to which the advertising relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.” The defendant’s conduct need not rise to the level of a fraud to be actionable (*Matter of People v Applied Card Sys., Inc.*, 27 AD3d 104, 107, 805 NYS2d 175, 178 [3d Dept 2005]). Further, a claim of false advertising must be premised on an advertisement published within the state that “is likely to mislead a reasonable consumer acting reasonably under the circumstances” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533). Reliance by the plaintiff on an advertisement is not a required element of a General Business Law § 350 claim (*Koch v Acker, Merrall & Condit Co.*, 18 NY3d 940, 941, 944 NYS2d 452, 453 [2012]; *Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d at 324 n. 1, 746 NYS2d 858, 865; *but see Pesce Bros., Inc. v Cover Me Ins. Agency of NJ, Inc.*, 144 AD3d 1120, 43 NYS3d 85); rather, the plaintiff must show the false advertisement caused it to suffer injury or loss (*cf. Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892).

Here, the plaintiffs sufficiently allege that the manufacturer defendants, through branded and unbranded print advertisements, public websites, and patient education materials, as well as through one-on-one contacts between sales representatives and physicians, made materially misleading statements regarding the benefits of prescription opioid therapy for chronic pain and the risks associated with opioid use, particularly the potential for abuse (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 290, 690 NYS2d 495). It is alleged, among other things, that, as marketing research showed physicians are more likely to prescribe a drug if specifically requested by a patient, the manufacturer defendants published misleading advertisements for both the

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general consuming public and prescribers. According to the complaint, false advertising was conducted by the manufacturer defendants directly, through branded print and online advertisements and through detailing, and indirectly, through unbranded advertisements, public websites, and various publications issued by front groups funded and controlled by such defendants. The plaintiffs allege, for example, that Purdue and Endo falsely advertised OxyContin and Opana as tamper-resistant and less prone to abuse; that Purdue, Endo, Janssen, and Actavis falsely advertised their respective brand drugs, namely OxyContin, MS Contin, Nucynta ER, Duragesic, Opana ER, and Kadian, as providing up to 12 hours of pain relief; and that Cephalon falsely advertised Actiq and Fentora as appropriate treatment for all cancer patients suffering from breakthrough pain, not only those who were opioid tolerant; and all defendants failed to reveal the substantial dangers associated with long-term use of such potent drugs. It is alleged the manufacturer defendants falsely represented on public websites aimed at patients and prescribers that warnings about the risks of opioid addiction were “overstated,” and promoted the concept of pseudoaddiction, for which there is no scientific basis. Further, the plaintiffs allege that the false advertisements materially misled consumers and prescribers about the benefits and risks of prescription opioid therapy for chronic pain, including by failing to reveal that opioids pose a higher risk of abuse and addiction than other analgesics and that there was no scientific basis for many of the claims contained therein.

As to the “impact on consumers” element of General Business Law § 350, the allegations in the complaint are sufficient to infer that false advertising by the manufacturer defendants dramatically increased consumer demand for and consumption of prescription opioids, and that it created public misperception about the safety and efficacy of such prescription drugs. As to the causation element, the allegations in the complaint are sufficient to infer that the opioid epidemic allegedly spawned in part by the manufacturer defendants’ false advertising caused the plaintiffs to suffer extraordinary losses, including the costs related to the care and treatment of residents suffering from prescription opioid addiction, and the costs of opioid prescriptions for employees receiving county-funded health insurance benefits and residents receiving Medicaid benefits that would not have been approved had the risks associated with long-term opioid therapy for chronic, non-cancer related pain been known (*see Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *cf. Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892).

Third Cause of Action/Public Nuisance

The manufacturer defendants jointly contend that the plaintiffs’ third cause of action, alleging public nuisance, is deficient as a matter of law for failure to plead either proximate causation or substantial interference with a public right. As to proximate causation, they contend that the alleged causal link between their conduct and the plaintiffs’ injury is too attenuated to state a valid claim. As to substantial interference with a public right, they contend that their production, promotion, and marketing of lawful, FDA-approved medications is not “interference,” and that the concept of “public right” is not so broad as to include a right to be free of the threat that some individuals might use the product in a way that might create a risk of harm.

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A public or “common” nuisance is an offense against the State and is subject to abatement or prosecution on application of the proper governmental agency (*Copart Indus. v Consolidated Edison Co. of N.Y.*, 41 NY2d 564, 394 NYS2d 169 [1977]). It consists of conduct or omissions which offend, interfere with, or cause damage to the public in the exercise of rights common to all, in a manner such as to offend public morals, interfere with use by the public of a public place, or endanger or injure the property, health, safety or comfort of a considerable number of persons (*id.*).

Section 821B of Restatement (Second) of Torts provides:

(1) A public nuisance is an unreasonable interference with a right common to the general public.

(2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

(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

© 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 upon the public right.

The manufacturer defendants’ arguments are insufficient to warrant dismissal. Addressing first the claimed lack of proximate causation, the defendants rely heavily on *People v Sturm, Ruger & Co.* (309 AD2d 91, 761 NYS2d 192, *lv denied* 100 NY2d 514, 769 NYS2d 200 [2003]), a case involving public nuisance claims against handgun manufacturers, wholesalers, and retailers. There, the plaintiff alleged, in part, that despite the defendants having been placed on notice that the guns sold, distributed, and marketed by them were being used in crimes, they were deliberately designing and marketing their product in a way that placed a disproportionate number of guns in the possession of people who use them unlawfully. In dismissing the public nuisance claims, the court, based on its reading of *Hamilton v Beretta U.S.A. Corp.* (96 NY2d 222, 727 NYS2d 7 [2002] [involving a negligent marketing claim against handgun makers]), relied primarily on a proximate cause analysis, noting that the harms alleged were too indirect and remote from the defendants’ conduct and expressing a general reluctance to “open the courthouse doors to a flood of limitless, similar theories of public nuisance” in matters involving commercial activity (*People v Sturm, Ruger & Co.*, 309 AD2d at 96, 761 NYS2d at 196). The court did, however, recognize that public nuisance might be an appropriate tool, in other contexts, to address consequential harm from commercial activity. And the court also noted, as in *Hamilton*, a break in the causative chain by the criminal activity of intervening third parties, i.e., that the parties most directly responsible for the unlawful use of handguns were the individuals unlawfully using them.

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Here, by contrast, it is alleged that the plaintiffs have been damaged not only by the illegal use of opioids but also by their legal use, consistent with the manufacturer defendants' marketing and promoting. As to such legal use, it is at least arguable that the manufacturer defendants were in a position to anticipate or prevent the claimed injuries; it does not seem unfair, therefore, to hold them potentially accountable. The court is doubtful, in any event, whether a discussion of proximate cause in a case based on negligence should even apply in a case based on public nuisance. "[W]here the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases" (*City of New York v A-1 Jewelry & Pawn*, 247 FRD 296, 347-348 [ED NY 2007]). As for the manufacturer defendants' claim that the plaintiffs have failed to plead substantial interference with a public right, it suffices to note the defendants' failure to establish why public health is not a right common to the general public, nor why such continuing, deceptive conduct as alleged would not amount to interference; it can scarcely be disputed, moreover, that the conduct at the heart of this litigation, alleged to have created or contributed to a crisis of epidemic proportions, has affected "a considerable number of persons" (*Copart Indus. v Consolidated Edison Co. of N.Y.*, 41 NY2d at 568, 394 NYS2d at 172).

