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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION
NO. 1884CV01808-BLS2

Notice sent (JRB) 9/17/19
O-MAG | S.B.A. J.L.W. J.J.L. G.F. E.M.G. J.T.W.
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COMMONWEALTH OF MASSACHUSETTS

vs.

PURDUE PHARMA L.P. & others[1]

MEMORANDUM OF DECISION AND ORDER ON THE DEFENDANT PURDUE'S MOTION TO DISMISS

The Commonwealth commenced this action against Purdue Pharma L.P. and Purdue Pharma Inc. (collectively, Purdue) seeking redress for harms that it claims were caused by Purdue's deceptive marketing and sale of its opioid products in Massachusetts. The First Amended Complaint (the Complaint) also names as defendants current and former Purdue directors, CEOs, and a vice president of sales. All defendants have moved to dismiss the claims against them pursuant to Mass. R. Civ. P. 12(b)(6). This Memorandum concerns only the Motion to Dismiss by Purdue.[2] For the following reasons, this Court concludes that it must be **DENIED**.

BACKGROUND

The Complaint is notable both in its length (274 pages) and its level of detail, including its citation to and quotations from Purdue's own internal communications. This Court only briefly summarizes those allegations, which are taken as true for purposes of this Motion.

[1] Purdue Pharma, Inc., Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Peter Boer, Paulo Costa, Cecil Pickett, Ralph Snyderman, Judith Lewent, Craig Landau, John Stewart, Mark Timney, and Russell J. Gasdia.

[2] The Court expects to issue decisions on the motions made by the individual defendants within the next few weeks.

Purdue manufactures prescription opioid medications used for the treatment of chronic pain. The Complaint largely focuses on Purdue's OxyContin, which is a tablet patients take orally, and which is sold in different dosing strengths. Butrans and Hysingla are Purdue's other opioid products.[3] Purdue's opioid formulations include "extended release" or "long acting" doses because they release the active ingredient into a person's system over time. Other opioids on the market are "immediate release" formulations. Opioids, including Purdue's products, carry several risks to the user, including physical dependence, addiction, and related withdrawal symptoms. Opioids can also cause respiratory depression, which is life-threatening.

Purdue released OxyContin in 1996. In the years thereafter, opioid-related deaths rose across the nation and in Massachusetts in particular. In 2007, after multiple state and federal investigations, a predecessor corporation and three executives pleaded guilty to illegal misbranding. An agreed statement of facts submitted in connection with that plea stated that Purdue supervisors and employees intentionally deceived doctors about OxyContin's addictive properties in the previous six years. Also in 2007, Purdue reached a consent judgment with several states, including Massachusetts (the 2007 Judgment). The 2007 Judgment prohibited Purdue from making "any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. It also required Purdue to establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, to stop promoting drugs to them, and to report them to authorities.

In the years following the 2007 Judgment, Purdue, despite its promises, did not substantively alter its deceptive and illegal marketing practices. Rather, it continued to downplay its opioids' propensities for addiction and abuse in its messaging to doctors so as to

[3] Butrans releases opioids into the body from a skin patch; the Complaint does not describe Hysingla's dosing route.

persuade them to prescribe the opioids at greater frequency, at ever-higher (and more expensive) doses, and for longer treatment durations. Purdue also influenced prescribing to inappropriate patient populations. For example, it promoted opioids for use by geriatric osteoarthritis patients, even though opioids were more dangerous for elderly individuals and studies had not shown opioids to be a more effective treatment for them. According to the Complaint, Purdue knew that its marketing tactics caused more patients to become addicted and substantially increased the likelihood that they would overdose and die. Despite this knowledge, Purdue continued to minimize the dangers associated with the use of its drugs and to make false representations regarding their safety. It did so in order to maximize its profits.

The Complaint goes into extensive detail about Purdue's marketing tactics. For example, Purdue deployed its sales staff to make frequent in-person visits to doctors' offices in Massachusetts, targeting doctors who were already suspected of overprescribing. It dispensed money, meals, or other gifts to prescribers, and paid doctors to act as spokespersons for its opioids. Purdue funded programs at Tufts University and Massachusetts General Hospital in order to influence physicians associated with those institutions. Its sales representatives dispensed savings cards, knowing that their use would encourage patients to stay on opioids longer.

