In Re Opioid Litig.
2020 NY Slip Op 34370(U)
February 3, 2020
Supreme Court, Suffolk County
Docket Number: 400000/2017
Judge: Jerry Garguilo

SHORT FORM ORDER **E-FILE** INDEX No. 400000/2017

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

PRESENT:

Hon. JERRY GARGUILO
Justice of the Supreme Court

	:	MOTION DATE 9/4/19 (#066, #068)
	:	MOTION DATE 9/10/19 (#070)
	:	ADJ. DATE 10/9/19
IN RE OPIOID LITIGATION	:	Mot. Seq. #066 - MD
	:	Mot. Seq. #068 - MotD
	:	Mot. Seq. #070 - MD
	:	
People of the State of New York v. Purdue Pharma L.P.	:	INDEX No. 400016/2018

Upon the reading and filing of the following papers in this matter: (1) Notice of Motion by defendants Cephalon Inc., Teva Pharmaceuticals USA Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (Mot. Seq. #066), dated May 31, 2019, and supporting papers (including Memorandum of Law); (2) Notice of Motion by defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Frederick Company Inc., P.F. Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Cephalon Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Mallinckrodt LLC, and SpecGx LLC (Mot. Seq. #068), dated May 31, 2019, and supporting papers (including Memorandum of Law); (3) Notice of Motion by defendant Mallinckrodt plc (Mot. Seq. #070), dated June 10, 2019, and supporting papers; (4) Memorandum of Law in Opposition by the plaintiff (Mot. Seq. #066), dated July 31, 2019; (5) Affirmation in Opposition by the plaintiff (Mot. Seq. #068), dated July 31, 2019, and supporting papers (including Memorandum of Law); (6) Reply Memorandum of Law by defendants Cephalon Inc., Teva Pharmaceuticals USA Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (Mot. Seq. #066), dated August 30, 2019, and supporting papers; (7) Reply Memorandum of Law by defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Frederick Company Inc., P.F. Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Cephalon Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Mallinckrodt LLC, and SpecGx LLC (Mot. Seq. #068), dated August 30, 2019; and (8) Notice of Supplemental Authority by the plaintiff (Mot. Seq. #068), dated September 6, 2019, and supporting papers; it is

ORDERED that these motions are hereby consolidated for purposes of this determination; and it is further

ORDERED that the motion by defendants Cephalon Inc., Teva Pharmaceuticals USA Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. for an order dismissing the complaint against them pursuant to CPLR 3211 (a) (1), (5), and (7), is denied; and it is further

ORDERED that the motion by defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., The P.F. Laboratories, Inc., Teva Pharmaceuticals USA Inc., Cephalon Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Mallinckrodt LLC, and SpecGx LLC for an order dismissing the complaint against them pursuant to CPLR 3211 (a) (7), is granted to the extent of dismissing the second, third, fourth, and seventeenth causes of action against defendants Teva Pharmaceuticals USA Inc., Cephalon Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Mallinckrodt LLC, and SpecGx LLC, and is otherwise denied; and it is further

ORDERED that the motion by defendant Mallinckrodt plc for an order dismissing the complaint against it pursuant to CPLR 3211 (a) (7), is denied.

The plaintiff, through its attorney general, brings this action on behalf of New York State and its residents to recover damages and abate the harms arising from the creation and perpetuation of an opioid crisis within its borders. The defendants are the opioid manufacturers and distributors alleged to have fueled the crisis. Among the defendants named in the complaint are Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., The P.F. Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Cephalon Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Mallinckrodt LLC, SpecGx LLC, and Mallinckrodt (hereinafter collectively referred to as the manufacturer defendants). The plaintiff generally alleges that the manufacturer defendants collaborated to falsely deny the serious risks of opioid addiction generally, and high-dose opioid prescriptions specifically; that they falsely claimed that their opioid drugs could be counted on to improve function and quality of life for patients with chronic pain; that they also claimed that opioid dependence and withdrawal could be easily managed and effectively prevented; and that they spent millions of dollars over a period of years to push these fraudulent messages, by targeting susceptible doctors, flooding medical publications with deceptive advertisements, sponsoring misleading seminars, and forming seemingly independent organizations that they funded and disguised as unbiased sources of cutting-edge medical research and information.