Fourth Cause of Action/Social Services Law § 145-b

The manufacturer defendants jointly contend that the plaintiffs' fourth cause of action, alleging violation of Social Services Law § 145-b, must be dismissed for failure to state a cause of action. The manufacturer defendants claim that the plaintiffs failed to plead facts showing that any defendant "attempt[ed] to obtain" or "obtain[ed] payment from public funds," or that they made any "false statement or representation." As to the pleading requirement with respect to false statements or representations, the manufacturer defendants note the plaintiffs' failure to identify any "claim for payment" made to the plaintiffs by any defendant or any specific "acknowledgment, certification, claim, ratification or report of data which serve[d] as the basis for a claim," or to allege that any such statement or representation was materially or knowingly false. Although the plaintiffs duly recite the elements of the cause of action in their complaint, the manufacturer defendants claim that such formulaic recitation is insufficient to withstand dismissal. The manufacturer defendants further claim that Social Services Law § 145-b applies only to providers and not to parties who, like the defendants, do not directly receive public funds.

The plaintiffs counter that their complaint does, in fact, plead each of the required elements, and that a cause of action alleging a violation of Social Services Law § 145-b need not be pleaded with the same degree of detail as a cause of action in fraud. The plaintiffs also contend that the statute is not limited in its application to Medicaid providers who receive direct payments of public funds but applies to any person who makes fraudulent statements to obtain such funds, whether directly or indirectly.

Social Services Law § 145-b states that "[i]t shall be unlawful for any person, firm or corporation knowingly by means of false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished" under the Social Services Law. A "statement or representation" includes, but is not limited to

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a claim for payment submitted to the State, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment[;] financial information whether in a cost report or otherwise[;] health care services available or rendered[;] and the qualifications of a person that is or has rendered health care services.

(Social Services Law § 145-b [1] [b]; see generally *State of New York v Lutheran Ctr. for the Aging*, 957 F Supp 393 [ED NY 1997]). A person, firm or corporation “has attempted to obtain or has obtained” payment from public funds “when any portion of the funds from which payment was attempted or obtained are public funds, or any public funds are used to reimburse or make prospective payment to an entity from which payment was attempted or obtained” (Social Services Law § 145-b [1] [c]). The statute vests the local social services district or the State the right to recover civil damages for Medicaid and Medicare fraud equal to “three times the amount by which any figure is falsely overstated or in the case of non-monetary false statements or representations, three times the amount of damages which the state, political subdivision of the state, or entity performing services under contract to the state or political subdivision of the state sustain as a result of the violation or five thousand dollars, whichever is greater” (Social Services Law § 145-b [2]).

The manufacturer defendants’ claims are rejected. To the extent they contend that this cause of action is deficient due to lack of factual specificity, the court is constrained to disagree. Even assuming the applicability of CPLR 3016 (b), which requires that causes of action based in fraud be pleaded with particularity, the pleading is sufficient. As discussed elsewhere in this order, the complaint adequately alleges the fraudulent and deceptive practices underlying the causes of action alleging violations of General Business Law §§ 349 and 350, as well as the cause of action for fraud; it is enough, therefore, for purposes of CPLR 3016 (b), to allege, as the plaintiffs have done, that the manufacturer defendants employed those practices to obtain or attempt to obtain public funds for themselves or others. “[T]he purpose underlying [CPLR 3016 (b)] is to inform a defendant of the complained-of incidents . . . CPLR 3016 (b) is satisfied when the facts suffice to permit a reasonable inference of the alleged misconduct” (*Eurycleia Partners v Seward & Kissel*, 12 NY3d 553, 559, 883 NYS2d 147, 150 [2009] [internal quotation marks omitted]). Nor, contrary to the manufacturer defendants’ argument, is there any pleading requirement that the plaintiffs allege facts showing that the defendants obtained or attempted to obtain public funds directly from the plaintiffs. Under subdivision (1) (a), it is unlawful for a person to fraudulently obtain or attempt to obtain public funds, whether “on behalf of himself or others”; under subdivision (1) ©, a person has obtained or attempted to obtain public funds when such funds “are used to reimburse or make prospective payment to an entity from which payment was obtained or attempted.” If, then, a defendant indirectly receives public funds by making a fraudulent statement to assist a Medicaid provider in procuring such funds, such conduct would seem to fall within the ambit of the statute (cf. *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F Supp 2d 165 [D Mass 2004]). Even if *People v Pharmacia Corp.* (2004 WL 5841904 [Sup Ct, Albany County 2004]), cited by the manufacturer defendants, may be to the contrary—and this court is not persuaded that it is—it suffices to

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note at this juncture that a decision of a court of equal jurisdiction, though entitled to respectful consideration, is not controlling (McKinney's Cons Laws of NY, Book 1, Statutes § 72 [b]). Likewise, it cannot be said that the plaintiffs failed to plead a "false statement or representation." While the manufacturer defendants correctly note that a "statement or representation" within the definition of the statute may include a "claim for payment" or an "acknowledgment, certification, claim, ratification or report of data" which serves as the basis for such a claim, the statute does not exclude, by its terms, statements and representations which are just that—statements and representations—and the defendants do not explain why the allegedly false statements and representations underlying the plaintiffs' other causes of action based in fraud and deceit would not serve to support this cause of action as well. Whether, then, the plaintiffs may have failed to identify specifically any "claim for payment" made to a county or any "acknowledgment, certification, claim, ratification or report of data" serving as the basis for such a claim is immaterial for purposes of this determination.

Fifth Cause of Action/Fraud

The manufacturer defendants move to dismiss the plaintiffs' fifth cause of action for fraud on the grounds, among other things, that the complaint does not conform to the pleading requirements of CPLR 3013 and CPLR 3016 (b). CPLR 3013 provides that the "[s]tatements in a pleading shall be sufficiently particular to give the court and the parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the material elements of each cause of action or defense." Here, the manufacturer defendants have not indicated that the complaint fails to give them adequate notice of the transactions, occurrences, or series of transactions or occurrences which the plaintiffs intend to prove regarding their fifth cause of action, or that they are unable to frame an answer to the allegations in the complaint.

CPLR 3016 (b) requires that in an action based upon fraud, "the circumstances constituting the wrong shall be stated in detail" in the pleading. Bare allegations of fraud without any allegation of the details constituting the wrong are not sufficient to sustain such a cause of action (CPLR 3016 [b]; see *Kline v Taukpoint Realty Corp.*, 302 AD2d 433, 754 NYS2d 899 [2d Dept 2003]; *Gill v Caribbean Home Remodeling*, 73 AD2d 609, 422 NYS2d 448 [2d Dept 1979]; *Biggar v Buteau*, 51 AD2d 601, 377 NYS2d 788 [3d Dept 1976]). However, the statute "requires only that the misconduct complained of be set forth in sufficient detail to clearly inform a defendant with respect to the incidents complained of" (*Lanzi v Brooks*, 43 NY2d 778, 780, 402 NYS2d 384, 385 [1978]; see also *Mandarin Trading Ltd. v Wildenstein*, 16 NY3d 173, 919 NYS2d 465 [2011]; *Mikulski v Battaglia*, 112 AD3d 1355, 977 NYS2d 839 [4th Dept 2013]). In addition, when the operative facts are "peculiarly within the knowledge of the party" alleged to have committed the fraud, it may not be possible at the pleading stage of the proceeding for the plaintiff to detail all the circumstances constituting the fraud (*Jered Contr. Corp. v New York City Tr. Auth.*, 22 NY2d 187, 194, 292 NYS2d 98, 104 [1968]; see also *Pludeman v Northern Leasing Sys., Inc.*, 10 NY3d 486, 860 NYS2d 422 [2008]). It has been held that CPLR 3016 (b) is satisfied when the facts suffice to permit a "reasonable inference" of the alleged misconduct (*Eurycleia Partners, LP v Seward & Kissel, LLP*, 12 NY3d 553, 883 NYS2d 147 [2009], citing *Pludeman v Northern Leasing Sys., Inc.*, 10 NY3d 486, 860 NYS2d 422).