The Complaint alleges that, because of Purdue's unfair and deceptive conduct, the Commonwealth has sustained substantial damage. In particular, the Commonwealth asserts that Purdue's actions significantly contributed to the opioid epidemic in Massachusetts, which has been the cause of thousands of deaths and non-fatal overdoses. Included within the thousands who have died are 671 people who filled prescriptions for Purdue opioids. Those that have survived their addictions have imposed a heavy burden on the Commonwealth: many cannot

work, and they require lengthy and expensive care and treatment, for both themselves and their dependents. The Commonwealth is seeking damages from the defendants to offset the costs of the opioid epidemic, which has been declared a public health emergency in Massachusetts.

DISCUSSION

The standard that this Court applies to the instant motion is well established. Although the complaint must contain more than "labels and conclusions," Iannacchino v. Ford Motor Co., 451 Mass. 623, 636 (2008), the ultimately inquiry is whether the plaintiff has alleged facts that are "adequately detailed so as to plausibly suggest an entitlement to relief." Greenleaf Arms Realty Trust, LLC v. New Boston Fund, Inc., 81 Mass. App. Ct. 282, 288 (2012) (reversing lower court's allowance of Rule 12(b)(6) motion). In ruling on the motion, the Court accepts the factual allegations as true and draws all reasonable inferences in the plaintiff's favor. Sisson v. Lhowe, 460 Mass. 705, 707 (2011). Its review is also confined to the four corners of the complaint, with consideration of other materials appropriate only where the complaint attaches them or where they are of the type of which this Court can take judicial notice. Schaer v. Brandeis Univ., 432 Mass. 474, 477 (2000).

Many of Purdue's arguments in support of its Motion disregard this standard. A good portion of Purdue's memoranda and a large part of its oral argument dispute the factual basis for the Commonwealth's allegations. For example, it argues that addiction is complex and multifaceted, and that the Commonwealth has itself contributed to the problem. It argues that OxyContin makes up only a small fraction of the opioids prescribed nationally and that Purdue is being unfairly scapegoated for a problem not of its making. Such arguments are better made to the fact finder at trial. They cannot be resolved under Rule 12(b)(6). Purdue also asks this Court to take into account matters beyond the four corners of the Complaint that it says contradict the

Complaint's allegations, citing to findings by the Massachusetts Department of Public Health, for example. This too ignores the standard this Court applies at this early stage of the case. The Court therefore declines to address these arguments, and turns instead to the legal arguments Purdue offers in support of the Motion.

The Complaint asserts two causes of action: violations of G. L. c. 93A (Count I) and public nuisance (Count II). In support of its Motion, Purdue argues that the Complaint fails to state a claim because its allegations conflict with federal law — namely, FDA approval of the opioids at issue. In a related vein, it contends that the challenged conduct is exempt from Chapter 93A because it is a "permitted practice." As to the nuisance claim, Purdue asserts that it fails as a matter of law because there is no allegation that Purdue has infringed on any "public right." More generally, Purdue contends that it cannot be legally liable for harms flowing from prescriptions written by doctors because the "learned intermediary" doctrine breaks the chain of causation between its conduct and the harms alleged. Similar arguments have been raised and rejected in litigation against Purdue proceeding in other states. See, e.g., Alaska v. Purdue Pharma L.P., 2018 WL 4468439 (Alaska Super. Ct. 2018); State of Arkansas v. Purdue Pharma L.P., No. 60CV-18-2018 (Ark. Cir. Ct. Apr. 5, 2019); Minnesota v. Purdue Pharma L.P., No. 27-CV-18-10788 (Minn. Dist. Ct. Jan. 4, 2019); New Hampshire v. Purdue Pharma Inc., 2018 WL 4566129 (N.H. Super Ct. 2018); Ohio v. Purdue Pharma L.P., 2018 WL 4080052 (Ohio C.P. 2018); Oklahoma v. Purdue Pharma L.P., 2017 WL 10152334 (Okl. Dist. Ct. 2017); Tennessee v. Purdue Pharma L.P., No. 1-173-18 (Tenn. Cir. Ct. Feb. 22, 2019); Vermont v. Purdue Pharma L.P., No. 757-9-18 (Ver. Super. Ct. March 19, 2019). In line with these other states, this Court concludes that Purdue's arguments do not support dismissal and offers the following by way of explanation.