In its complaint, the plaintiff alleges 17 causes of action, each of which is pleaded against some or all of the manufacturer defendants. The first through fourteenth are alleged against all of the manufacturer defendants, the fifteenth and sixteenth are alleged only against Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and The P.F. Laboratories, Inc., and the

seventeenth is alleged against all of them except for Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica Inc. The plaintiff has since voluntarily discontinued its ninth, eleventh, twelfth, thirteenth, and fourteenth causes of action against each of the manufacturer defendants except for Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and The P.F. Laboratories, Inc. (NYSCEF Doc. No. 1956). The first cause of action alleges common-law public nuisance. The second, third, and fourth causes of action allege violations of the New York False Claims Act (NYFCA), State Finance Law article 13; the second alleges a violation of State Finance Law § 189 (1) (a), the third alleges a violation of State Finance Law § 189 (1) (b), and the fourth alleges a violation of State Finance Law § 189 (1) (c). The fifth cause of action asserts a claim for violation of Social Service Law § 145-b. The sixth cause of action alleges deceptive business practices in violation of General Business Law § 349, and the seventh cause of action alleges false advertising in violation of General Business Law § 350. The eighth cause of action alleges violation of the New York Controlled Substance Act (NYCSA), Public Health Law article 33. The tenth cause of action alleges illegality in violation of Executive Law § 63 (12). The fifteenth cause of action alleges intentionally fraudulent conveyances in violation of Debtor and Creditor Law § 276, and the sixteenth cause of action alleges constructively fraudulent conveyances in violation of Debtor and Creditor Law §§ 273, 273-a, 274, and 275. Finally, the seventeenth cause of action seeks a judgment declaring that each license obtained by each defendant under the NYCSA to manufacture, distribute, import and/or export controlled substances within, into and/or from the state "was *void ab initio* on the ground it was procured under false pretenses through false and/or misleading statements and/or omissions contained in each such Defendant's applications to engage in controlled substances activity."

The manufacturer defendants now move, pre-answer, for an order dismissing the complaint pursuant to CPLR 3211 (a) (1), (5), and (7).

Preliminarily, the court notes that several of the manufacturer defendants—Cephalon Inc., Teva Pharmaceuticals USA Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.—are seeking CPLR 3211 relief in two of the pending motions. While subdivision (e) of CPLR 3211 permits a defendant to make only one motion under subdivision (a) (*see* ***Ramos v City of New York***, 51 AD3d 753, 858 NYS2d 702 [2d Dept 2008]), the court will, with respect to the motions filed under sequence numbers 066 and 068, waive compliance with the single-motion rule and consider them to have been jointly made. The court, however, cannot extend such consideration to the motion filed under sequence number 070. By order dated December 2, 2019, the court granted a prior motion by Mallinckrodt plc to dismiss the complaint against it for lack of personal jurisdiction, on condition that it file both a certificate of authentication and a certificate of conformity with respect to the supporting affidavit of Alasdair J. Fenlon within 30 days (NYSCEF Doc No. 2072). Mallinckrodt plc did not comply with the condition; consequently, the court now considers its prior motion to have been abandoned. Since Mallinckrodt plc's prior motion to dismiss was decided on the merits (*see* ***Rivera v Board of Educ. of the City of N.Y.***, 82 AD3d 614, 919 NYS2d 154 [1st Dept 2011]), its current motion violates the single-motion rule and, therefore, is denied (*see* ***McLearn v Cowen & Co.***, 60 NY2d 686, 468 NYS2d 461 [1983]).

The court also notes that after the pending motions were submitted for decision, a preliminary injunction was filed in the United States Bankruptcy Court for the Southern District of New York, as a

result of which the plaintiff's case against Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and The P.F. Laboratories, Inc. was effectively stayed through at least April 8, 2020. The court finds it appropriate, therefore, to deny the motion filed under sequence number 068 to the extent it was made on behalf of those defendants, without prejudice to timely renewal upon expiration of the stay.

Turning to the substantive issues raised, the manufacturer defendants initially contend that the plaintiff's false marketing claims against generic manufacturers Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively referred to as Actavis) are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), which was promulgated by Congress to regulate pharmaceutical drugs (*see* ***Wyeth v Levine***, 555 US 555, 129 S Ct 1187 [2009]; ***Pharmaceutical Mfrs. Assn. v Whalen***, 54 NY2d 486, 446 NYS2d 217 [1981]). Under the doctrine of conflict preemption, federal law reigns supreme, and a state law that conflicts with federal law must yield thereto (***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], *cert denied* 562 US 948, 131 S Ct 215 [2010]). Included in the conflict preemption doctrine is impossibility preemption, which dictates that where a private party cannot comply with both a state law and a federal law, the state law shall be preempted (***Doomes v Best Tr. Corp.***, 17 NY3d 594, 603, 935 NYS2d 268, 273 [2011]; *see generally* ***Matter of People v Applied Card Sys., Inc.***, 11 NY3d 105, 863 NYS2d 615 [2008], *cert denied sub nom.* ***Cross Country Bank, Inc. v New York***, 555 US 1136, 129 S Ct 999 [2009]).