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The elements of a cause of action for fraud are (1) a misrepresentation of fact, (2) which was false and known to be false by the defendant, (3) made for the purpose of deceiving the plaintiff, (4) upon which the plaintiff justifiably relied, (5) causing injury (e.g. *Clearview Concrete Prods. Corp. v S. Charles Gherardi, Inc.*, 88 AD2d 461, 453 NYS2d 750 [2d Dept 1982]; see also *Ozelkan v Tyree Bros. Envtl. Servs.*, 29 AD3d 877, 815 NYS2d 265 [2d Dept 2006]). Thus, a plaintiff seeking to recover for fraud must establish that the defendant knowingly made a false representation (see e.g. *Wilson v Neighborhood Restore Hous.*, 129 AD3d 948, 12 NYS3d 166 [2d Dept 2015]; *Miller v Livingstone*, 25 AD2d 106, 267 NYS2d 249 [1st Dept], *aff'd* 18 NY2d 967, 278 NYS2d 206 [1966]), that the defendant made such misrepresentation with an intent to defraud (*Marine Midland Bank v Russo Produce Co., Inc.*, 50 NY2d 31, 427 NYS2d 961 [1980]), and that the misrepresentation was false in a material and substantial respect (see *Ozelkan v Tyree Bros. Envtl. Servs., Inc.*, 29 AD3d 877, 815 NYS2d 265). A plaintiff alleging fraud also must prove that it relied on the alleged misrepresentation and that such misrepresentation was a substantial factor in inducing it to act (see *Ginsburg Dev. Cos., LLC v Carbone*, 134 AD3d 890, 22 NYS3d 485 [2d Dept 2015]). Significantly, the plaintiff's reliance on the misrepresentation must have been reasonable or justified under the circumstances (see *McDonald v McBain*, 99 AD3d 436, 952 NYS2d 486 [1st Dept 2012]; *East End Cement & Stone, Inc. v Carnevale*, 73 AD3d 974, 903 NYS2d 420 [2d Dept 2010]). Reliance will not be justified if the plaintiff could have discovered the truth through due diligence (see *Wildenstein v 5H&Co., Inc.*, 97 AD3d 488, 950 NYS2d 3 [1st Dept 2012]).

The plaintiffs have pled a cognizable cause of action for fraud. The plaintiffs allege that the manufacturer defendants purposefully misrepresented that opioids improve function and quality of life, that addiction risks can be managed, that withdrawal is easily managed, that higher doses of opioids pose no greater risks to patients, and that they deceptively minimized the adverse effects of opioids while overstating the risks of NSAIDs (nonsteroidal anti-inflammatory drugs). The plaintiffs further allege that the manufacturer defendants created a body of false, misleading, and unsupported medical and popular literature about opioids, that they disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations, and that they spent "hundreds of millions of dollars" in this false and misleading marketing campaign to improperly influence individual prescribers. The plaintiffs allege that the strategies employed by the manufacturer defendants "were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns."

The plaintiffs also allege that the manufacturer defendants' "misrepresentations were material to, and influenced, the plaintiffs' decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use)," and that the plaintiffs have taken "steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required." Thus, the plaintiffs allege that the manufacturer defendants intended that the plaintiffs, physicians, patients, and others would rely on their misrepresentations and omissions, and that the plaintiffs reasonably relied upon said misrepresentations and omissions.

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Finally, the plaintiffs allege that the manufacturer defendants' misrepresentations caused them direct injury as they have incurred costs related to opioid addiction and abuse, including health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. As discussed above, to the extent the manufacturer defendants urge the application of the rule barring recovery of indirect or derivative injuries sustained by others, the court notes that the plaintiffs are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (*cf. Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 205, 785 NYS2d 399 [2004]).

Sixth Cause of Action/Unjust Enrichment

The manufacturer defendants contend that the plaintiffs' sixth cause of action, sounding in unjust enrichment, must be dismissed because it is derivative and duplicative of their other claims, and because the plaintiffs have failed to allege facts showing that the defendants were enriched, that such enrichment was unjust and at the plaintiffs' expense, that the plaintiffs suffered any cognizable loss, or that it would be against equity or good conscience to permit the manufacturer defendants to retain what it sought to be recovered. The manufacturer defendants also contend that the parties lack a sufficiently close relationship to support a cause of action for unjust enrichment.

In order to adequately plead a cause of action for unjust enrichment, it must be alleged that the defendant was enriched, at the plaintiff's expense, and that it is against equity and good conscience to permit the defendant to retain what is sought to be recovered (*Mandarin Trading v Wildenstein*, 16 NY3d 173, 919 NYS2d 465 [2011]). The theory of unjust enrichment "lies as a quasi-contract claim" and contemplates "an obligation imposed by equity to prevent injustice, in the absence of an actual agreement between the parties" (*Georgia Malone & Co. v Rieder*, 19 NY3d 511, 516, 950 NYS2d 333, 336 [2012] [internal quotation marks omitted]). "Although privity is not required for an unjust enrichment claim, a claim will not be supported if the connection between the parties is too attenuated" (*Mandarin Trading v Wildenstein*, 16 NY3d at 182, 919 NYS2d at 472; *accord Sperry v Crompton Corp.*, 8 NY3d 204, 831 NYS2d 760 [2007]).

Here, the plaintiffs plead that the manufacturer defendants, as an expected and intended result of their conscious wrongdoing alleged elsewhere in the complaint, were enriched from opioid purchases made by the plaintiffs and that it would be unjust and inequitable to permit them to enrich themselves at the plaintiffs' expense.

The court finds the pleading sufficient to withstand the manufacturer defendants' claims. It does not appear, for purposes of this determination, that this cause of action is either derivative or duplicative of any other cause of action. As pleaded, it is the only cause of action by which the plaintiff seek disgorgement of profits and other monetary benefits resulting from the manufacturer defendants' alleged misconduct; moreover, as New York law specifically allows for the pleading of alternative causes of action and alternative forms of relief (CPLR 3014, 3017), the plaintiffs need not elect any theory over another at this preliminary stage. To the extent the manufacturer defendants urge the application of the rule barring recovery of indirect or derivative injuries sustained by others, the court notes, as before, that

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the plaintiffs here are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (cf. *Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399 [2004]). The manufacturer defendants have also failed to explain why, as a pleading matter, the retention of profits wrongfully obtained would not be unjust. As for the relationship between and among the parties, the plaintiffs allege, in relevant part, that the manufacturer defendants created a body of false and misleading literature intended to shape the perceptions of third-party payors such as the plaintiffs, encouraging them to pay for long-term opioid prescriptions and effectively depriving them of the chance to exercise informed judgment; implicit in those allegations is that the manufacturer defendants knew the plaintiffs were to be the source of a significant portion of their profits. Accepting those facts as true and according the plaintiffs the benefit of every favorable inference (*Leon v Martinez*, 84 NY2d 83, 614 NYS2d 972 [1994]), it is evident that the plaintiffs have pleaded a relationship—or “at least an awareness” by the manufacturer defendants of the plaintiffs’ existence (*Mandarin Trading v Wildenstein*, 16 NY3d at 182, 919 NYS2d at 472)—sufficient to maintain their cause of action.