1. Conflict with Federal Law

Purdue argues that the Commonwealth's claims conflict with FDA decisions approving the sale of the opioids at issue in this litigation and the labeling that accompanied them. In particular, Purdue maintains that, because the representations and conduct that the Commonwealth claims to be deceptive conform to determinations the FDA made in the exercise of its regulatory authority, then it necessarily follows that those statements are not actionable as a matter of law. Although Purdue does not use the term "preemption," that appears to be the doctrine upon which it is relying. Neither the law nor the facts as alleged in the Complaint support Purdue's position, however.

"In all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, [the court starts] 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" (alterations removed; internal quotations and citations omitted). Wyeth v. Levine, 555 U.S. 555, 565 (2009). Conflict preemption (which Purdue appears to assert) is a type of implied preemption that "occurs where compliance with both federal and state regulations is a physical impossibility, . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (internal quotations and citations omitted). Reckis v. Johnson & Johnson, 471 Mass. 272, 283 (2015). A party's contention that state law claims are preempted because it is impossible it to comply both with state and federal law has been described as a "demanding defense." Wyeth, 555 U.S. at 573. Purdue falls well short of demonstrating what the case law requires for this type of preemption to apply. In particular, there is nothing about this lawsuit which seeks to impose

restraints on Purdue that would put it at odds with the FDA, or which would make it impossible for Purdue to comply both with federal and state regulations.

This becomes particularly apparent upon a fair reading of the Complaint itself. It does not challenge the contents of the relevant opioid labels, nor does it seek to remove Purdue's opioids from the marketplace. Instead, the Complaint contains numerous allegations that Purdue's marketing activities were *inconsistent* with label warnings. For example, despite prominent warnings in the label concerning the risk of abuse and addiction, Purdue put out publications which sought to minimize those risks in a false and deceptive manner.[4] Its sales force also actively and forcefully marketed opioids for elderly arthritis patients, even though the FDA approved label clearly warned against use in that population.[5]

The Commonwealth points out that courts in other states have rejected similar arguments made by Purdue. See, e.g., Delaware v. Purdue Pharma L.P., 2019 WL 446382 (Del. Super. 2019); Grewal, Attorney General of New Jersey v. Purdue Pharma L.P., 2018 WL 4829660 (N.J. Super. Ct. 2018), and state decisions cited at page 5, supra. Those courts reasoned that there was no conflict between the state and federal law, given the allegations leveled against Purdue that it promoted use of opioids far beyond that which was consistent with the FDA-approved labeling. Purdue makes no effort to explain why the reasoning of these other courts is flawed except to direct this Court to a single decision handed down by a North Dakota court which concluded that federal law did preempt that state's claims against Purdue. See North Dakota v. Purdue Pharma

[4] One Purdue publication cited in the Complaint stated: "addiction is rare in patients who become physiologically dependent on opioids while using them for pain control." Another stated that only "a small minority of people may not be reliable or trustworthy" and therefore not suitable for opioids. A third stated that addiction "is not caused by drugs."

[5] The OxyContin label provides: "Life-threatening respiratory depression is more likely to occur in elderly . . . patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. . . . Monitor such patients closely, particularly when initiating and titrating OXYCONTIN and when OXYCONTIN is given concomitantly with other drugs that depress respiration . . . . Alternatively, consider the use of non-opioid analgesics in these patients."

L.P., Case No. 08-2018-CV-01300 (May 10, 2019), attached to Purdue's Reply Brief as Exhibit A. This holding appears to be an outlier and is of questionable value, however, particularly given a decision handed down by the United States Supreme Court that same day which clarified the showing a drug manufacturer must make on a claim of "impossibility preemption." Merck Sharp & Dohme Corp. v. Albrecht, ____U.S. ____, 139 S.Ct. 1668 (May 20, 2019).

2. Permitted Practice Under c. 93A

Purdue argues that even if federal law does not preempt the state law claims, it cannot be held liable on a c. 93A claim because the conduct that the Commonwealth challenges is actually permitted by federal law and, as such, is a "permitted practice" exempt from c. 93A liability. In support, it relies on G. L. c. 93A, §3, which expressly exempts from the reach of the statute "transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." Purdue argues that, because the FDA approved high-dose opioids, the conduct at issue here falls within that § 3 exemption. This Court disagrees, for much the same reasons that it concludes there is no federal preemption.