In support of their motion, the manufacturer defendants make arguments similar to the arguments made in the related actions filed by the municipal plaintiffs. They argue that the plaintiff's claims against Actavis for misrepresentation and false marketing are based upon an alleged failure to "disclose the risks of opioids or to correct any false marketing statements by others" (NYSCEF Doc. No. 1115 at 6), and inasmuch as the plaintiff is effectively seeking to force them to make statements that are contrary to the rules expressed by the Food and Drug Administration (FDA) concerning opioids, those claims are preempted and must be dismissed.

As the court has stated in a prior order dated June 21, 2019 (NYSCEF Doc. No. 1197 at 7-9), it is not impossible for a generic drug manufacturer to adhere to both state law and the federal law when promoting and advertising its generic drugs. By way of background, the FDA's process for approving a generic drug is different from that for approving the brand-name version of the drug (*see* ***Morris v Wyeth, Inc.***, 582 F Supp 2d 861 [WD Ky 2008]). The FDCA mandates that any manufacturer seeking to market a new drug must submit a New Drug Application (NDA) to the agency for review (*see* 21 USC § 355 [i]; ***Premo Pharm. Labs., Inc. v United States***, 629 F2d 795 [2d Cir 1980]). The NDA requires that extensive investigations and clinical trials be conducted before the application is submitted, and the manufacturer must demonstrate that the drug is safe and effective (***Merck KGaA v Integra Lifesciences I, Ltd.***, 545 US 193, 196, 125 S Ct 2372, 2377 [2005]; ***Mitchell v Wyeth Pharms., Inc.***, 2017 WL 7361751, *3, 2017 US Dist LEXIS 73276, *7 [WD Tex, Jan. 19, 2017], *report and recommendation adopted* 2017 WL 7361750, 2017 US Dist LEXIS 73277 [WD Tex, Feb. 9, 2017]). By contrast, a manufacturer seeking to market a generic verison of a brand-name drug must submit an Abbreviated New Drug Application (ANDA) to the FDA (***Premo Pharm. Labs., Inc. v United States***, 629 F2d 795, 798). The agency's review process is expedited, and the manufacturer must demonstrate that the brand-

name drug upon which it bases its new generic product has been approved by the FDA. The generic drug must have the same active ingredients as the brand-name drug, and the manufacturer "must supply information to show that the labeling proposed for the [generic] drug is the same as the labeling approved for the listed drug" (***Morris v Wyeth, Inc.***, 582 F Supp 2d 861, 865). Essentially, the labeling of the generic drug must be the same as the labeling of its brand-name counterpart at all times (***PLIVA, Inc. v Mensing***, 564 US 604, 613, 131 S Ct 2567, 2574 [2011]).

Two Supreme Court decisions serve as a guide to courts when analyzing preemption in this context. In ***PLIVA, Inc. v Mensing*** (*id.*), the plaintiffs alleged that drug manufacturers were liable for their injuries under state tort law for failing to provide adequate warning labels on their generic drug. They further alleged that at the time that they were prescribed the drug, the generic manufacturers had evidence to show that long-term use of the drug could cause a condition called tartive dyskinesia, and that the generic manufacturers failed to include a warning on the label in violation of state law imposing a duty upon the manufacturers to be aware of its product's danger and to label that product in a way that rendered it reasonably safe. The *Mensing* Court found that under the circumstances, the state tort laws required the manufacturers to "attach a safer label to their generic drug, while Federal law demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels" (*id.* at 618, 131 S Ct at 2578); thus, the Court held that the state tort law was preempted (*id.*).

Similarly, in ***Mutual Pharm. Co., Inc. v Bartlett*** (570 US 472, 133 S Ct 2466 [2013]), the state law imposed a duty on manufacturers to ensure that the drugs that they marketed were not unreasonably unsafe, effectively requiring a drug manufacturer to change a certain drug label to provide stronger warnings. The plaintiff in that case developed toxic epidermal necrolysis as a result of taking a generic form of Sulindac, a nonsteroidal anti-inflammatory drug. The *Bartlett* Court found that the plaintiff's claim was essentially a failure-to-warn claim, and held that inasmuch as it had previously determined in *Mensing* that federal law prohibited generic drug manufacturers from independently changing their drugs' labels, a state law that imposed a duty on a manufacturer to alter or update its label, without there first being a change by the brand-name manufacturer, was preempted (*id.*).

In both *Mensing* and *Bartlett*, the plaintiffs' claims centered upon the defendants' failure to provide adequate warnings with regard to their generic drugs. In both cases, the plaintiffs would have required that the generic drug manufacturers independently alter their drug labeling, or communicate information to doctors and patients about the drugs that was not in the labeling of the brand-name drug. Here, the manufacturer defendants contend that the duty of sameness under the federal law prohibits Actavis from altering the promotional and advertising material or labeling of its generic opioids if such promotional and advertising material are not first changed or updated by the brand-name manufacturer of the drug.