Seventh Cause of Action/Negligence

To prove a prima facie case of negligence, a plaintiff must demonstrate the existence of a duty, a breach of that duty, and that the breach of such duty was a proximate cause of his or her injuries (see *Pulka v Edelman*, 40 NY2d 781, 390 NYS2d 393 [1976]; see also *Pasquaretto v Long Is. Univ.*, 106 AD3d 794, 964 NYS2d 599 [2d Dept 2013]; *Schindler v Ahearn*, 69 AD3d 837, 894 NYS2d 462 [2d Dept 2010]). A duty of reasonable care owed by the alleged tortfeasor to the plaintiff is essential to any recovery in negligence (*Eiseman v State of New York*, 70 NY2d 175, 187, 518 NYS2d 608 [1987]; see *Espinal v Melville Snow Contrs.*, 98 NY2d 136, 746 NYS2d 120 [2002]). Although juries determine whether and to what extent a particular duty was breached, it is for the courts to decide in the first instance whether any duty exists and, if so, the scope of such duty (*Church v Callanan Indus.*, 99 NY2d 104, 752 NYS2d 254 [2002]; *Darby v Compagnie Natl. Air France*, 96 NY2d 343, 728 NYS2d 731 [2001]; *Waters v New York City Hous. Auth.*, 69 NY2d 225, 513 NYS2d 356 [1987]).

The manufacturer defendants contend that the plaintiffs’ cause of action for negligence must be dismissed because New York does not impose a duty upon manufacturers to refrain from the lawful distribution of a non-defective product. Citing *Hamilton v Beretta U.S.A. Corp.*, 96 NY2d 222, 727 NYS2d 7 (2001), they also argue that they do not owe the plaintiffs a duty to protect against the misconduct of third parties, that New York does not impose a legal duty on manufacturers to control the distribution of potentially dangerous products, and that “the alleged foreseeability of injuries is not a reason to find that a duty exists” herein. They further contend that the plaintiffs must allege a “specific duty” is owed to them, and that they may not rely upon a “general duty to society” to support their cause of action for negligence.

“A critical consideration in determining whether a duty exists is whether ‘the defendant’s relationship with either the tortfeasor or the plaintiff places the defendant in the best position to protect against the risk of harm’” (*Davis v South Nassau Communities Hosp.*, 26 NY3d 563, 572, 26 NYS2d 231 [2015], quoting *Hamilton v Beretta U.S.A. Corp.*, 96 NY2d 222, 233, 727 NYS2d 7 [2001]).

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Unlike *Hamilton*, where the Court of Appeals found that gun manufacturers were not in the best position to protect against the risk of harm from the misuse of its product by third parties, here the plaintiffs allege facts sufficient to support the existence of a duty of care. Specifically, the plaintiffs allege that because the manufacturer defendants had knowledge of the actual risks and benefits of their products, including their addictive nature, which they did not disclose, they were in the best position to protect the plaintiffs against the expenses incurred for opioids prescribed for their employees and for Medicaid beneficiaries that would not have been approved for payment, and against the extraordinary amounts expended to combat the opioid crisis allegedly caused by the deceptive marketing campaigns.

Courts traditionally “fix the duty point by balancing factors, including the reasonable expectations of parties and society generally, the proliferation of claims, the likelihood of unlimited or insurer-like liability, disproportionate risk and reparation allocation, and public policies affecting the expansion or limitation of new channels of liability” (*Palka v Servicemaster Mgt. Servs. Corp.*, 83 NY2d 579, 586, 611 NYS2d 817, 821 [1994]; see *Tagle v Jakob*, 97 NY2d 165, 737 NYS2d 331 [2001]). In balancing these factors, the plaintiffs have adequately pled that their expectations and those of society would require different behaviors on the part of the manufacturer defendants, that there is a finite number of counties in the State of New York with potential claims against said defendants, that the allegedly negligent acts and omissions of said defendants do not create unlimited liability, that the risks allegedly created by said defendants do not disproportionately outweigh the possible reparations to be awarded herein, and that public policy must address the issues raised in the complaint. It is noted that New York courts have recognized a cause of action for negligent marketing of prescription drugs (see *Bikowicz v Sterling Drug, Inc.*, 161 AD2d 982, 557 NYS2d 551 [3d Dept 1990]).

The plaintiffs also allege sufficient facts to support a separate duty not to deceive (see e.g. *Cipollone v Liggett Group, Inc.*, 505 US 504, 112 S Ct 2608 [1992]; *In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369 [SD NY 2015]; see also *Tomasino v American Tobacco Co.*, 23 AD3d 546, 807 NYS2d 603 [2d Dept 2005]). The plaintiffs allege that the manufacturer defendants failed to comply with 10 NYCRR 80.22, which requires manufacturers of controlled substances to “establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” It is well settled that a violation of a regulation or ordinance constitutes some evidence of negligence (see *Bauer v Female Academy of Sacred Heart*, 97 NY2d 445, 741 NYS2d 491 [2002]; *March Assoc. Constr., Inc. v CMC Masonry Constr.*, 151 AD3d 1050, 58 NYS3d 423 [2d Dept 2017]). A “violation of the statute’s implementing rules and regulations . . . constitutes some evidence of negligence” (*Watral & Sons, Inc. v OC Riverhead 58, LLC*, 34 AD3d 560, 567, 824 NYS2d 392, 398 [2d Dept 2006], *revd on other grounds* 10 NY3d 180, 855 NYS2d 49 [2008]).

Moreover, the manufacturer defendants’ contention that the plaintiffs have failed to adequately allege “but for” causation is without merit, as the test for legal causation is proximate cause (see *Burlington Ins. Co. v NYC Tr. Auth.*, 29 NY3d 313, 57 NYS3d 85 [2017]). Similarly, the manufacturer defendants’ contention that plaintiffs have failed to adequately allege causation in a general sense is not dispositive herein. “Generally, issues of proximate cause are for the fact finder to

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resolve” (*Gray v Amerada Hess Corp.*, 48 AD3d 747, 748, 853 NYS2d 157 [2d Dept 2008], quoting *Adams v Lemberg Enters., Inc.*, 44 AD3d 694, 695, 843 NYS2d 432 [2d Dept 2007]). Even at the more advanced stage of litigation, “the absence of direct evidence of causation [does] not necessarily compel a grant of summary judgment in favor of the defendant, as proximate cause may be inferred from the facts and circumstances underlying the injury, the evidence must be sufficient to permit a finding based on logical inferences from the record and not upon speculation alone” (*Hartman v Mountain Val. Brew Pub*, 301 AD2d 570, 570, 754 NYS2d 31, 32 [2003]; see also *Schneider v Kings Hwy. Hosp. Ctr.*, 67 NY2d 743, 500 NYS2d 95 [1986]; *Mitchell v Mongoose, Inc.*, 19 AD3d 380, 796 NYS2d 421 [2d Dept 2005]). Here, the plaintiffs have adequately pled that the alleged breach of the manufacturer defendants’ duty herein was a proximate cause of their injuries.

Finally, the manufacturer defendants contend that the economic-loss doctrine bars the plaintiffs’ cause of action for negligence. The economic loss doctrine provides that economic losses with respect to a product and consequential damages resulting from an alleged defect in that product are not recoverable in a cause of action for strict products liability and negligence against a manufacturer (*New York Methodist Hosp. v Carrier Corp.*, 68 AD3d 830, 892 NYS2d 110 [2d Dept 2009]). A product may be defective due to a mistake in the manufacturing process, a negligent design, or a failure to provide adequate warnings regarding the use of the product (*Sprung v MTR Ravensburg*, 99 NY2d 468, 758 NYS2d 271 [2003]; *Gebo v Black Clawson*, 92 NY2d 387, 392, 681 NYS2d 221 [1998]; *Voss v Black & Decker Mfg. Co.*, 59 NY2d 102, 463 NYS2d 398 [1983]). “The rationale behind the economic loss doctrine is that economic losses resulting from a defective product are best treated under the law of contracts, not tort” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d 194 [ED NY 2010]; see also *Hydro Invs., Inc. v Trafalgar Power Inc.*, 227 F3d 8, 16 [2d Cir 2000]). “This is because ‘[t]he particular seller and purchaser are in the best position to allocate risk at the time of their sale and purchase, and this risk allocation is usually manifested in the selling price’” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d at 205, quoting *Bocre Leasing Corp. v General Motors Corp.*, 84 NY2d 685, 688, 621 NYS2d 497, 498 [1995] [internal citations omitted]).