Section 3 precludes the assertion of a 93A claim "when a regulator authorized to review the defendant's actions has determined that those actions, in particular, were not unfair or deceptive." O'Hara v. Diageo-Guinness, USA, Inc., 306 F. Supp. 3d 441, 454 (D. Mass. 2018), and cases cited therein. A defendant who seeks protection from c. 93A liability under this section bears a "heavy" burden of proving that the exemption applies. Aspinall v. Philip Morris, Inc., 453 Mass. 431, 434 (2009). In particular, the defendant "must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction." Bierig v. Everett Sq. Plaza Assocs., 34 Mass. App. Ct. 354, 367 n.14 (1993). Rather, the defendant

must demonstrate that the regulatory scheme "affirmatively *permits* the practice which is alleged to be unfair or deceptive." Id. (italics in original).

The Complaint in the instant case does not describe conduct that has been affirmatively approved by the FDA. Instead, it describes marketing practices that minimized addiction risks, promoted misuse of the drugs, and targeted inappropriate patient populations — conduct which no state or federal regulatory authority has condoned. Citing a September 10, 2013, letter from the FDA in response to a citizen's petition, Purdue argues that the FDA rejected proposed labeling restrictions on the dose and duration for opioid use. It does not follow, however, that this action authorized Purdue to make the false claims the Complaint alleges that it did regarding addiction and abuse. In any event, the exemption enunciated in § 3 is an affirmative defense that is rarely decided on a Rule 12(b)(6) motion. Compare Fleming v. Nat'l Union Fire Ins. Co. 445 Mass. 381, 389-391 (2005).

3. Public Nuisance

Purdue attacks Count II of the Complaint both on factual and legal grounds. As already, explained, factual disputes cannot be resolved on a motion to dismiss. As to the legal basis, Purdue contends that the Complaint fails to state a claim for public nuisance because it does not allege an interference with a public right. Rather, the Commonwealth's nuisance claim is (according to Purdue), "exactly the sort of poorly disguised, repackaged products liability claim courts have rejected." Purdue cites decisions by courts in Delaware and Connecticut dismissing similar public nuisance claims against it. See Delaware, 2019 WL 446382 at *12-*13; New Haven v. Purdue Pharma, L.P., 67 Conn. L. Rptr. 644, 2019 WL 423990 (January 8, 2019). Applying Massachusetts law, this Court reaches a different conclusion.

A public nuisance, as opposed to a private nuisance, is one that "interferes with the exercise of a public right by directly encroaching on public property or by causing a common injury." Sullivan v. Chief Justice for Admin. & Mgmt. of Trial Court, 448 Mass. 15, 34 (2006), quoting Connerty v. Metropolitan Dist. Comm'n, 398 Mass. 140, 148 (1986), and citing Restatement (Second) of Torts § 821B (1979) ("A public nuisance is an unreasonable interference with a right common to the general public"). "In determining whether there has been an unreasonable interference with a public right, a court may consider, inter alia, '[w]hether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.'" Sullivan, 448 Mass. at 15, quoting Restatement (Second) of Torts § 821B. Applying these legal principles, this Court concludes that the Complaint's allegations are sufficient to support a claim that Purdue's conduct has interfered with public health and safety.

This Court also disagrees with Purdue that this is simply a repackaged product liability claim that cannot as a matter of law be brought as a public nuisance claim. In fact, Massachusetts courts have allowed public nuisance claims concerning dangerous products. See, e.g., Evans v. Lorillard Tobacco Co., 2007 WL 796175 at *18-*19 (Mass. Super. Ct. 2007) (denying motion to dismiss public nuisance action against cigarette manufacturer); Boston v. Smith & Wesson Corp., 2000 WL 1473568 at *14 (Mass. Super. 2000) (denying motion to dismiss public nuisance action against gun manufacturer). In support of its position that the claims here fall outside the traditional scope of public nuisance law, Purdue relies on Jupin v. Kask, 447 Mass. 141 (2006). In that case, however, the SJC concluded only that the storage of a lawfully obtained unloaded weapon in one's home could not support a claim for public nuisance. The allegations in the Complaint against Purdue are far different.