The manufacturer defendants misconstrue the relevant allegations. The plaintiff does not allege that their opioids contain a design defect, nor does it allege that they failed to adequately warn users of the drug about the risks of consuming the drug. Rather, the plaintiff seeks to hold the manufacturer defendants, including Actavis, liable for fraudulently promoting and marketing their opioid medications within the state. Throughout its complaint, the plaintiff alleges that the manufacturer defendants failed to fulfill their duty under New York law not to deceive residents while conducting their business

activities (*see* ***Cipollone v Liggett Group, Inc.***, 505 US 504, 112 S Ct 2608 [1992]; ***In re Ford Fusion & C-Max Fuel Economy Litig.***, 2015 WL 7018369, 2015 US Dist LEXIS 155383 [SD NY, Nov. 12, 2015]). The plaintiff alleges that the promotional practices employed by the manufacturer defendants misled doctors and patients, in that the defendants made statements about their drugs and promoted their products in a manner that was inconsistent with their labeling. The plaintiff further alleges that the manufacturer defendants generally promoted scientific studies in a deceptive manner; that they omitted or downplayed the risks and adverse effects of opioid use in their presentations about the drugs; that they misused treatment guidelines; that they suppressed negative information about the effects of opioids; and that they used unbranded and unregulated advertising and marketing to present information to medical professionals and consumers regarding opioids that they knew to be false and misleading. Taking the plaintiff's allegations as true, the court cannot conclude that their claims are "in essence failure to warn claims" as the defendants suggest (*see* ***Arters v Sandoz Inc.***, 921 F Supp 2d 813 [SD Ohio 2013]).

Accordingly, the court finds the allegations in the complaint that Actavis's marketing and promotion practices contravened state law are not preempted by federal law (*see* ***In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings***, 2016 WL 861213, 2016 US Dist LEXIS 28920 [ND Ill, Mar. 7, 2016]; ***Rusk v Wyeth-Ayerherst Labs., Inc.***, 2015 WL 3651434, 2015 US Dist LEXIS 75557 [WD Tex, June 11, 2015], *report and recommendation adopted sub nom.* ***Rusk v Wyeth-Ayerst Labs., Inc.***, 2015 WL 11050913, 2015 US Dist LEXIS 179113 [WD Tex, Oct. 26, 2015]; *see generally* ***Elmore v Gorsky***, 2012 WL 6569760, 2012 US Dist LEXIS 177793 [SD Tex, Dec. 17, 2012]). As to the argument that the plaintiff has failed to identify in the complaint any marketing statements made by Actavis about the efficacy or safety of its generic opioid products, the court notes the statements in the complaint that Actavis promoted its products through direct mail and email campaigns, as well as through the activities of its distributors, including the creation of an incentive program to maximize sales. That Actavis now denies having engaged in any marketing of its products, false or otherwise, does not constitute evidence convincingly refuting the material facts alleged in the complaint (*see* ***Lubonty v U.S. Bank N.A.***, 159 AD3d 962, 74 NYS3d 279 [2d Dept 2018], *affd* 2019 WL 6255790, 2019 NY LEXIS 3250 [Nov. 25, 2019]).

The branches of the manufacturer defendants' motions which seek dismissal of the second, third, and fourth causes of action against them are granted. These causes of action, alleging violations of the NYFCA, are predicated on the theory that the manufacturer defendants' false marketing campaigns caused the plaintiff to have increased expenditures due to "false claims for opioid prescriptions" and to "claims for medications and services to treat physical and behavioral health conditions that accompany opioid abuse disorder." The plaintiff broadly asserts that the manufacturer defendants' false representations regarding the risks and benefits of prescription opioids "induced" third-party health care providers treating patients insured under Medicaid, the New York State Health Insurance Program, and the New York State Insurance Fund to write prescriptions that were "medically unnecessary," thereby rendering false "a substantial number" of claims for reimbursement submitted to such programs by healthcare providers. More particularly, it alleges that the Medicaid program "reimbursed claims for opioid prescriptions that were not medically necessary," including claims for certain noncancer patients identified as Patients D through L, who received from certain physicians prescriptions that were "excessive, long-term doses of opioids for noncancer patients." The plaintiff asserts that the manufacturer defendants' misrepresentations about such drugs "rendered prescribers unable to assess the

risks and benefits of opioids," which thereby "necessarily rendered false those prescribers' certifications that [the] opioid prescriptions were medically necessary." The plaintiff further alleges that the manufacturer defendants made false statements to the plaintiff concerning their compliance with the NYCSA and eligibility for licenses to conduct activity involving controlled substances, and that such false statements "rendered each relevant HCP's express or/or implied certification that the supplies being paid for were supplied in compliance with applicable law." The court notes that while the complaint states that the abbreviation "HCPs" refers to "doctors and other health care providers authorized to write prescriptions," and refers to third parties who supply prescription drugs to patients as "licensed dispensaries" or pharmacies, it also uses the terms "third-party health care providers" and "HCPs" to refer to third parties who present claims to state payors for "reimbursement of opioid drugs prescribed to patients."