“New York does not permit recovery through tort actions for damages that result from the poor performance of a contracted-for product” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d at 205 [internal citations omitted]). It is well settled that a simple breach of contract is not considered a tort unless a legal duty independent of the contract has been violated (*Clark-Fitzpatrick, Inc. v Long Is. R.R. Co.*, 70 NY2d 382, 389, 521 NYS2d 653, 656 [1987]; see *New York Univ. v Continental Ins. Co.*, 87 NY2d 308, 639 NYS2d 283 [1995]; *Sommer v Federal Signal Corp.*, 79 NY2d 540, 583 NYS2d 957 [1992]). Here, the plaintiffs have not asserted a cause of action against the manufacturer defendants for breach of contract or an alleged defect in the product produced by said defendants. In addition, the plaintiffs’ allegations indicate that the relevant transactions between the parties were not contractual, that they did not afford the plaintiffs the opportunity to allocate the attendant risks associated with the alleged improper acts and omissions of the manufacturer defendants, and that this is more than a “case of economic disappointment” which would make the economic-loss doctrine applicable herein (see *Bellevue S. Assoc. v HRH Constr. Corp.*, 78 NY2d 282, 294, 574 NYS2d 165, 170 [1991]; see e.g. *Hydro Invs., Inc. v Trafalgar Power Inc.*, 227 F3d 8; *Assured Guar. (UK) Ltd. v J.P. Morgan Inv. Mgt. Inc.*, 80 AD3d 293, 915 NYS2d 7 [1st Dept 2010]). Accordingly,

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that branch of the manufacturer defendants' motion which seeks to dismiss the plaintiffs' seventh cause of action for negligence is denied.


Conclusion

In accordance with the foregoing analysis, the manufacturer defendants' motions are denied, except to the extent that the complaint against Allergan plc is dismissed for lack of personal jurisdiction. As to any contentions by the manufacturer defendants not specifically addressed above, the court finds that they lack merit or that they state defenses more appropriately considered on a motion for summary judgment or at the trial of this action.

The manufacturer defendants shall serve their answer(s) to the complaint within 10 days after the date on which this order is uploaded on the NYSCEF site (*see* CPLR 3211 [f]).

Dated: _____

June 18, 2018


J.S.C.
HON. JERRY GARGUILO

SHORT FORM ORDER

INDEX No. 400000/2017

SUPREME COURT - STATE OF NEW YORK
NEW YORK STATE OPIOID LITIGATION PART 48 - SUFFOLK COUNTY

PRESENT:**E-FILE**

Hon. JERRY GARGUILO
Justice of the Supreme Court

-----X
IN RE OPIOID LITIGATION
-----X

MOTION DATE 2/7/18
ADJ. DATE 3/21/18
Mot. Seq. #009 - MD

Upon the reading and filing of the following papers in this matter (1) Notice of Motion by defendant Insys Therapeutics, Inc. (Mot. Seq. #009), dated November 10, 2017, and supporting papers (including Memorandum of Law); (2) Memorandum of Law in Opposition (Mot. Seq. #009), dated January 19, 2018; (3) Reply Memorandum of Law (Mot. Seq. #001), dated February 23, 2018;

ORDERED that the motion by defendant Insys Therapeutics, Inc. for an order pursuant to CPLR 3211, dismissing the master long form complaint against it is denied.

The plaintiffs are counties within the State of New York that have commenced separate actions against certain pharmaceutical manufacturers for harm allegedly caused by false and misleading marketing campaigns promoting semi-synthetic, opium-like pharmaceutical pain relievers, including oxycodone, hydrocodone, oxymorphone, and tapentadol, as well as the synthetic opioid prescription pain medication fentanyl, as safe and effective for long-term treatment of chronic pain. Also named as defendants in those actions are certain pharmaceutical distributors that allegedly distributed those opium-like medications (hereinafter referred to as prescription opioids or opioids) to retail pharmacies and institutional health care providers for customers in such counties, and individual physicians allegedly "instrumental in promoting opioids for sale and distribution nationally" and in such counties. Briefly stated, the plaintiffs allege that tortious and illegal actions by the defendants fueled an opioid crisis within such counties, causing them to spend millions of dollars in payments for opioid prescriptions for employees and Medicaid beneficiaries that would have not been approved as necessary for treatment of chronic pain if the true risks and benefits associated with such medications had been known. They also allege that the defendants' actions have forced them to pay the costs of implementing opioid treatment programs for residents, purchasing prescriptions of naloxone to treat prescription opioid overdoses, combating opioid-related criminal activities, and other such expenses arising from the crisis.

One such lawsuit was commenced in August 2016 by Suffolk County and assigned to the Commercial Division of the Supreme Court. By order dated July 17, 2017, the Litigation Coordinating Panel of the Unified Court System of New York State directed the transfer of eight opioid-related actions brought by other counties, and any prospective opioid actions against the manufacturer, distributor, and individual defendants, be transferred to this court for pre-trial coordination. That same day, the

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undersigned issued a case management order reiterating that the individual actions are joined for coordination, not consolidated, and directing that a master file, known as “In re Opioid Litigation,” assigned index number 400000/2017, be established for the electronic filing of all documents related to the proceeding. The undersigned further directed the plaintiffs to file and serve a master long form complaint subsuming the causes of action alleged in the various complaints, and directed the manufacturer defendants, the distributor defendants, and the individual defendants to file joint motions pursuant to CPLR 3211, seeking dismissal of the master complaint, all by certain dates.

The plaintiffs have adopted the master long form complaint (hereinafter the complaint) in accordance with the court’s directive. In response, the defendant manufacturers and distributors have submitted numerous motions, individually and jointly, for dismissal of the complaint. Among the motions submitted to the court is a joint motion by the defendant manufacturers seeking dismissal of the long form complaint. Defendant Insys Therapeutics, Inc. (herein referred to as “Insys”), the lone defendant manufacturer not listed as a party to the joint motion, now moves, individually, for an “[order, pursuant to CPLR 3211, dismissing the Complaint . . . in its entirety.” In seeking judgment in its favor, Insys purports to adopt and incorporate by reference the arguments and authorities set forth in the abovementioned joint motion by the remaining defendant manufacturers. Additionally, Insys asserts that the plaintiffs failed to state viable causes of action against it, because the sales of its drug “Subsist accounted] for approximately .01% of opioids prescribed in New York in the last 10 years, and less than approximately .03% of opioids prescribed in New York since the beginning of 2012.” Insys argues, in connection with this assertion, that the allegations against it in the complaint are general in nature and lack any specific facts to suggest that Subsist was prescribed in the plaintiff counties, that the plaintiff counties ever paid for Subsist prescriptions, or that Subsist either caused harm to a single person in any of the counties or caused such persons to become addicted to opioids.

In addition, Insys argues that the allegations contained in the complaint relating to the harm sustained by to the residents of Nassau, Niagara, Rensselaer, and Schoharie counties are general in nature and implausible on their face when applied to Insys, and that they are impermissibly based upon national rather than county specific data. To this end, Insys asserts that the complaint is devoid of a single fact about any false advertising or misrepresentation it allegedly conducted within the confines of the plaintiff counties. Insys further asserts that the plaintiffs erroneously allege that it was responsible for fraudulent marketing that allegedly took place in the year 2000, when, in fact, its drug was not introduced to the New York market until 2012. Insys then makes a final generalized argument that the complaint contains “myriad other defects, such as impermissible group pleading, a wholesale failure to plead damage causation, and others, which are addressed in detail by the primary motion.”