4. Causation

Purdue argues that the Complaint does not contain sufficient factual allegations to show causation. In opposing the Motion, the Commonwealth points out (quite correctly) that questions of causation generally should not be decided on a motion to dismiss, given their fact intensive nature. The Commonwealth also contends that, at least with respect to the c. 93A claim, it need not prove that any consumer actually was harmed. See Commonwealth v. Equifax, Inc., 35 Mass. L. Rptr. 106, 2018 WL 3013918 at *5 (Mass. Super. 2018) (the Attorney General, unlike a private litigant, need only prove that the unfair and deceptive acts took place in trade or commerce, not that they caused any quantifiable economic injury). That is because, in actions by the Attorney General under c. 93A, the court may impose civil penalties and require the defendant to pay the costs of abatement in lieu of damages. See G. L. c. 93A, §4. For purposes of this Motion, however, this Court assumes that some causation between the conduct at issue and some quantifiable harm must be established. The Court concludes that the Complaint contains sufficient allegations to meets the standard applicable to a 12(b)(6) motion.

In order to show causation, the Commonwealth must plead and prove both "cause in fact" and proximate cause. Cause in fact means injury or harm that would not have occurred but for the defendant's conduct. Proximate cause is an injury to a plaintiff that was a "foreseeable result" of the defendant's actions. Kent v. Commonwealth, 437 Mass. 312, 320 (2002). Purdue contends that this case raises several causation issues. Many of these arguments are fact-based, which this Court sees no need to discuss, given the standard applicable to a Rule 12(b)(6) motion. There is one legal issue that does merit some comment, however. Purdue argues that, because doctors prescribed the drugs alleged to have caused the harm here, they are an

intervening cause that shields Purdue from liability. This argument appears to rely in large part on the learned intermediary doctrine.

The learned intermediary doctrine is based on the proposition that a drug manufacturer's duty to warn may be discharged if the manufacturer provides the physician with an adequate warning about any risks associated with its prescription drug. Niedner v. Ortho-McNiel Pharm., Inc., 90 Mass. App. Ct. 306, 309 (2016). If an adequate warning is provided, then the chain of causation between the defendant drug maker and the consumer plaintiff is broken, since the physician is presumed to make an independent and educated prescribing decision. Liu v. Boehringer Ingelheim Pharm., Inc., 230 F. Supp. 3d 3, 9 (D. Mass. 2017). That causation chain is not broken, however, where the prescribing decision is affected by deceptive and misleading conduct on the part of the drug manufacturer. See, e.g., In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 39 (1st Cir. 2013) (physician held not to be an independent intervening cause in case involving fraudulent marketing of prescription drug). In other words, because of the defendant's wrongful conduct, the physician is no longer acting independently and the learned intermediary doctrine is not applicable. That is precisely what the Complaint alleges here: by actively undermining the warnings on its products through its deceptive conduct, Purdue is alleged to have caused physicians to write prescriptions they otherwise would not have written. That is sufficient.

5. Miscellaneous Arguments

Purdue's remaining arguments require little discussion. It asserts that the 2007 Judgment estops the Commonwealth from bringing the present action because its terms require Purdue to market its products consistently with approved uses and labeling, which it has done. This is not what the Complaint alleges, however: it accuses Purdue of engaging in marketing practices that

were inconsistent with the relevant approved product labels, and, thus, in violation of the 2007 judgment. Purdue next argues that the statute of limitations bars any claim that relies on allegations predating 2012.[6] The statute of limitations begins to run, however, only when the plaintiff knew or should have known of the defendant's harmful conduct. Koe v. Mercer, 450 Mass. 97, 101 (2007); see also Szymanski v. Boston Mut. Life Ins. Co., 56 Mass. App. Ct. 367, 370 (2002) (discovery rule applies to G. L. c. 93A actions). That is ordinarily a question of fact. Doe v. Creighton, 439 Mass. 281, 283-284 (2003). The Complaint contains sufficient factual allegations with regard to the pre-2012 conduct to raise at least a factual issue. Finally, Purdue argues that certain of the damages the Commonwealth seeks are unavailable, and, for that reason, those portions of the Complaint must be dismissed. A motion to dismiss, however, tests the plaintiff's entitlement to *any* relief under the causes of action pleaded, not the scope of that relief following a determination of liability. Mass. R. Civ. P. 12(b)(6); Iannacchino, 451 Mass. at 635-636. Purdue may pursue these arguments at later stages of litigation, where appropriate.

Janet L. Sanders
Justice of the Superior Court

Dated: September 16, 2019

[6] The Complaint was filed on June 12, 2018. Claims under G. L. c. 93A have a four-year statute of limitations, G. L. c. 260, § 5A. Moreover, the parties entered into a consent agreement to toll the statute of limitations during the period from August 2, 2016, through May 18, 2018.