The NYFCA, which follows the federal False Claims Act (31 USC § 3729 *et seq.*) was enacted in 2007 as a part of a federal incentive to limit Medicaid fraud. As relevant to this action, liability is incurred under the NYFCA where a person or entity (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or (c) conspires to commit a violation of paragraph (a), (b), (d), (e), (f), or (g) of the act (State Finance Law § 189 [a], [b], and [c]). Because the NYFCA mirrors the federal statute in many respects, "it is appropriate to look toward federal law when interpreting the New York act" (***State of New York ex rel. Seiden v Utica First Ins. Co.***, 96 AD3d 67, 71, 943 NYS2d 36, 39 [1st Dept], *lv denied* 19 NY3d 810, 951 NYS2d 468 [2012]).

Pursuant to the NYFCA, a "false claim" is defined as "any claim which is, either in whole or part, false or fraudulent" (State Finance Law § 188 [2]). The statute defines "claim," in part, as

> any request or demand, whether under contract or otherwise, for money or property that (i) is presented to an officer, employee or agent of the state or local government, or (ii) is made to a contractor, grantor or other recipient, if the money or property is to be spent or used on the state or local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded, or (B) will reimburse such contractor, grantee or other recipient for any portion of the money or property which is requested or demanded.

(State Finance Law § 188 [1] [a]). Thus, a "claim" includes both a direct request to the government for payment and a request for reimbursement made to the recipient of government funds under government benefits programs, such as requests to be reimbursed for health care expenses submitted to Medicare and Medicaid (*see* ***Universal Health Servs., Inc. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989 [2016]).

Proof of intent to defraud is not required to establish a violation of the NYFCA; rather, the government, or the relator in a *qui tam* action asserting a NYFCA claim on behalf of the government, must show that the person or entity knowingly made a false statement or knowingly filed a false record when submitting a claim for payment from the government for goods or services (*see* ***People v Sprint***

Nextel Corp., 26 NY3d 98, 21 NYS3d 158 [2015], *cert denied sub nom.* ***Sprint Nextel Corp. v New York***, ___ US ___, 136 S Ct 2387 [2016]; *see also* ***United States ex rel. Raffington v Bon Secours Health Sys., Inc.***, 405 F Supp 3d 549 [SD NY 2019]; ***United States ex rel. Fox RX, Inc. v Omnicare, Inc.***, 38 F Supp 3d 398 [SD NY 2014]). Briefly stated, a violation occurs when a person or entity "knowingly asks the government to pay amounts it does not owe" (***United States ex rel. Quinn v Omnicare Inc.***, 382 F3d 432, 438 [3d Cir 2004]), and liability extends to claims "rendered false by one party, but submitted to the government by another" (***United States ex rel. Feldman v City of New York***, 808 F Supp 2d 641, 650 [SD NY 2011]; *see* ***United States v Bornstein***, 423 US 303, 96 S Ct 523 [1976]). A defendant acts "knowingly" if it "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard to the truth or falsity of the information" (State Finance Law § 188 [3]). Thus, to establish a claim under section 189 (1) (a), a plaintiff must show that there was a false or fraudulent claim for payment, and that the defendant presented, or caused to be presented, the claim to the government knowing it was false or fraudulent (***State of New York v MedImmune, Inc.***, 342 F Supp 3d 544, 551 [SD NY 2018]). For a claim under section 189 (1) (b), a plaintiff must demonstrate that both a false record or statement and a corresponding false claim for payment were submitted to the government (*id.*; ***United States ex rel. Kester v Novartis Pharms. Corp.***, 23 F Supp 3d 242, 252 [SD NY 2014]).

The courts have recognized two types of claims actionable under the federal statute: legally false claims and factually false claims. A legally false claim occurs when the person or entity submitting the claim certifies compliance with a statute, regulation, or contractual term that is a condition of payment with knowledge that there was no compliance with such statute or regulation (***United States ex rel. Conner v Salina Regional Health Ctr., Inc.***, 543 F3d 1211, 1217 [10th Cir 2008]). Legally false claims are further distinguished as based either on the express false certification theory or on the implied false certification theory. The express false certification theory holds that a false claim occurs when a person or entity expressly certifies compliance with an applicable rule or regulation required for payment of government funds when not actually in compliance (***United States ex rel. Wilkins v United Health Group, Inc.***, 659 F3d 295, 305 [2d Cir 2011]; ***Mikes v Straus***, 274 F3d 687, 698 [2d Cir 2001], *abrogated on other grounds by* ***Universal Health Servs. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989). According to the implied false certification theory, a person or entity that submits a claim for payment which makes specific representations about providing goods or services, but knowingly fails to disclose the claimant's noncompliance with a material statutory, regulatory or contractual requirement, may be liable (*id.* at 2001; *see* ***United States ex rel. Conner v Salina Regional Health Ctr., Inc.***, 543 F3d 1211). The latter theory is premised on the idea that when a person or entity submits a claim for payment to the government, such person or entity is considered to have impliedly certified compliance with all of the material conditions for the requested payment (*id.* at 1995; ***Mikes v Straus***, 274 F3d 687, 699; ***State of New York ex rel. Khurana v Spherion Corp.***, 2017 WL 1437204, 2017 US Dist LEXIS 61158 [SD NY, Apr. 21, 2017]). Significantly, to be liable under the implied false certification theory for making a fraudulent claim, the defendant must have "knowingly violated a requirement that the defendant knows is material" to the government's decision to pay the claim (***Universal Health Servs., Inc. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989, 1997). The ***Escobar*** decision provides the following guidance for assessing whether a misrepresentation about compliance with a statute, regulation or contract provision is material:

> [T]he Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

(*id.* at 2003-2004; *see* ***United States ex rel. Conner v Salina Regional Health Ctr., Inc.***, 543 F3d 1211; ***United States ex rel. Prather v Brookdale Senior Living Communities, Inc.***, 892 F3d 822 [6th Cir 2018], *cert denied* ___ US ___, 139 S Ct 1323 [2019]). In contrast, a claim is factually false where the person or entity submitted "an incorrect description of goods or services provided or a request for reimbursement of goods or services never provided" (***United States ex rel. Conner v Salina Regional Health Ctr., Inc.***, 543 F3d 1211, 1217, quoting ***Mikes v Straus***, 274 F3d 687, 697).

Additionally, where a claim sounds in fraud, a complaint must meet the heightened pleading standard of CPLR 3016. Under that section, when pleading a cause of action based on misrepresentation or fraud, "the circumstances constituting the wrong shall be stated in detail" (CPLR 3016; *see* ***Eurycleia Partners, LP v Seward & Kissel, LLP***, 12 NY3d 553, 883 NYS2d 147 [2009]). As the NYFCA is designed to punish and to deter fraudulent conduct (***State of N.Y. ex rel. Grupp v DHL Express [USA], LLC***, 19 NY3d 278, 286-287, 947 NYS2d 368, 374 [2012]), the pleading requirement of CPLR 3016 applies to the claims that the manufacturer defendants violated State Finance Law § 189 (*cf.* State Finance Law § 192).

The court finds that the plaintiff has failed to plead a valid cause of action against the manufacturer defendants under State Finance Law § 189 (1) (a). The court notes the plaintiff does not plead that any manufacturer defendant presented a false claim for payment to the state or an agent of the state; rather, the plaintiff alleges that the defendants caused healthcare providers to submit false claims for reimbursement for medical services rendered. According to the plaintiff, claims submitted to insurance programs by healthcare providers that "certified prescriptions and associated services were medically necessary" were legally false, because the prescribers "were unable to assess the risks and benefits of opioids" due to the manufacturer defendants' false representations about their products. The plaintiff, however, does not identify in the complaint the certifications required of physicians or other healthcare providers when submitting claims for reimbursement to the State programs at issue—particularly providers authorized to write prescriptions for opioids. Nor does it sufficiently allege how false or fraudulent conduct on the part of the manufacturer defendants rendered false any claim for reimbursement submitted by a New York healthcare provider whose treatment included prescribing opioids to a patient; instead, the plaintiff relies on a conclusory statement that physicians who prescribed opioids for their patients "were unable to adequately assess whether the risks associated with the drugs were outweighed by the benefits" (*cf.* ***United States ex rel. Piacentile v Amgen, Inc.***, 336 F Supp 3d 119 [ED NY 2018]; ***United States ex rel. Kester v Novartis Pharms. Corp.***, 23 F Supp 3d 242).

Similarly missing from the complaint are allegations that certifications by the healthcare providers were material to a state payor's decision to pay claims for reimbursement, as well as allegations that the manufacturer defendants knew both that such certifications would be made by the providers in connection with their claims and that they were material to such a decision (*see* ***Universal Health Servs., Inc. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989; ***United States ex rel. Petratos v Genentech Inc.***, 855 F3d 481 [3d Cir 2017]). Rather, the plaintiff merely states that "the false claims or false statements relating to [the claims submitted by HCPs who prescribed opioids] were material because they had a natural tendency to affect the State's evaluation of whether its core requirement that medical treatments be medically necessary . . . had been met as to each claim."