The plaintiffs oppose Insys’ motion on three grounds. The plaintiffs reject Insys’ argument that they cannot adequately allege causation or harm because the sales of Insys’ drug accounted for only a “minuscule” percentage of all the opioids sold in New York, arguing that even if there was a minuscule number of Subsist sales within the counties, the court may determine Insys’ liability for such sales in proportion to its market share of all the opioids sold in the New York market generally. Alternatively, the plaintiffs contend that dismissal based on this argument would be inappropriate where, as in this case, there has been no discovery and additional facts may be later discovered showing that the volume

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of Subsist sales within the state is much larger than indicated in Insys' moving papers. As to Insys' argument that plaintiffs will be unable to establish a cause of action against it for alleged fraudulent marketing that took place prior to 2012 when Subsist allegedly entered the New York market, plaintiffs assert that Insys may nonetheless be held liable for the prior conduct of other drug manufacturers or suppliers with whom Insys acted with as a co-conspirator when it later adopted their common scheme. To substantiate their claim of a conspiracy between Insys and some of the other drug manufacturers, plaintiffs point to the specific allegations made in the complaint that detail how ex-employees of Cephalon, Inc., another defendant drug manufacturer named in the complaint, became employed by Insys and participated in the rollout of a scheme substantially similar to the one utilized by their prior employer to deceptively market Subsist to county residents for off-label use.

As to Insys' general assertion that the complaint lacks specific allegations concerning its alleged deceptive practices within the plaintiff counties, the plaintiffs assert that the complaint provides detailed allegations describing deceptive and fraudulent marketing tactics deployed by Insys to avoid prior authorization from insurance companies, their creation of a fraudulent speakers program used to bribe doctors to write numerous off-label prescriptions for Subsist, and Insys' wilful failure to impose sufficient compliance procedures to prevent prescription fraud and to audit interactions between their employees and outside entities. Finally, plaintiffs request, should the court deem the complaint deficient in any way, that they be granted leave to amend the pleading pursuant to CPLR 3025 (b).

"On a motion to dismiss the complaint pursuant to CPLR 3211 (a) (7) for failure to state a cause of action, the court must afford the pleading a liberal construction, accept all facts as alleged in the pleading to be true, accord the plaintiff the benefit of every possible inference, and determine only whether the facts as alleged fit within any cognizable legal theory" (*Antoine v Kalandrishvili*, 150 AD3d 941, 941, 56 NYS3d 142 [2d Dept 2017]; see *Leon v Martinez*, 84 NY2d 83, 87, 614 NYS2d 972 [1994]). "Whether a plaintiff can ultimately establish [his or her] allegations is not part of the calculus in determining a motion to dismiss" (*EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d 11, 19, 799 NYS2d 170 [2005]; see *Kaplan v New York City Dept. of Health and Mental Hygiene*, 142 AD3d 1050, 38 NYS3d 563 [2d Dept 2016]), and a plaintiff is not obligated to demonstrate the existence of evidentiary facts to support the allegations contained in the complaint (see *Rovello v Orofino Realty Co.*, 40 NY2d 633, 389 NYS2d 314 [1976]; *Stuart Realty Co. v Rye Country Store*, 296 AD2d 455, 745 NYS2d 72 [2d Dept 2002]). Indeed, when determining a motion to dismiss pursuant to CPLR 3211(a) (7) an assessment of the "relative merits of the complaint's allegations against the defendant's contrary assertions" is not authorized (*Salles v Chase Manhattan Bank*, 300 AD2d 226, 228, 754 NYS2d 236 [1st Dept 2002]), and the burden never shifts to the nonmoving party to rebut a defense asserted by the movant (see *E & D Group, LLC v Violet*, 134 AD3d 981, 21 NYS3d 691 [2d Dept 2015]; *Sokol v Leader*, 74 AD3d 1180, 904 NYS2d 153 [2d Dept 2010]). The sufficiency of a complaint need only be measured against what the law requires of the pleadings in a particular case, and will be met so long as they give the court and parties notice of the transactions, occurrences, or series of transactions or occurrences intended to be proved and the material elements of each cause of action (see CPLR 3013; *East Hampton Union Free Sch. Dist. v Sandpebble Bldrs., Inc.*, 66 AD3d 122, 884 NYS2d 94 [2d Dept 2009]). Moreover, it is well established that a motion to dismiss made pursuant to CPLR 3211 (a) (7) "will be denied in its entirety where the complaint asserts several causes of action, at least one of

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which is legally sufficient, and . . . the motion [wa]s aimed at the pleading as a whole without particularizing the specific causes of action sought to be dismissed” (*Long Is. Diagnostic Imaging v Stony Brook Diagnostic Assoc.*, 215 AD2d 450, 452, 626 NYS2d 828, 829 [2d Dept 1995], quoting *Martirano Constr. Corp. v Briar Contr. Corp.*, 104 AD2d 1028, 481 NYS2d 105 [2d Dept 1984]; *see Advance Music Corp. v American Tobacco Co.*, 296 NY 79 [1946]; *Chase v Town of Camillus*, 247 AD2d 851, 668 NYS2d 830 [4th Dept 1998]; *Great N. Assoc. v Continental Cas. Co.*, 192 AD2d 976, 596 NYS2d 938 [3d Dept 1993]).

Initially, the court notes that Insys’ motion, which is aimed at the pleadings as a whole, fails to particularize which of the seven causes of action contained in the complaint it wishes to be dismissed, or which one of the many arguments contained in the joint motion it wishes to adopt and deploy against the unique set of allegations made against it in the complaint. Indeed, Insys failed to identify what section of CPLR 3211 it intends to rely upon in support of its application to dismiss the complaint. The court, therefore, is left in the untenable position of having to speculate which arguments relate to the unique set of allegations made against Insys, and how such arguments should be applied to the particular causes of action. As a result, the court concludes that Insys has not only failed to meet its initial burden of demonstrating entitlement to judgment in its favor pursuant to CPLR 3211, but the motion, which was addressed to the long form master complaint as a whole, must be denied in its entirety, since the court finds, as discussed below, that the plaintiff counties have sufficiently pleaded a cognizable claim pursuant to section 349 of the General Business Law (*see Advance Music Corp. v American Tobacco Co.*, 296 NY 79; *Long Is. Diagnostic Imaging v Stony Brook Diagnostic Assoc.*, 215 AD2d 450, 626 NYS2d 828; *Great N. Assoc. v Continental Cas. Co.*, 192 AD2d 976, 596 NYS2d 938; *Elias v Handler*, 155 AD2d 583, 548 NYS2d 33 [2d Dept 1989]; *Gedan v Home Ins. Co.*, 144 AD2d 338, 533 NYS2d 945 [2d Dept 1988]; *Wright v County of Nassau*, 81 AD2d 864, 438 NYS2d 875 [2d Dept 1981]).

General Business Law § 349 (a) provides that it is unlawful to perform “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” The statute is “meant to curtail deceptive acts and practices – willful or otherwise – directed at the consuming public” (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177 [1999]). Although the statute as originally enacted was only enforceable by the Attorney General, it was amended in 1980 to allow actions by private plaintiffs, including corporate entities, injured by such illegal conduct (*see* General Business Law § 349 [h]; *Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 205, 785 NYS2d 399 [2004]; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 290, 690 NYS2d 495 [1999]; *Blue Cross & Blue Shield of N.J., Inc. v Phillips Morris USA Inc.*, 344 F3d 211 [2003] [a party has standing under General Business Law § 349 when its complaint alleges a consumer injury or harm to the public interest, regardless of whether the plaintiff is a consumer]). To state a cause of action under General Business Law § 349, a plaintiff must allege that a defendant engaged in consumer-oriented conduct, that the conduct was materially deceptive or misleading, and that the plaintiff suffered injury as a result of such conduct (*see Stutman v Chemical Bank*, 95 NY2d 24, 29, 709 NYS2d 892 [2000]; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529 [1995]). The court notes that, for the reasons set forth in the related order

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issued today, the court has determined that the General Business Law § 349 cause of action alleged by the plaintiff counties is not preempted by the Food Drug and Cosmetic Act (21 USC § 301 et seq.).

For pleading purposes, the claim of consumer-oriented conduct must be premised on allegations of facts sufficient to show that the challenged acts or practices were “directed at the consuming public” (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 343, 704 NYS2d 177), had a broad impact on consumers at large (*Karlin v IVF Am.*, 93 NY2d 282, 290, 690 NYS2d 495), or was harmful to the general public interest (see *Securitron Magnalock Corp. v Schnabolk*, 65 F3d 256 [SD NY 1995]; *Azby Brokerage, Inc. v Allstate Ins. Co.*, 681 F Supp 1084, 1089 [SD NY 1988]). The element of pleading consumer-oriented conduct may also be satisfied where the plaintiff alleges facts demonstrating that the deceptive acts were standardized such that “they potentially affect[ed] similarly situated consumers” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 27, 623 NYS2d 529; see *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 14, 953 NYS2d 96 [2d Dept 2012]). Sufficient consumer-oriented conduct has been found where a defendant employed “multimedia dissemination of information to the public” (*Karlin v IVF Am.*, 93 NY2d 282, 293, 690 NYS2d 495), or employed an “extensive marketing scheme” that had a broad impact on consumers (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 343, 704 NYS2d 177).

With respect to the second element of misleading or deceptive conduct, a plaintiff must allege that the challenged act or practice was “misleading in a material way” (*Stutman v Chemical Bank*, 95 NY2d at 30, 709 NYS2d at 895). “In determining whether a representation or omission is a deceptive act, the test is whether such act is ‘likely to mislead a reasonable consumer acting reasonably under the circumstances’” (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d 608, 609, 752 NYS2d 400, 402 [2d Dept 2015], quoting *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533). The statute is aimed at addressing those omissions or misrepresentations “which undermine a consumer’s ability to evaluate his or her market options and to make a free and intelligent choice” (*North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d at 26, 953 NYS2d at 102). Furthermore, the deceptive representation or omission in question need not arise to the level of common-law fraud to be actionable (see *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177), and no proof of intent to defraud by the defendant or justifiable reliance by the consumer is required (see *Small v Lorillard Tobacco Co.*, 94 NY2d 43, 698 NYS2d 615 [1999]; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529). As a result, courts have determined that the strict pleading requirements imposed by CPLR 3016 are inapplicable to a cause of action predicated on General Business Law § 349 (see *Joannou v Blue Ridge Ins. Co.*, 289 AD2d 531, 735 NYS2d 786 [2d Dept 2001]; *McGill v General Motors Corp.*, 231 AD2d 449, 647 NYS2d 209 [1st Dept 1996]).

As to the third element relating to injury, a plaintiff is required to allege “actual injury,” though not necessarily pecuniary harm, that results from a defendant’s deceptive act or practice (*City of New York v Smokers-Spirits.Com, Inc.*, 12 NY3d 616, 623, 883 NYS2d 772 [2009]; *Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892; *Small v Lorillard Tobacco Co.*, 94 NY2d 43, 698 NYS2d 615). A plaintiff need not quantify the amount of harm to the public at large or specify consumers who suffered

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pecuniary loss due to the defendant's alleged deceptive conduct (*see North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96). While courts have rejected General Business Law § 349 actions predicated on derivative claims that "arise[] solely as a result of injuries sustained by another party" (*Blue Cross & Blue Shield of N.J., Inc. v Phillip Morris USA Inc.*, 3 NY3d 200, 206, 785 NYS2d 399; *see City of New York v Smokers-Spirits.Com, Inc.*, 12 NY3d 616, 883 NYS2d 772), they have repeatedly held that a cause of action under the statute has been adequately stated where the plaintiff has alleged that it suffered direct loss of its own as a result of a defendant's deceptive or misleading conduct (*see M.V.B. Collision, Inc. v Allstate Ins. Co.*, 728 F Supp 2d 205, 217-218 [ED NY 2010]; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96; *In re Pharm. Indus. Average Wholesale Price Lithog.*, 2007 WL 1051642 [D Mass 2007]). General Business Law § 349 claim by New York City and a number of New York State counties alleging that drug manufacturers deceptively raised their prices on consumers was found to not be derivative in nature where the court found that the plaintiffs, which had an independent duty to pay for medicaid reimbursement costs, were directly harmed in having to overpay for such prescriptions]).

Here, a review of the complaint reveals that plaintiffs pleaded specific conduct by Insys sufficient to meet all of the elements required to state a cognizable claim under section 349 of the General Business Law (*see Karlin v IVF Am.*, 93 NY2d 282, 293, 690 NYS2d 495; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96; *Wilner v Allstate Ins. Co.*, 71 AD3d 155, 893 NYS2d 208 [2d Dept 2010]; *In re Pharm. Indus. Average Wholesale Price Lithog.*, 2007 WL 1051642; *compare Small v Lorillard Tobacco Co.*, *supra*; *Baron v Pfizer, Inc.*, 94 NY2d 43, 698 NYS2d 615). Significantly, the plaintiffs allege that despite the limited approval by the Food and Drug Administration ("FDA") for the sale of Subsist, a fentanyl sublingual spray, only to treat opioid tolerant cancer patients experiencing breakthrough pain, Insys conducted an extensive and sophisticated public marketing scheme meant to exploit a loophole in the FDA guidelines which permitted physicians to make numerous "off-label" prescription of the drug to treat chronic pain in patients who had neither developed a tolerance to opioid pain killers or who had experienced the same grade of pain as end-stage cancer patients. According to the complaint, Insys' marketing scheme aimed to change the institutional and public perception of the risk-benefit assessment of the utilization of its drug for the treatment of non-cancer related chronic pain and, by doing so, enabling it to market an addictive drug to residents of the counties for uses, and in volumes, that precipitated the opioid epidemic. The complaint describes in detail how Insys engaged in acts and practices which were either directed at the consuming public or had a broad impact on consumers at large, and how such practices were harmful to the overall public interest. In particular, the plaintiffs allege that Insys formed an entity known as the Insys Reimbursement Center ("IRC"), which served as a liaison between the members of the public, their doctors, their insurers, and prescriptions managers, for the purpose of maximizing the volume of Subsist dispensations. According to the complaint, employees of the IRC would do whatever it took, including misrepresenting medical conditions and impersonating patients and doctors, to obviate the practice of prior authorization, whereby insurers or their pharmacy benefit managers assessed the appropriateness of the prescription before authorizing the dispensation of powerful drugs like Subsist.

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In addition, the plaintiffs allege that Insys published “education articles” to the public which falsely praised Subsist as non-addictive, and funded public patient advocacy groups which unwittingly promoted the manufacturer’s agenda of raising the overall profile of pain to justify the use of powerful opioids like Subsist to treat chronic pain. The plaintiffs allege that Insys simultaneously created a scam “legal speakers program” meant to disseminate information convincing a broad range of physicians – other than oncologists – about the benefits of making off-label Subsist prescriptions to non-cancer patients, and lauding the drug’s nonaddictive nature. It is alleged that the speakers program not only sought to leverage the scientific reputation of Insys to the physicians in order to persuade them to make off-label prescriptions, but that the manufacturer, who paid doctors attendance fees, routinely forged attendance sheets and paid bribes to top prescribers. In this way, Insys allegedly deceived consumers, and the doctors to whom they looked for confirmation, into accepting as a new norm the practice of using Subsist as a legitimate option for treating comparatively low-grade chronic pain. Further explaining the deliberate and serious nature of Insys’ deceptive marketing scheme, the plaintiffs allege that the manufacturer complimented its external acts and practices with internal strategic maneuvers, such as building an infrastructure to train and assist employees in obtaining prior authorization on behalf of the public and establishing an internal 1-800 reimbursement assistance hotline for those who failed to procure prior authorization.