The court notes, as discussed above, that the plaintiff alleges that numerous claims were paid by the Medicaid program for "excessive, long-term dosages" of branded opioid products prescribed to certain noncancer patients, that such prescriptions were "medically unnecessary," and that the manufacturer defendants "caused" the physicians to write such prescriptions. However, the plaintiff fails to explain how those claims violated statutory, regulatory or contractual obligations governing Medicaid providers, or how the violations were material to the payor's decision to allow reimbursement, (*see* ***United States ex rel. Petratos v Genentech Inc.***, 855 F3d 481). Rather, the plaintiff merely states that its "requirement that medical treatment be medically necessary . . . necessarily includes the requirement that each prescription . . . for which reimbursement is sought be the result of untainted and independent medical judgment that adequately assesses the risks and benefits of that product . . . for that particular patient." The lack of sufficient allegations on the materiality element is highlighted by the fact that, despite years of public allegations that the manufacturer defendants made misrepresentations about their opioid drugs, the plaintiff continued to pay for such products. Liability under the False Claims statute attaches to the "knowing" filing of a materially false claim for payment, not to the underlying fraudulent activity or the government's wrongful payment (*see* ***Universal Health Servs., Inc. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989; ***United States v Rivera***, 55 F3d 703 [1st Cir 1994]).

The court also finds the third and fourth causes of action to be legally insufficient. As related to the manufacturer defendants, the plaintiff alleges in the third cause of action that "in the course of presenting each claim for reimbursement of opioid drugs prescribed to patients, HCPs made express and/or implied certifications that the opioid drug prescriptions being reimbursed were medically necessary, and that the services and drugs in question were otherwise provided in accordance with applicable State law," including the NYCSA, and that false statements or records by such defendants were "material to each claim presented by HCPs that asserted that prescriptions were medically necessary." The plaintiff further alleges that each defendant made false statements or records related to "compliance with the NYCSA that were material to each claim presented by HCPs that certified that the supplies being reimbursed had been provided in compliance with NYCSA," and that the false statements regarding eligibility for licenses rendered each claim for reimbursement by the HCPs factually false, "because drugs actually supplied to each patient" through any given chain of manufacturer defendants and distributor defendants "were illegal contraband . . . pursuant to Public Health Law § 3387, and thus not the 'genuine article' represented as the item for which reimbursement was sought." The fourth cause of action alleges that each defendant knowingly agreed, "explicitly . . . or implicitly as evidenced by the acts set forth above, that collectively they would violate State Finance Law §§ 189 (1) (a) and/or (b)," and that each defendant committed at least one overt act in furtherance of the conspiracy.

Under any of the applicable theories relating to legal and factual falsity, the court finds the allegations related to the third cause of action insufficient to state a claim for NYFCA liability. As to the express false certification theory, the plaintiff has failed to identify in the complaint any claims for payment actually submitted to the insurance programs at issue that falsely certified compliance with a statutory, regulatory or contractual requirement material to the program payor's decision to pay such claims, which relied on false records or statements of the manufacturer defendants, and that the manufacturer defendants knew such requirement was material to the reimbursement decision (***United States ex rel. Petratos v Genentech Inc.***, 855 F3d at 490; *cf.* ***United States ex rel. Groat v Boston Heart Diagnostics Corp.***, 296 F Supp 3d 166 [D DC 2017]). Notably, a plaintiff asserting a violation of the related FCA section (31 USC § 3729 [a] [1] [A]) must plead the submission of a false claim with a high enough degree of specificity that a defendant can reasonably "identify particular false claims for payment that were submitted to the government" (***United States ex rel. Kester v Novartis Pharms. Corp.***, 23 F Supp 3d 242, 258; *see also* ***United States ex rel. Ibanez v Bristol-Myers Squibb Co.***, 874 F3d 905 [6th Cir 2017], *cert denied* ___ US ___, 138 S Ct 2582 [2018]). The plaintiff's implied certification theory also is deficient, as the plaintiff does not identify any claims for payment submitted by physicians or other healthcare providers that failed to disclose the manufacturer defendants' noncompliance with statutory, regulatory or contractual obligations related to the eligibility of their opioid products for reimbursement that they knew would impact the payor's decisions on such claims (*cf.* ***Universal Health Servs. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989; ***United States ex rel. Campie v Gilead Sciences, Inc.***, 862 F3d 890 [9th Cir 2017]; ***United States ex rel. Raffington v Bon Secours Health Sys., Inc.***, 405 F Supp 3d 549). In addition, the plaintiff does not allege that compliance with a particular provision or provisions of the NYCSA was material to a state payor's decision to pay claims for reimbursement in connection with prescribing opioids, or that the manufacturer defendants knew a violation of such provision or provisions was material to any such decision (*see* ***Universal Health Servs. v United States ex rel. Escobar***, ___ US ___, 136 S Ct 1989; ***United States v Strock***, 2019 WL 4640687, 2019 US Dist LEXIS 163290 [WD NY, Sept. 24, 2019]). And as to the theory of factual falsity on which the plaintiff relies, such a claim must generally be based on an allegation that a claimant has submitted "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided" (***Mikes v Straus***, 274 F3d 687, 697); while acts in violation of Public Health Law § 3387 might render drugs subject to forfeiture, such acts are not alleged to have effected any change in the quality or quantity of the drugs actually provided. Nor, as to the fourth cause of action, has the plaintiff included any allegations in the complaint supporting the claim that the manufacturer defendants entered into an agreement to induce the payment of false claims in violation of the NYFCA (*see* ***United States ex rel. Ibanez v Bristol-Myers Squibb Co.***, 874 F3d 905; ***United States v Strock***, 2019 WL 4640687, 2019 US Dist LEXIS 163290).