Moreover, a review of the allegations contained in the complaint reveals the plaintiffs’ description of the very type of materially misleading conduct aimed at the public General Business Law § 349 was meant to proscribe; the plaintiffs allege a scheme of practices and conduct meant to undermine the ability of members of the public “to evaluate [their] market options and to make a free and intelligent choice” regarding the use of a powerful and addictive drug (*North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 13, 953 NYS2d 96). Insys allegedly accomplished this erosion of free and intelligent choice through a series of misrepresentations and omissions meant not only to change ordinary consumer “perception of the risk-benefit assessment” of using Subsist to treat chronic pain, but by facilitating the dispensation of a drug – known to be up to 50 times stronger and more addictive than heroine – that would likely alter the decision-making apparatus of members of the public who became addicted to opioids. And by discussing an internal compliance review conducted by Insys, the allegations in the complaint reveals the manufacturer’s knowledge of the potential legal problems with the content of IRC employees’ communications with the public and health care professionals regarding prior authorizations for Subsist. Despite such knowledge, the plaintiffs allege that the IRC staff continued to flout Insys’ own internal compliance guidelines so much so that within a year of the compliance review, an IRC employee allegedly misled a pharmacy benefit manager about his or her affiliation to Insys and the diagnosis of a patient requesting dispensation of Subsist.

The allegations contained in the complaint also include numerous examples of direct pecuniary harm sustained by the plaintiff counties. The plaintiffs allege that, as mandated payors of a portion of the state’s medicaid expenses, the counties suffered direct financial loss as a result of the explosion of long term and emergency care costs which accompanied the burgeoning opioid epidemic. The complaint also identifies other forms of direct pecuniary harm incurred by the counties that correlate with the growth of the opioid epidemic. The complaint lists, among others, direct financial losses the counties allegedly

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incurred in having to increase their expenditures on social services, drug addiction treatment and diversion programs, additional policing and criminal justice costs, as well as expenditures associated with the purchase of Narcan and the implementation of programs to train the public and public personnel in its use. In addition, the allegations in the complaint delineates how the plaintiff counties, which provide both full and partial medical insurance and workers' compensation insurance coverage to their employees, suffered direct harm when they were made to pay the cost of excessive claims for Subsisit or other opioid prescriptions made by their employees, who were either deceived or addicted, to the powerful drugs. Affording the plaintiffs the benefit of every possible inference, as the court is required to do when determining a motion to dismiss, the court finds neither of the aforementioned alleged categories of pecuniary harm to be derivative in nature, as such harm was directly incurred by the counties because they bore independent duties, whether as municipalities constitutionally and statutorily mandated to protect the welfare, safety, and public health of their citizens or as self-funded health and workers' compensation insurance providers, to make the expenditures necessary to meet such obligations (*see M.V.B. Collision, Inc. v Allstate Ins. Co.*, 728 F Supp 2d 205; *In re Pharm. Indus. Average Wholesale Price Lithog.*, 2007 WL 1051642; *compare Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399; *Small v Lorillard Tobacco Co.*, 94 NY2d 43, 698 NYS2d 615). Furthermore, unlike insurers or third-party payors who may seek to recover indirect losses via the equitable remedy of subrogation, the plaintiff counties have no other means of seeking compensation for the pecuniary harms they allegedly suffered as a result of Insys' conduct (*compare Blue Cross & Blue Shield of N.J., Inc. v Phillip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399).

Finally, the court rejects Insys' arguments that the plaintiff counties will be unable to show causation in connection with their General Business Law § 349 claim because Subsisit accounted for approximately .01% of opioids prescribed in New York in the last 10 years, and less than approximately .03% of opioids prescribed in the State since the beginning of 2012. Insys' assertion is erroneous. Causation, in the context of a General Business Law §349 action, merely refers to the link between an alleged deceptive practice and the actual injury sustained by a plaintiff (*see Stutman v Chemical Bank*, 95 NY2d 24, 30, 709 NYS2d 892). Thus, the plaintiffs will be deemed to have adequately pleaded causation where, as here, they have alleged a causal connection between a defendant's deceptive conduct and the actual harm they suffered as a result of such conduct (*see Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892). Indeed, a defendant's harmful conduct need not be repetitive or recurring to come within the purview of the statute (*see North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 14, 953 NYS2d 96). With regards to Insys' assertion that the complaint lacks specificity as to the number of prescriptions made in the counties or whether Subsisit caused harm to any individual or the counties themselves, as noted above, the strict pleading requirements imposed by CPLR 3016 are inapplicable to a cause of action predicated on the violation of General Business Law § 349 (*see Joannou v Blue Ridge Ins. Co.*, 289 AD2d 531, 735 NYS2d 786; *McGill v General Motors Corp.*, 231 AD2d 449, 647 NYS2d 209). Rather, the pleading requirements will be met where, as in this case, they have set forth the material elements of the cause of action and given the court and the parties involved notice of the series of transactions or occurrences intended to be proved (*see CPLR 3013; East Hampton Union Free School Dist. v Sandpebble Bldrs., Inc.*, 66 AD3d 122, 884 NYS2d 94). Furthermore, the court need not address the parties' relative arguments concerning conspiracy or the proposed use of the

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“market share theory” to determine the quantum of Insys’ liability, as such a discussion is inapposite as to whether the plaintiff counties have met their pleading requirements (*see EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d 11, 799 NYS2d 170; *Rovello v Orofino Realty Co.*, 40 NY2d 633, 389 NYS2d 314) and is not authorised in the context of a CPLR 3211 (a) (7) motion to dismiss the complaint (*see Salles v Chase Manhattan Bank*, 300 AD2d 226, 754 NYS2d 236; *E & D Group, LLC v Violet*, 134 AD3d 981, 21 NYS3d 691).

Accordingly, the motion by defendant Insys Therapeutics, Inc. for an order pursuant to CPLR 3211, dismissing the complaint against it is denied.

Dated: _____

June 18, 2018

Jerry Garguilo
J.S.C.
HON. JERRY GARGUILO

EXHIBIT 10

**THE STATE OF NEW HAMPSHIRE
SUPERIOR COURT**

MERRIMACK, SS.

No. 217-2017-CV-00402

State of New Hampshire

v.

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

ORDER

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 user's 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

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.

Cerveney 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); Cerveney 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).

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 manufacturer 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."

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 Purdue's 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 all 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 be* 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.)

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 prescribers,” (*id.*), because Purdue “knows that in-person marketing works,”

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.

(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.").)

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.)

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.

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

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.

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.)

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

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.”

of his products" and, in the prescription drug context, "provides that a drug manufacturer's 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.").

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 doctrine⁷ 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 whatsoever. 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 Mktg. & Sales Practices Litig., 712 F.3d 21 (1st Cir. 2013).⁸ Like Purdue, that

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

drug manufacturer “argue[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.

articles in medical journals that reported positive information about [the drug’s] off-label effectiveness.” Id. at 28.

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

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, the 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. Tobacco 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)).

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

detering 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. Ill. 2016).

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.)

Some of these alleged injuries are less 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

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

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

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. New 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 plaintiff's 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).

an individual who received such drugs at the State's expense would herself recover damages based on the costs of their administration.

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.

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).

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,

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.

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.

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. Litig., 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. Nargol 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 § 821B(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.”).

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)).

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.

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.

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.

Date

9/18/18


John C. Kissinger, Jr.
Presiding Justice