As to the limited argument regarding the inadequacy of "alleged violations of the New York Controlled Substances Act" (NYSCEF Doc. No. 1115 at 14) pleaded in the complaint, it suffices to note that the allegations as to the manufacturer defendants' failure to comply with their diversion monitoring and reporting obligations under the NYCSA (*e.g.* Public Health Law § 3322 [3]; 10 NYCRR 80.22) are sufficiently particular to provide notice of the claims asserted against them and the transactions or occurrences sought to be proven (*see* CPLR 3013; ***Archer-Vail v LHV Precast Inc.***, 168 AD3d 1257, 92 NYS3d 434 [3d Dept 2019]).

The court agrees, however, with the manufacturer defendants' argument that because license revocation is a matter which has been placed solely within the purview of the commissioner of health of the state of New York, the plaintiffs' seventeenth cause of action fails as a matter of law. Section 3390 of the Public Health Law specifies the grounds on which the commissioner may seek revocation of a license to manufacture of distribute controlled substances; section 3391 authorizes the commissioner to commence an administrative proceeding to revoke a license or, alternatively, to impose a civil penalty. In seeking the entry of judgment declaring that each of the defendants' licenses was void *ab initio*, the plaintiff is essentially asking the court to do what the NYCSA authorizes only the commissioner to do, and because the power to revoke a license derives from statute, it cannot be treated expansively. Accordingly, this lawsuit is not a proper vehicle to address whether the defendants' licenses should be continued in effect, and the plaintiff is not entitled to the declaratory relief sought.

The manufacturer defendants further request that the court deny and dismiss the plaintiff's request for certain injunctive relief set forth in its prayer for relief, *i.e.*, that each defendant be enjoined, pursuant to Executive Law § 63 (12),

> a. From manufacturing, distributing, selling, or marketing opioids within the State unless it complies with heightened, independently-monitored safeguards against the recurrence of its fraudulent, illegal, and/or unlawful practices, which are to be set forth in a compliance plan reviewed and approved by Plaintiff and the Court; and
>
> b. To issue public corrective statements regarding their false and misleading public statements and omissions.

The manufacturer defendants contend that Executive Law § 63 (12) does not authorize the court to direct them to engage in affirmative conduct; they also contend that such relief is preempted to the extent it would require them to change the labeling or warnings on their medications in a way that conflicts with determinations made by the FDA, and would create an unprecedented and imprudent expansion of the court's equity powers.

The plaintiff, however, correctly notes that the substance of a prayer for relief is not a proper subject of a motion to dismiss for failure to state a cause of action. Regardless of whether the nature of the injunctive relief requested is beyond the scope of relief that can properly be awarded, a cause of action is not subject to dismissal for a mistake in the remedy chosen. "The prayer for relief is no part of the cause of action. It does not matter that the plaintiffs have asked for the wrong relief, or that they may not be entitled to all the relief they seek or to any of it or that it is inconsistent with the cause of action stated" (***Lonsdale v Speyer***, 249 App Div 133, 141, 291 NYS 495, 505 [1st Dept 1936], quoted in ***Ballioti v Walkes***, 134 AD2d 554, 521 NYS2d 453 [2d Dept 1987]; *accord* ***Planned Consumer Mktg. v Coats & Clark***, 127 AD2d 355, 513 NYS2d 417 [1st Dept 1987], *affd* 71 NY2d 442, 527 NYS2d 185 [1988]). As such, it "normally is not considered in determining . . . the sufficiency of the pleading," which is a matter to be established by the statements in the complaint (1 Weinstein, Korn & Miller CPLR Manual § 19.07 [g] [2020]).

Finally, to the extent the manufacturer defendants seek, in order to preserve for appeal, to "re-

raise" certain arguments (*see* NYSCEF Doc. No. 1123 at 25-26) initially raised on their motions to dismiss the master long form complaint filed by the municipal plaintiffs, it is noted that all of those were previously rejected by the court for the reasons stated in its June 18, 2018 order (NYSCEF Doc. No. 454) and are, in the absence of any persuasive reason to warrant reconsideration, rejected anew.

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: February 3, 2020

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